iontorrent

Genexus™ Purification System

USER GUIDE

Catalog Number A48148

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Revision F

For Research Use Only. Not for use in diagnostic procedures.

ThermoFisher SCIENTIFIC

Life Technologies Holdings Pte Ltd |
Block 33 |
Marsiling Industrial Estate Road 3 |
#07-06, Singapore 739256

Products manufactured at this site:

- Genexus™ Purification System

Life Technologies Corporation |
200 Oyster Point Blvd |
South San Francisco, California 94080 USA

Products manufactured at this site:

- Genexus™ Software

Life Technologies Corporation |
7335 Executive Way |
Frederick, Maryland 21704 USA

Products manufactured at this site:

- Ion Torrent™ Genexus™ FFPE DNA and RNA Purification Kit
- Ion Torrent™ Genexus™ Multisample DNA Purification Kit
- Ion Torrent™ Genexus™ Cell-Free Total Nucleic Acid Purification Kit
- Ion Torrent™ Genexus™ Total RNA Purification Kit
- Genexus™ Purification Install Kit
- Genexus™ FFPE DNA and RNA Purification
- Genexus™ Multisample DNA Purification
- Genexus™ Cell-Free Total Nucleic Acid Purification
- Genexus™ Total RNA Purification
- Genexus™ Nucleic Acid Quantitation
- Genexus™ Nucleic Acid Quantitation, Broad Range
- Genexus™ Purification Supplies 1
- Genexus™ Purification Supplies 2

For descriptions of symbols on product labels or product documents, go to thermofisher.com/symbols-definition.

Revision history: F MAN0018475 (English)

Revision	Date	Description
F	27 August 2025	Update UPS specifications and data storage recommendations.
E.0	21 September 2023	• Updated for Genexus™ Software 6.8 • Correction to use PK Digestion Buffer in preparation of whole blood, bone marrow, and PBL samples.
D.0	28 October 2022	• Updated for Genexus™ Software 6.6 • Updated Genexus™ Cell-Free Total Nucleic Acid Purification Kit contents (page 19). • Updated the cfTNA purification protocol for addition of cfTNA Lysis/Binding Solution (page 84).
C.0	16 March 2021	• Correction of the Genexus™ Cell-Free Total Nucleic Acid Purification Kit and Genexus™ Total RNA Purification Kit Cat. Nos. (page 19 and 23). • Correction to the PK Digestion Buffer and DNase Buffer component quantities included in the Genexus™ Total RNA Purification kit (Part. No. A45534) (page 19). • Updated run planning in Chapter 4, “Plan and manage runs”. • Additional troubleshooting content added (page 153).

The information in this guide is subject to change without notice.

Contents

About this guide

CAUTION! ABBREVIATED SAFETY ALERTS. Hazard symbols and hazard types specified in procedures may be abbreviated in this document. For the complete safety information, see the "Safety" appendix in this document.

IMPORTANT! Before using this product, read and understand the information in the "Safety" appendix in this document.

Purpose of this guide

This user guide provides detailed instructions for operating the Genexus™ Purification Instrument, as well as product information, troubleshooting, instrument maintenance, and other instrument information. In addition, the guide provides basic instructions for assay creation, sample entry, and run planning in Genexus™ Software 6.8.

For detailed instructions on using Genexus™ Software for sample management, assay creation, data analysis, data review, and system management, see the *Genexus™ Software 6.8 User Guide* (Pub. No. MAN0026409), or the software help system.

For detailed instructions on using the Genexus™ Integrated Sequencer for sample sequencing, see the *Genexus™ Integrated Sequencer User Guide* (Pub. No. MAN0017910).

For a list of Oncomine™ GX assay-specific user guides, see "Related documentation" on page 191.

Prerequisites

Category	Prerequisites
Instrument	• Genexus™ Purification Instrument • Reagents and supplies for operating the Genexus™ Purification Instrument
Software	Genexus™ Software 6.8 or later
Functional knowledge and understanding	• Key steps in a next-generation sequencing (NGS) workflow • Main functions of the Genexus™ Purification Instrument • Main features of the Genexus™ Software 6.8 or later

1 Product information

Product description

The Ion Torrent™ Genexus™ Purification System automates the extraction of nucleic acids in as little as 2 hours from various sample types.

- Formalin-fixed paraffin-embedded (FFPE) lysate
- Plasma
- Whole blood
- Fresh or frozen tissue
- Peripheral blood leukocytes (PBLs)
- Cultured cells
- Bone marrow aspirate

Consumables for the system come prefilled with reagents and support up to 12 samples per run, or 6 samples when extracting from plasma. The system includes an onboard Qubit™ Fluorometer to automate post-extraction nucleic acid quantification.

The system is validated for use with the Ion Torrent™ Genexus™ Integrated Sequencer System as part of a complete **Sample to Result** workflow. The system offers the following features.

- MagMAX™ technology that supports consistent extraction results.
- Prefilled consumables that can help reduce setup hands-on time.
- Integrated nucleic acid quantitation that reduces post run processing times.
- Vision system that provides real time feedback on consumables during run setup to prevent setup error.

The Genexus™ Purification System automates the extraction and quantitation of nucleic acids from various tissue types for use on the Genexus™ Integrated Sequencer. With a single touch point, and 10 minutes of hands-on time, the Genexus™ Purification System can extract both DNA and RNA sequentially from FFPE lysates, cfTNA from plasma, and DNA or RNA separately from whole blood, fresh or frozen tissue, bone marrow or PBLs. When connected to the Genexus™ Integrated Sequencer, the Ion Torrent™ Genexus™ Software streamlines the NGS workflow by integrating the **Sample to Result** workflow within a single software ecosystem.

Prefilled reagents—The Genexus™ Purification System consumables are prefilled with most reagents that are necessary to perform the extraction. Therefore, only a few pipetting steps are needed per sample to set up the run. Simply remove the foil seal, add enzymes and your samples, then place the consumables onto the instrument.

Vision system—The Genexus™ Purification System uses an onboard vision system to detect and verify reagent placement to catch setup errors in real time. The vision system continuously checks that the consumables are appropriate to the purification run type and prevents running expired or previously used consumables. Feedback on the consumables that are loaded in the system is displayed on the instrument touchscreen. This feedback alerts the user to immediately correct errors.

MagMAX™ technology—MagMAX™ Technology uses magnetic beads to perform nucleic acid extraction. MagMAX™ beads offer superior binding capacity due to their large surface area, accept a greater range of samples with differing viscosities, and allow for efficient elution in small volumes.

48-Well Nucleic Acid Archive Plate—After extraction, all nucleic acids are transferred directly to the 48-well archive plate and kept cool for up to 1 hour after run completion. The 48-Well Nucleic Acid Archive Plate is barcoded to help track sample extractions across several stored archive plates.

Automated quantitation—The Genexus™ Purification System automates quantitation of extracted nucleic acids using an onboard Qubit™ Fluorometer. Two dyes are used to measure the concentration of DNA or RNA from each extracted sample. Automating post-run quantitation saves hands-on time and allows for immediate use of the extracted samples in genetic analysis workflows after run completion.

Rapid turnaround—Run times on the Genexus™ Purification System range from 2 to 5.5 hours depending on the number of samples extracted and the protocol that you run. Automated quantitation significantly reduces post-run hands-on time allowing for rapid transition to subsequent genetic analysis workflows.

Post run clean— After each run, all consumables that touch the sample are discarded by the researcher, after which the Genexus™ Purification System uses a UV light to clean the deck. This automated UV cleaning prevents any possible run-to-run carryover of nucleic acid, which could otherwise lead to contamination of downstream sequencing.

The Ion Torrent™ Genexus™ Purification System is part of the Ion Torrent™ Genexus™ Integrated Sequencer System. When the Genexus™ Purification System is connected to the Genexus™ Integrated Sequencer, additional workflow benefits include:

Ion Torrent™ Genexus™ Software—The software on the Genexus™ Integrated Sequencer is used to plan the complete **Sample to Result** workflow. Researchers use this software to select the NGS assay and assign samples to be run. The software tracks samples from purification through sequencing and post-run sample reports.

NGS-ready output plate—When the Genexus™ Purification System is connected to the Genexus™ Integrated Sequencer and run as part of an integrated workflow, a predefined aliquot of each extracted nucleic acid is transferred from the archive plate to an NGS-ready 96-Well Nucleic Acid Output Plate, which serves as the sample input to the Genexus™ Integrated Sequencer.

Review concentrations—When the Genexus™ Purification System is paired with the Genexus™ Integrated Sequencer and run as part of an integrated workflow, extracted nucleic acid concentrations are passed to the Genexus™ Software. Researchers can set assay-specific nucleic acid concentration thresholds to determine which samples proceed to sequencing, or they can review extraction outputs manually before proceeding. Review of nucleic acid concentrations can prevent waste of sequencing reagents on samples in which the quantity is not sufficient.

Pipet-free transfer to the Genexus™ Integrated Sequencer—When the Genexus™ Purification System is connected with the Genexus™ Integrated Sequencer and run as part of an integrated workflow, the post extraction nucleic acid concentrations are sent to the Genexus™ Software on the sequencer. Pipet-free transfer of the NGS-ready output plate to the sequencer is made possible as the nucleic acid concentrations provided allow the sequencer to perform dilutions of the nucleic acids to the assay specific input amount for the sequencing workflow.

Genexus™ Purification System

The Genexus™ Purification System (Cat. No. A48148) includes the following components.

Components	Cat. No.
Genexus™ Purification Instrument	A47646
Genexus™ Purification Install Kit	A48549[1]

[1] Not available for separate purchase.

The Ion Torrent™ Genexus™ Purification Install Kit (Part No. A48549) is available to first-time owners of a Genexus™ Purification System and is shipped with the instrument. The kit contains the following supplies that are used during installation of the instrument.

Table 1 Genexus™ Purification Install Kit

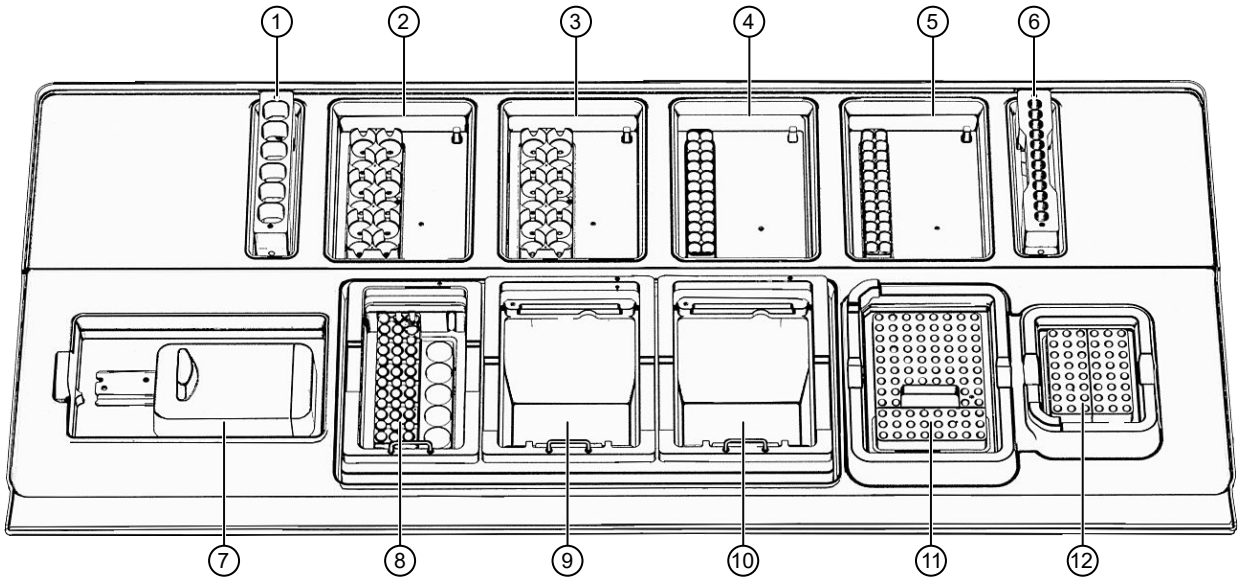
Contents	Quantity	Storage
12-Well Tip Comb	1 each	15°C to 30°C
6-Well Tip Comb	4 each	
96 Deep-Well plate	1 plate	
Quantitation Tube	4 each	

Genexus™ Purification Instrument features

External features of the Genexus™ Purification Instrument.

1. Power button
2. USB port
3. Touchscreen

Genexus™ Purification Instrument deck stations

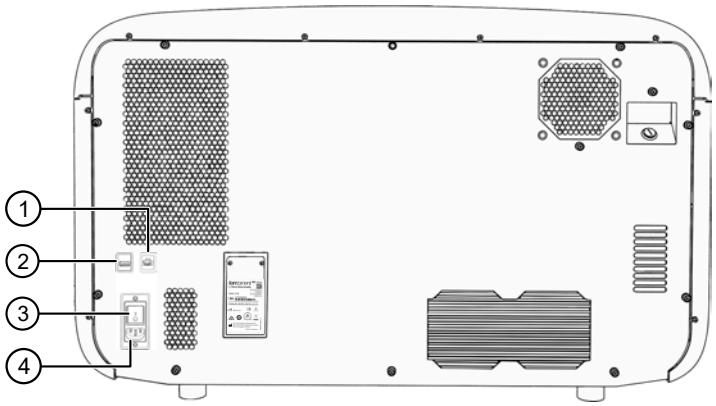


Interior deck stations of the Genexus™ Purification Instrument.

1. 6-well tip comb
2. 24 Deep-well plate 1
3. 24 Deep-well plate 2
4. 96 Deep-well plate 1
5. 96 Deep-well plate 2
6. 12-well tip comb
7. Quantitation module
8. Quantitation tray
9. Tip box 1
10. Tip box 2
11. 96-well output plate
12. 48-well archive plate

Genexus™ Purification Instrument input and output connections

The connection panel, power port, and an on/off switch are located on the left side of the rear panel of the instrument.



① Ethernet port—An RJ45 port that provides Ethernet (Gigabit) communication between the instrument and a local area network.

② USB port—Connects a USB device to the instrument.

③ On/off switch—Power switch, where the states are on (|) or off (O).

④ Power port—100–240VAC port that provides power to the instrument.

Network and password security requirements

Network configuration and security

The network configuration and security settings of your laboratory or facility (such as firewalls, anti-virus software, network passwords) are the sole responsibility of your facility administrator, IT, and security personnel. This product does not provide any network or security configuration files, utilities, or instructions.

If external or network drives are connected to the software, it is the responsibility of your IT personnel to ensure that such drives are configured and secured correctly to prevent data corruption or loss. It is the responsibility of your facility administrator, IT, and security personnel to prevent the use of any unsecured ports (such as USB, Ethernet) and ensure that the system security is maintained.

Data backup and data storage

You must have an established setup for regularly backing up and archiving your data. Data backup is solely your responsibility. In the event your system needs repair, Thermo Fisher Scientific is not responsible for data backup or any loss of data.

Note: A paid data migration service is available if needed. Contact your Thermo Fisher Scientific representative for more information.

For more information about data storage compatibility, contact your local support team.

Password security

Thermo Fisher Scientific strongly recommends that you maintain unique passwords for all accounts in use on this product. All passwords should be reset upon first sign in to the product. Change passwords according to your organization's password policy.

It is the sole responsibility of your IT personnel to develop and enforce secure use of passwords.

Antivirus software

Thermo Fisher Scientific has tested Genexus™ Software with the following antivirus software products and found them compatible as antivirus solutions.

- Bitdefender GravityZone™ Business Security
- Avast Antivirus

Antivirus software definition files are updated frequently, sometimes daily. Definition file updates for antivirus software can bring added settings or updates to the system, which can affect the function of Genexus™ Software.

2 Required reagents, supplies, and materials

This chapter lists the reagents, supplies, and materials that are needed to operate the Genexus™ Purification Instrument, and provides consumables ordering and storage information.

Genexus™ Purification Instrument reagents and supplies can be ordered as kits and starter packs. Most consumables can also be ordered individually as your needs require.

Consumables that have catalog numbers are orderable. Components that have part numbers cannot be ordered individually.

Ion Torrent™ Genexus™ FFPE DNA and RNA Purification Kit

The Ion Torrent™ Genexus™ FFPE DNA and RNA Purification Kit (Cat. No. A45539) includes the following subkits sufficient for 48 sequential DNA and RNA isolations from FFPE curls or slides.

IMPORTANT! Store all kit components in the upright orientation.

Component	Part No.	Storage
Genexus™ FFPE DNA and RNA Purification	A45532	15°C to 30°C
Genexus™ Nucleic Acid Quantitation	A45538	2°C to 8°C
Genexus™ Purification Supplies 2	A45574	15°C to 30°C

Genexus™ FFPE DNA and RNA Purification kit

The Genexus™ FFPE DNA and RNA Purification kit (Part No. A45532) includes sufficient reagents and consumables for 48 sequential DNA and RNA isolations.

IMPORTANT! Store all kit components in the upright orientation.

Component	Quantity	Storage
FFPE DNA and RNA Purification Plate 1	4 plates	15°C to 30°C
FFPE DNA and RNA Purification Plate 2	4 plates	
12-Well Tip Comb	4 each	
DNase (yellow cap)	115 µL	
DNase Buffer (blue cap)	4 × 1.2 mL	
Proteinase K (red cap)	1.2 mL	
FFPE Protease Buffer	15 mL	

Genexus™ Nucleic Acid Quantitation kit

The Genexus™ Nucleic Acid Quantitation kit (Part No. A45538) includes sufficient consumables for 48 DNA and 48 RNA quantitations.

IMPORTANT! Store all kit components in the upright orientation.

Component	Quantity	Storage
Quantitation Plate[1]	4 plates	2°C to 8°C
Quantitation Tube[2]	4 each	15°C to 30°C

[1] Store the Quantitation Plate in the dark to prevent photobleaching of the preloaded reagents.
[2] Can be stored at 15°C to 30°C upon receipt.

Genexus™ Purification Supplies 2 kit

The Genexus™ Purification Supplies 2 kit (Part No. A45574) includes sufficient consumables for 48 isolations.

Component	Quantity	Storage
48-Well Nucleic Acid Archive Plate	4 plates	15°C to 30°C
48-Well Nucleic Acid Archive Plate Seal	4 each	
Purification Tip Cartridge	8 each	

Ion Torrent™ Genexus™ Cell-Free Total Nucleic Acid Purification Kit

The Ion Torrent™ Genexus™ Cell-Free Total Nucleic Acid Purification Kit (Cat. No. A45542) includes the following subkits sufficient for 24 cell-free total nucleic acid (cfTNA) isolations from whole blood or cell-free plasma samples.

IMPORTANT! Store all kit components in the upright orientation.

Component	Part No.	Storage
Genexus™ Cell-Free Total Nucleic Acid Purification	A45535	15°C to 30°C
Genexus™ Nucleic Acid Quantitation	A45538	2°C to 8°C
Genexus™ Purification Supplies 1	A45529	15°C to 30°C

Genexus™ Cell-Free Total Nucleic Acid Purification kit

The Genexus™ Cell-Free Total Nucleic Acid Purification kit (Part No. A45535) includes sufficient reagents and consumables for 24 cell-free total nucleic acid (cfTNA) isolations.

IMPORTANT! Store all kit components in the upright orientation.

Component	Quantity	Storage
Cell-Free Total Nucleic Acid Purification Plate 1	4 plates	15°C to 30°C
Cell-Free Total Nucleic Acid Purification Plate 2	4 plates	
Cell-Free Total Nucleic Acid Purification Plate 3	4 plates	
6-Well Tip Comb	4 each	
12-Well Tip Comb	4 each	
Proteinase K (red cap)	1.2 mL	
cfTNA Lysis/Binding Solution	4 × 85 mL	

Genexus™ Nucleic Acid Quantitation kit

The Genexus™ Nucleic Acid Quantitation kit (Part No. A45538) includes sufficient consumables for 48 DNA and 48 RNA quantitations.

IMPORTANT! Store all kit components in the upright orientation.

Component	Quantity	Storage
Quantitation Plate[1]	4 plates	2°C to 8°C
Quantitation Tube[2]	4 each	15°C to 30°C

[1] Store the Quantitation Plate in the dark to prevent photobleaching of the preloaded reagents.
[2] Can be stored at 15°C to 30°C upon receipt.

Genexus™ Purification Supplies 1 kit

The Genexus™ Purification Supplies 1 kit (Part No. A45529) includes sufficient consumables for 48 isolations.

Component	Quantity	Storage
48-Well Nucleic Acid Archive Plate	4 plates	15°C to 30°C
48-Well Nucleic Acid Archive Plate Seal	4 each	
Purification Tip Cartridge	4 each	

Ion Torrent™ Genexus™ Multisample DNA Purification Kit

The Ion Torrent™ Genexus™ Multisample DNA Purification Kit (Cat. No. A45540) includes the following subkits sufficient for 48 DNA isolations from whole blood, bone marrow, peripheral blood leukocytes, cultured cells, and fresh or frozen tissue samples.

IMPORTANT! Store all kit components in the upright orientation.

Component	Part No.	Storage
Genexus™ Multisample DNA Purification	A45533	15°C to 30°C
Genexus™ Nucleic Acid Quantitation, Broad Range	A45537	2°C to 8°C
Genexus™ Purification Supplies 1	A45529	15°C to 30°C

Genexus™ Multisample DNA Purification kit

The Genexus™ Multisample DNA Purification kit (Part No. A45533) includes sufficient reagents and consumables for 48 DNA isolations.

IMPORTANT! Store all kit components in the upright orientation.

Component	Quantity	Storage
Multisample DNA Purification Plate	4 plates	15°C to 30°C
12-Well Tip Comb	4 each	
Proteinase K (red cap)	2 x 1.2 mL	
DNA Enhancer (black cap)	2 x 1.2 mL	
DNA Homogenization	2 x 22 mL	

Genexus™ Nucleic Acid Quantitation, Broad Range kit

The Genexus™ Nucleic Acid Quantitation, Broad Range kit (Part No. A45537) includes sufficient consumables for 48 DNA and 48 RNA quantitations.

IMPORTANT! Store all kit components in the upright orientation.

Component	Quantity	Storage
Quantitation Plate Broad Range[1]	4 plates	2°C to 8°C
Quantitation Tube[2]	4 each	15°C to 30°C

[1] Store the Quantitation Plate in the dark to prevent photobleaching of the preloaded reagents.
[2] Can be stored at 15°C to 30°C upon receipt.

Genexus™ Purification Supplies 1 kit

The Genexus™ Purification Supplies 1 kit (Part No. A45529) includes sufficient consumables for 48 isolations.

Component	Quantity	Storage
48-Well Nucleic Acid Archive Plate	4 plates	15°C to 30°C
48-Well Nucleic Acid Archive Plate Seal	4 each	
Purification Tip Cartridge	4 each	

Ion Torrent™ Genexus™ Total RNA Purification Kit

The Ion Torrent™ Genexus™ Total RNA Purification Kit (Cat. No. A45541) includes the following subkits sufficient for 48 total RNA isolations from whole blood, bone marrow, peripheral blood leukocytes, cultured cells, and fresh or frozen tissue samples.

IMPORTANT! Store all kit components in the upright orientation.

Component	Part. No.	Storage
Genexus™ Total RNA Purification	A45534	15°C to 30°C
Genexus™ Nucleic Acid Quantitation, Broad Range	A45537	2°C to 8°C
Genexus™ Purification Supplies 1	A45529	15°C to 30°C

Genexus™ Total RNA Purification kit

The Genexus™ Total RNA Purification kit (Part. No. A45534) includes sufficient reagents and consumables for 48 total RNA isolations.

IMPORTANT! Store all kit components in the upright orientation.

Component	Quantity	Storage
Total RNA Purification Plate	4 plates	15°C to 30°C
12-Well Tip Comb	4 combs	
Proteinase K (red cap)	1.2 mL	
PK Digestion Buffer (amber tube and cap)	4 x 1.25 mL	
DNase (yellow cap)	115 µL	
DNase Buffer (blue cap)	4 x 1.2 mL	
RNA Homogenization Buffer	2 x 22 mL	

Genexus™ Nucleic Acid Quantitation, Broad Range kit

The Genexus™ Nucleic Acid Quantitation, Broad Range kit (Part No. A45537) includes sufficient consumables for 48 DNA and 48 RNA quantitations.

IMPORTANT! Store all kit components in the upright orientation.

Component	Quantity	Storage
Quantitation Plate Broad Range[1]	4 plates	2°C to 8°C
Quantitation Tube[2]	4 each	15°C to 30°C

[1] Store the Quantitation Plate in the dark to prevent photobleaching of the preloaded reagents.
[2] Can be stored at 15°C to 30°C upon receipt.

Genexus™ Purification Supplies 1 kit

The Genexus™ Purification Supplies 1 kit (Part No. A45529) includes sufficient consumables for 48 isolations.

Component	Quantity	Storage
48-Well Nucleic Acid Archive Plate	4 plates	15°C to 30°C
48-Well Nucleic Acid Archive Plate Seal	4 each	
Purification Tip Cartridge	4 each	

Required materials—general laboratory equipment and supplies

Unless otherwise indicated, all materials are available through **thermofisher.com**. "MLS" indicates that the material is available from **fisherscientific.com** or another major laboratory supplier.

Item	Source
20-, 200-, and 1,000-µL pipettes and appropriate filtered tips[1]	**MLS**
Aerosol-resistant pipette tips	**MLS**
Microcentrifuge tubes, 1.5-mL or 1.7-mL (low retention for nucleic acids)	**MLS**
Vortex mixer with a rubber platform	**MLS**
Gloves, powder-free nitrile	**MLS**
PBS (1X), pH 7.2	**MLS**
Nuclease-free water, molecular biology grade	**MLS**
Isopropanol, 100% and 70% solution	**MLS**
2-Mercaptoethanol	**MLS**
Wipes, disposable lint-free	**MLS**
Uninterruptible Power Supply (UPS)[2]	**MLS**

[1] We recommend use of positive displacement pipettes and RNase free tips for use when isolating RNA.

[2] We recommend the use of at least 1.5-kVA dual-conversion uninterruptible power supply (UPS) with a power rating of 800W or higher, especially in areas prone to power failure. Additional battery pack capacity may be required depending on how much hold up time is required. Other factors may also affect hold up time including but not limited to high temperature, frequent discharges, and battery age. Regular preventative maintenance of the UPS system and battery pack(s) is recommended. Power failures and other events that abruptly terminate the function of the instrument and computer can corrupt data and possibly damage the system. These recommendations are for one single instrument.

Recommended materials not supplied for use with the Genexus™ Purification System

Unless otherwise indicated, all materials are available through **thermofisher.com**. "MLS" indicates that the material is available from **fisherscientific.com** or another major laboratory supplier.

Item	Source
Equipment	
Bench top microcentrifuge	• Cole-Parmer, EW-17414-06 • Eppendorf, 022620304
1,000 µL Multichannel Pipette	**MLS**

(continued)

Item	Source
For use with Genexus™ FFPE DNA and RNA Purification Kit	
Sorvall™ ST 8 Small Benchtop Centrifuge (or equivalent)[1], with Thermo Scientific™ M10 Microplate Swinging Bucket Rotor (or equivalent)[2], and Sealed Bucket; Capacity: 4 Standard or 2 Midi-Deepwell plates (Set of 2) (or equivalent)	75007200 75005706 75005721
Economy Standard Incubator (2, 60°C and 90°C)	S50441A **fisherscientific.com**
Heating block (2, 60°C and 90°C)	**MLS**
Precision™ General Purpose Water Bath (or equivalent)	**MLS**
Equipment and consumables for AutoLys M FFPE sample extraction[3]	
AutoLys M Tubes and Caps kit	A38738
AutoLys M Tube Rack	A37955
AutoLys M Tube Locking Lid	A37954
AutoLys M TubeLifter or AutoLys M Tube Pliers	A37956 A38261
For use with Genexus™ Multisample DNA Purification Kit and Genexus™ Total RNA Purification Kit	
Fisherbrand™ Bead Mill 24 Homogenizer (or equivalent)	15-340-163
Homogenizer (rotor-stator generator)	**MLS**
Tubes, plates, and other consumables	
MicroAmp™ EnduraPlate™ Optical 96-Well Clear Reaction Plates with Barcode	4483354, 4483352
Adhesive PCR Plate Foils	AB0626
RNA*later*™ Stabilization Solution	AM7020
RNase*Zap*™ RNase Decontamination Solution	AM9780
CitriSolv™ Clearing Agent	22-143-975
Xylene	**MLS**
Ethanol, 100%	**MLS**

[1] Centrifuge must achieve an X G of 2000 × *g*, have a swinging bucket rotor and accommodate deepwell plates.
[2] Swinging bucket rotor must carry deepwell plates in the landscape orientation (see page 53).
[3] For use with the Genexus™ FFPE DNA and RNA Purification Kit.

3 Before you begin

Precautions

Avoid nucleic acid contamination

IMPORTANT! A primary source of contamination is spurious DNA fragments from previous sample processing steps. Do not introduce amplified DNA into the work area where the instrument is located.

- Use good laboratory practices to minimize cross-contamination of products and reagents.
- When designing the laboratory layout, dedicate separate areas for purification and sequencing activities. Dedicate laboratory supplies and/or equipment to the appropriate area.

Confirm that consumables are installed correctly

IMPORTANT! To ensure correct and safe instrument operation, confirm that all consumables are installed correctly on the deck before you start a run. The instrument vision system confirms that required reagents are in place, no reagents are expired, and foil seals are removed. The vision system does not verify all aspects of the consumable setup before beginning each run.

Avoid instrument vibration

IMPORTANT! The Genexus™ Purification Instrument must be installed on a bench that is free from vibrations. The bench should not be in contact with equipment that can cause vibrations to the bench, such as freezers, pumps, large benchtop centrifuges, and other similar equipment. An air table is not required, and securing the instrument to the bench is not required.

Avoid strong electromagnetic radiation

WARNING! Do not use the instrument in close proximity to sources of strong electromagnetic radiation (for example, unshielded intentional RF sources), as these sources can interfere with proper operation.

Protection by equipment

WARNING! The protection that is provided by the equipment can be impaired if the instrument is operated outside the environment and use specifications, the user provides inadequate maintenance, or the equipment is used in a manner that is not specified by the manufacturer (Thermo Fisher Scientific).

Guidelines for Genexus™ Purification Instrument operation

- Follow guidance that is provided by Genexus™ Software when you create a run plan to determine which consumables must be loaded for each run.
- Follow guidance that is provided by the software when you create a run plan to determine how many samples can be run with a given purification kit in an instrument run.
- Ensure that deep-well plates are placed in the correct stations and in the correct orientation on the instrument deck. Press plates firmly into the appropriate station to seat properly.
- Ensure that tip racks are placed in the correct station, in the correct orientation, and locked in place to avoid damage to the automated liquid handler.
- If the instrument encounters a problem, for example, stuck pipet tip or obstructed movement of the gantry arm, the run is aborted. You must restart the run with new consumables.
- The instrument can be operated in either the integrated configuration, connected to a Genexus™ Integrated Sequencer directly by local area network allowing control by Genexus™ Software 6.8, or in standalone configuration.

Power the Genexus™ Purification Instrument on or off

Power on

If the touchscreen is unresponsive, check the power switch on the back of the instrument and ensure that the switch is in the on (|) position. If the power switch is in the off (O) position, proceed with step 1. If the power switch is already in the on position, proceed to step 2.

1. On the back of the instrument, turn the power switch to the on (|) position.
2. On the front of the instrument, press the power button.
   The button illuminates.
3. In the **Sign In** screen, enter the username and password created by the field service engineer when the instrument was set up, or the unique username and password set up for you as an instrument user.
   When the instrument **Home** screen appears, the instrument is ready for use.

Power off

If the instrument or Genexus™ Software will not be used for more than 3 days, power off the instrument.

It is not necessary to power off the instrument overnight or over the weekend.

IMPORTANT! Do *not* press the power button during a run. Interrupting power to the instrument during a run can result in run failure and loss of sample.

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1. In the **Home** screen, tap **Settings** ▸ **System Tools** ▸ **Shut down**.
2. Select **Shutdown**.
   A confirmation message appears. Select **Yes** to power off the instrument.

Reboot the instrument

IMPORTANT! Do *not* press the power button during a run. Interrupting power to the instrument during a run can result in run failure and loss of sample.

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1. In the **Home** screen, tap **Settings** ▸ **System Tools** ▸ **Shut down**.
2. Select **Reboot**.
   A confirmation message appears. Select **Yes** to reboot the instrument.

Switch accounts in standalone configuration

The Genexus™ Purification Instrument in standalone configuration has three fixed user profiles: Operator, Administrator, and Service. Additional accounts cannot be created. To switch between accounts.

1. Sign out from the account in use. Tap **(User profile)**, then tap **Sign out**.
2. Enter the credentials for the desired user profile (for example, Admin + password), then tap **Sign in**.

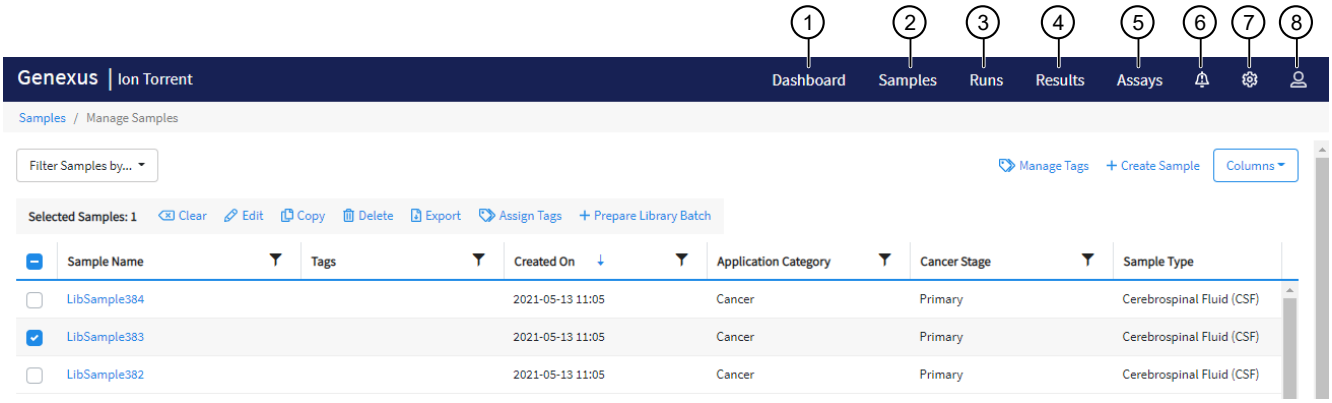
User-access levels on the Genexus™ Purification Instrument in standalone configuration

Users at this level	Can perform these actions
Operator	• Plan, save, and delete runs • Perform purification runs • View results • Access system tools
Administrator	Operator functions, plus: • Manage instrument settings • Manage network settings • Manage software updates
Service	Access Service tools

Get started with Genexus™ Software

Genexus™ Software

Genexus™ Software provides menus to help you add, select, and manage samples, libraries, runs, and assays. You can also view and manage sequencing results, monitor Genexus™ Purification Instrument runs in progress, and manage software settings.



① **Dashboard**—View recent run history, and current purification or sequencing run status.

② **Samples**—Add new samples, import samples, prepare library batches, import library batches and manage attributes.

③ **Runs**—Plan a run starting from a sample, a nucleic acid sample, a BAM sample, or a library. View, edit, and manage runs. **Sample to Result** runs are for nucleic acid isolation on a Genexus™ Purification Instrument followed by sequencing on a Genexus™ Purification Instrument.

④ **Results**—View sample results, run results, and verification results.

⑤ **Assays**—Manage, create, and import assays. Manage assay preset parameters and panels.

⑥ **Notifications**—Receive alerts and messages regarding completion of runs and other processes.

⑦ **Settings**—Access audit records and run logs, configure network settings, manage backup settings, restore runs, manage gene lists, link to Thermo Fisher™ Connect Platform user accounts and Ion Reporter™ Software accounts, check for software updates, and manage data archiving, disk space, and users. Field Service Engineers access verification templates during sequencer installation.

⑧ **Profile**—Access the Help system, manage and edit user profile settings and SSH key, and sign out.

User-access levels

Users at this level	Can perform these actions
Report	• Access the **Sample Results** and **Run Results** screens to view results • Generate, view, and sign variant reports • Send notifications • Download results files • View and edit notes for the sample result • View the audit trail for sample results • View notifications

(continued)

Users at this level	Can perform these actions
Operator	Report functions, plus: • Add, import, and export sample files • Edit sample files • Prepare library batches • Plan, save, audit, and delete runs • Monitor runs • View results and reports • Upload sample results files to Ion Reporter™ Software • View the audit trail for samples, library batches, runs, and assays • Reanalyze runs and run plugins
Manager	Operator functions, plus: • Create, edit, and obsolete sample attributes • Create and import assays • Create presets for annotation sets, filter chains, copy number baselines, sequence variant baselines, exon tile assay baselines, and report templates • Edit and delete sample files • Add or edit Thermo Fisher accounts • Manage gene lists • Restart a stalled or failed run • Manage reference sequences and panel, hotspot, and other sequence files • Access services information
Administrator	Operator and manager functions, plus: • View, export, and print audit records • Configure network settings • View and manage software updates • Install and manage plugins • Configure backup settings and restore runs • Manage sequencer and software log files • Add and manage user accounts

System tracking

The system tracks and checks user, sample, workflow, reagents, and QC metrics for auditable records. If the software detects an error at any step, for example, a scanned barcode is inconsistent with the information given for the run, the software alerts the user and does not proceed with the run.

Request and sign in to a new user account

Operator-level users must request a new user account from the manager- or administrator-level user before they can sign in to Genexus™ Software.

Administrator-level users receive the request and create the user account.

Your user name and password must be unique and must not be shared with other users.

- To request a new account, contact your administrator-level user.

  After the administrator creates a new account, the software sends an email to the new user with a user name and temporary password.

- To sign in to a new account for the first time:
  a. Obtain your user name and temporary password that is supplied by your administrator in an email message.

  b. Browse to the Genexus™ Software sign in page (for example, ***https://<your server address>***), then enter your user name and the temporary password that is supplied by your administrator.

  c. Press **Enter**, or click **Sign In**.

  d. In the **End User License Agreement** that appears at first sign on, read the agreement, then click **Accept**.

  e. In the **Change Password** screen, enter your temporary password that is supplied by your administrator.

  f. Type a new password, confirm the password, then click **Change**.
     - Passwords must be between 8 and 80 characters.
     - Passwords must contain only alphanumeric characters (numbers 0 to 9 and letters A to Z), and no spaces or special characters.
     - Passwords must contain at least one alphabetic character (a–z, A–Z).
     - Passwords must contain at least one numeric character (0–9).
     - Passwords are case-sensitive.

Genexus™ Software opens to the **Dashboard** screen.

Sign in

Before you can sign in to Genexus™ Software, you must have a registered account. See “Request and sign in to a new user account” on page 33.

1. Go to the Genexus™ Software sign in page.
2. Click **Switch Language**, then select the preferred language from the list, if desired.
3. Enter your user name and password, then press **Enter** or click **Sign In**.

   If a message appears that indicates that there is a problem with the security token, refresh the browser, then enter the user name and password again.

The software opens to the **Dashboard** screen.

Genexus™ Purification Instrument integrated and standalone configuration workflows

The Genexus™ Purification Instrument can be used in either a standalone or an integrated configuration.

- The integrated configuration yields a 96-well output plate that can be used directly in a Genexus™ Integrated Sequencer **Sample to Result** run with no further handling.

  Note: If using the Genexus™ Purification Instrument in standalone configuration, proceed to the appropriate purification kit protocol chapter and follow the guidance for on-instrument run planning.

- The standalone configuration yields a 48-well archive plate of purified and quantified nucleic acid samples that can be used in multiple downstream applications.

Integrated **Sample to Result** workflow

30 min

Select an Assay (page 39)

System-installed assays are available in the Genexus™ Software for use with the Genexus™ Purification Instrument. Each system-installed assay is configured with settings that are optimized for a specific sample type. Create a new assay by copying an existing system-installed assay and then modifying the parameters.

Enter samples (page 40)

Before you plan a run in Genexus™ Software, first enter sample information in the software to assign sample names and provide other information.

Plan a Sample to Result run (page 41)

In the Genexus™ Software create a Sample to Result run plan to automate both nucleic acid purification and sequencing. The run plan defines the samples, assays, purification kit, sequencing reagents, and the number of sequencing chip lanes that are needed.

up to 3 hr

Prepare samples

Depending on the sample type, samples may require preprocessing before loading into the appropriate purification plate and starting the run. For more information see the appropriate purification protocol chapter.

5 min

Load the Genexus™ Purification Instrument

The Sample to Result run plan is selected and the run initiated. The instrument performs a UV cleaning, then samples, reagents, and consumables are loaded onto the instrument.

Integrated **Sample to Result** workflow

1–2 hr

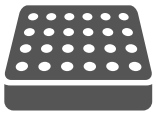
Start the run

After the sample plate and all reagents and consumables are loaded, the instrument door is closed, and the run is started.

5 min

Unload the purified nucleic acids

Remove the 96-Well Nucleic Acid Output Plate and proceed immediately to sequencing of the purified sample. Remove and seal the 48-Well Nucleic Acid Archive Plate, then store as directed for later use. Used reagents and consumables are removed from the instrument, then the instrument performs a UV cleaning.



up to 24 hr

Sequence the purified nucleic acids on the Genexus™ Integrated Sequencer

Load the output plate with the purified nucleic acids, and all reagents and consumables that are required for the run, onto the integrated sequencer. Select the **Sample to Result** run plan, then press **Start**.

Standalone **Nucleic Acid to Result** workflow

5 min

Create a purification run plan

Add a new purification run plan or copy an existing purification run plan that best represents your experiment, then edit the settings as needed.

up to 3 hr

Prepare samples

Depending on the sample type, samples may require preprocessing before loading into the appropriate purification plate and starting the run. For more information see the appropriate purification protocol chapter.

5 min

Load the Genexus™ Purification Instrument

The purification run plan is selected and the run initiated. The instrument performs a UV cleaning, then samples and consumables are loaded onto the instrument.

1–2 hr

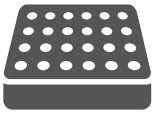
Start the run

After the sample plate and all reagents and consumables are loaded, the instrument door is closed and the run is started.

5 min

Unload the purified nucleic acids

Remove and seal the 48-Well Nucleic Acid Archive Plate, then store as directed for later use. Used reagents and consumables are removed from the instrument, then the instrument performs a UV cleaning.

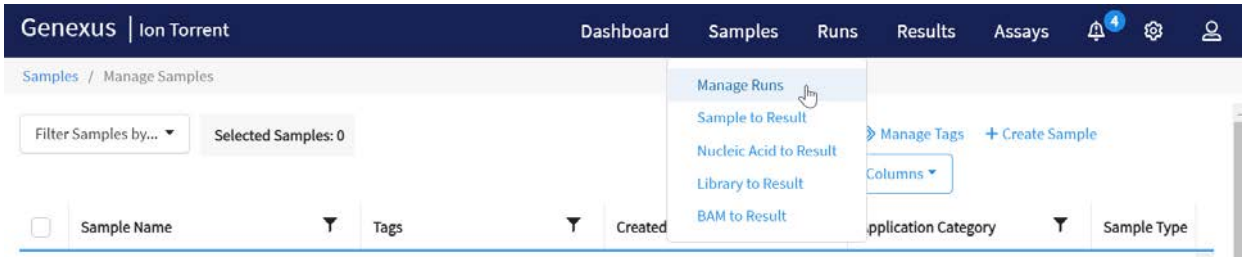


up to 24 hr

Sequence the purified nucleic acids on the Genexus™ Integrated Sequencer

Transfer extracted nucleic acid from the archive plate to a 96-well plate, which serves as the sample input plate for the Genexus™ Integrated Sequencer. Load the input plate with the purified nucleic acids, and reagents and consumables that are required for the run, onto the integrated sequencer. Select the **Nucleic Acid to Result** run plan, then press **Start**.

4 Plan and manage runs



Runs plans that are created in Genexus™ Software contain the settings that are used in sample purification, library preparation, templating, sequencing, and analysis, including sample information and plate location, assays, and barcodes. Run plans are used to track samples, consumables, and chips throughout purification, library preparation, templating, sequencing, and data analysis.

For more information on run planning, see the software help system, or the *Genexus™ Software 6.8 User Guide* (Pub. No. MAN0026409).

Types of runs

The type of run that you plan depends on your instrument configuration, assay, and sample type.

Genexus™ Software guides you step-by-step through the process to set up a run. The software prompts you to select required information and consumables, then provides a printed run setup guide to help you load consumables on the Genexus™ Integrated Sequencer and the Genexus™ Purification Instrument, if applicable.

Run type	Description
Sample to Result	A run that performs sequential and automated nucleic acid purification, quantitation, and sequencing. This run type requires the Genexus™ Purification Instrument in integrated configuration.
Nucleic Acid to Result	A sequencing run that starts with purified nucleic acid samples of known concentration as input. Purified nucleic acids can be isolated and quantified using the Genexus™ Purification Instrument in standalone configuration. Alternatively, users can use other manual purification and quantitation kits to isolate purified nucleic acid samples. For a list of recommended kits, see the relevant assay user guide for guidance.

For more information on planning other types of runs, see the software help system, or the *Genexus™ Software 6.8 User Guide* (Pub. No. MAN0026409).

System-installed assays

An assay is a reusable experimental design that contains the settings and parameters for sample purification, library preparation, templating, controlling the sequencing run, analyzing, and reporting the results. Assays also define the panels, kits, and chips that are used in a run, and specify the reference files and threshold values for quality control and variant detection. The software files that contain the assay settings and parameters are packaged in a ZIP file called an assay definition file (ADF).

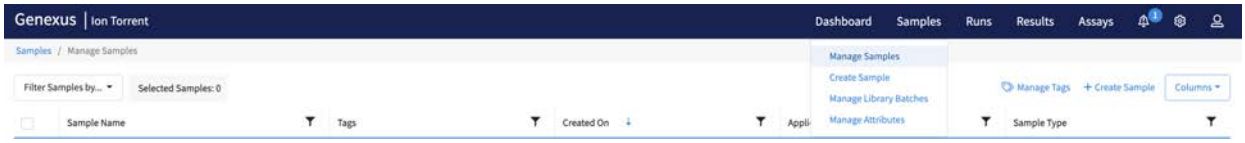
An assay can be used to plan many runs and plays an important role in enabling rapid throughput across the purification and sequencing instruments. Assays help reduce the chance of errors, because information is stored and then applied to runs instead of entered manually for each run. Each system-installed assay is configured with settings that are optimized for a specific sample type.

Note: Make sure to update your software to the latest available versions of the system-installed assays. For more information, contact your field service representative. For information on how to perform software and assay package updates, see the software help system, or see the *Genexus™ Software 6.8 User Guide* (Pub. No. MAN0026409).

You can use the system-installed assays in your run plan without change. To modify any assay settings, you can copy the system-installed assay that best represents your sequencing experiment and sample type, then edit assay settings as needed. For detailed information on how to manage assays or how to modify a system-installed assay with custom settings, see the software help system, or see the *Genexus™ Software 6.8 User Guide* (Pub. No. MAN0026409).

If you are using a system-installed assay without changes, proceed directly to “Enter samples in the Genexus™ Software” on page 40 and “Plan a Sample to Result run” on page 41 or “Plan a Nucleic Acid to Result run” on page 45.

Enter samples in the Genexus™ Software



In Genexus™ Software, the data and attributes that characterize a purified nucleic acid—or a specimen that requires nucleic acid purification and quantitation—to be sequenced are called samples.

Before you plan a run in the Genexus™ Software, you must first enter sample information in the software to assign sample names and provide other information.

From the **Samples** menu, you can add samples in multiple ways. For more information on creating and managing samples, see the software help system, or the *Genexus™ Software 6.8 User Guide* (Pub. No. MAN0026409).

Integrated run planning

The Genexus™ Purification Instrument can be used in either a standalone configuration or an integrated configuration. The standalone configuration yields a single 48-well archive plate with up to 12 purified and quantified nucleic acid samples that can be used in multiple downstream applications. When in standalone configuration, run plans must be created on the Genexus™ Purification Instrument through the instrument touchscreen. When in integrated configuration, the Genexus™ Purification Instrument yields a 96-well output plate in addition to the archive plate. The 96-well output plate contains sufficient quantified sample to be used directly in a Genexus™ Integrated Sequencer **Sample to Result** run. The remaining purified and quantifed sample volume is transferred to the archive plate for storage and later use.

Note: The Oncomine™ Myeloid v2 - GX5 - DNA and Fusions assay requires transfer of samples from both DNA and RNA output plates to a single new 96-well input plate.

When using the Genexus™ Purification Instrument in integrated configuration, plan a **Sample to Result** (page 41) run in the Genexus™ Software. A **Sample to Result** run integrates automated nucleic acid purification and sequencing.

When using the Genexus™ Purification Instrument in standalone configuration, proceed to the appropriate purification chapter and follow the guidance to plan a purificaition-only (page 45) run through the instrument touchscreen.

- **Sample to Result** run—Start from unprocessed samples and isolate nucleic acid on the Genexus™ Purification Instrument, then load the purified and quantified nucleic acid samples directly into the Genexus™ Integrated Sequencer for library preparation, templating, and sequencing.
- **Nucleic Acid to Result** run—Pipet purified and quantified nucleic acid samples into a 96-well sample input plate and load into the Genexus™ Integrated Sequencer for library preparation, templating, and sequencing.

  The Genexus™ Purification Instrument is not needed for **Nucleic Acid to Result** sequencing runs.

Integrated nucleic acid purification and sequencing

A **Sample to Result** run is an integrated run for sequential and automated nucleic acid purification and sequencing. You can create **Sample to Result** runs for the multiple sample types.

- Core Needle Biopsy (CNB)
- FFPE
- Fine Needle Aspiration (FNA)
- Fresh Frozen Tissue
- Blood (Buffy Coat)
- Blood (Plasma)
- Blood (Whole)
- Bone marrow

When you plan a **Sample to Result** run with multiple assays, the nucleic acid isolation is performed in a separate batch for each assay. Nucleic acid isolation is also performed in a separate batch for each sample type, except for FFPE and FNA, which are grouped together in a single batch for each assay. The Genexus™ Purification Instrument can run one nucleic acid isolation batch at a time. You can run different nucleic acid isolation batches simultaneously on multiple purification instruments or sequentially on a single instrument.

You can choose to sequence all or some of the samples after nucleic acid isolation.

- Sequence all samples.
- Sequence only the samples that have a concentration within a specified threshold.
- Review the samples individually, then choose which samples to sequence on a per sample-basis.

Plan a Sample to Result run

You can plan runs for sequencing that start from various sample types. In Genexus™ Software, a run that includes purification of nucleic acids from samples is called a **Sample to Result** run.

Planning a **Sample to Result** run is organized into steps: **Setup**, **Assays**, **Samples**, **Purification**, and **Review**. You can view progress through the steps in the upper left corner of the **Runs / Sample to Result** screen.

1. In the menu bar, click **Runs** ▸ **Sample to Result**.

   You can also click + **Sample to Result** in the **Runs / Manage Runs** screen.

2. In the **Setup** step, enter or make the following selections.
   a. In the **Plan** section, enter a unique name.

      The name is limited to 50 characters and no spaces are allowed.

   b. *(Optional)* In the **Reporting (Optional)** section, enable **Generate Report** to generate a variant report that uses the default report template.

      To create a report template, click **Assays** ▸ **Manage Presets**, then in the **Report Templates** tab, click + **Add New**.

   c. Click **Next**.

      If a chip is installed in the sequencer, the **Chip View** graphic in the lower left corner indicates the lanes that are available for sequencing.

3. In the **Assays** step, select the **Application Type** of each assay that you want to use in the run.

   Use the **(Filter)** tools in table column headings or the **Filter Assays By** list to find assays of interest.

   IMPORTANT! Ensure that you select the assay that corresponds with the sample type that you use in the run. If you select the wrong assay when you plan a run, the instrument uses incorrect settings during the run, resulting in invalid sequencing results. Available assays are listed in the **Assays / Manage Assays** screen.

   Only assays that are configured for **Sample to Result** runs are listed.

   After selecting an assay, the list is filtered to show compatible assays that can be selected and run at the same time.

4. Click **Next**.

5. In the **Samples** step, select the checkbox next to each sample from the list that you want to run with the assay, then in the **Selected Assays** pane, click **Assign**.

   The **Chip View** updates to show the lanes to be used in the run. Lane usage is calculated based on the number of samples (including a no template control or control sample, if selected) and minimum reads per sample entered at assay setup. Green denotes a chip lane to be used in the run containing assigned samples within lane capacity. If the `minimum reads per sample` × `number of samples` exceeds the chip or lane well capacity, a dialog box appears after you click **Assign** asking you to confirm that you want to continue. After confirmation, the **Chip View** updates and shows the lane color as red instead of green. The run is allowed if the lane capacity is exceeded, but you may not achieve the required reads per sample to pass QC metrics.

Green lane color ① denotes lane usage and sample assignment within lane capacity. Red lane color ② denotes sample assignment that exceeds lane capacity.

6. Select the **Include NTC** checkbox to include a no template control for the assay.

7. *(Optional)* Select the **Control Sample** checkbox to designate a sample as a positive control for the assay.

8. If you selected more than one assay, repeat step 5 through step 7 for each assay added.

9. Click **Next**.

10. If needed, edit samples in one of the following ways, then click **Next**.

    - Click **View & Remove**, make your selections, then click **Update**.
    - Click **Remove All**, make your selections, then click **Assign**.

11. In the **Purification** step, review and edit purification selections, then click **Next**.

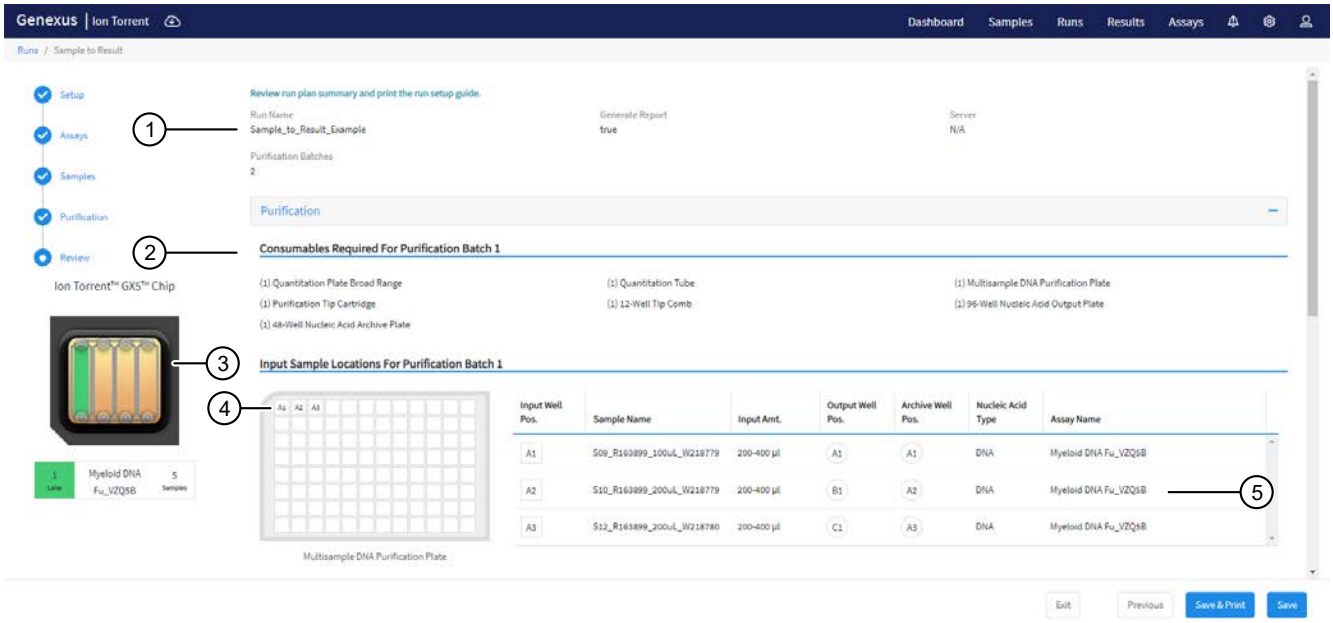
Option	Description
Protocol Selection	Select a protocol from the dropdown list for each purification kit.
Elution Vol. (µL)	Modify the elution volume within the allowable range, if needed. Quantitation requires up to 5 µL of the eluted sample. If retesting is needed, up to 10 µL of the eluted sample is used. If the expected sample yield is limiting, manual sample quantitation may be preferred to preserve the sample. Alternatively, you can increase the sample elution volume in the run plan before starting the purification.
Review?	• Select the checkbox in the row of a purification kit to review the sample concentrations after purification, before sequencing. This lets you review whether a sample concentration is out of range for automated dilution or below the minimum concentration needed threshold. You can then decide on a per sample-basis whether to sequence the samples. • Deselect the **Review?** checkbox in the row of a purification kit to exclude out of range samples from sequencing. This option does not require you to review samples during the run.

12. In the **Review** step, review the run plan summary.

    If desired, click **Save & Print** to print the run setup guide. Click **Save** to save the run without printing.

    The run plan summary lists the following details:

    - The consumables that are needed for this run
    - How much sample volume to load
    - Where to load samples and primer pool tubes
    - Details about the assay



① Run information
② List of consumables needed for the run
③ Chip view showing the lanes to be used in the run
④ Positions in the sample plate to load the samples
⑤ Table that lists the sample plate position, sample type, volume to load, concentration, dilution factor, and assay for each sample

Tip: Click **Sequencing** to expand the sequencing section of the run plan summary.

If the **Sample to Result** run requires more than one purification batch (for example a Oncomine™ Myeloid v2 - GX5 - DNA and Fusions run) you can select which purification batch to run first. Or, if there are multiple purification instruments integrated with one sequencer, select the instrument on which to purify each batch.

After saving, the run appears in the **Manage Runs** screen in the run list with the name you specified.

After you select the run and load the purification instrument, the run is started on the instrument screen.

Plan a Nucleic Acid to Result run

You can plan a run for sequencing that start with nucleic acid samples. In Genexus™ Software, a run that starts with nucleic acid samples is called a **Nucleic Acid to Result** run.

Planning a **Nucleic Acid to Result** run is organized into steps: **Setup**, **Assays**, **Samples**, **Sample Plate**, and **Review**. You can view progress through the steps in the upper left corner of the **Runs / Nucleic Acid to Result** screen. For more detailed run planning information, see the *Genexus™ Integrated Sequencer User Guide* (Pub. No. MAN0017910), the software help system, or the *Genexus™ Software 6.8 User Guide* (Pub. No. MAN0026409).

Ensure that the following prerequisites are complete before you plan a **Nucleic Acid to Result** run.

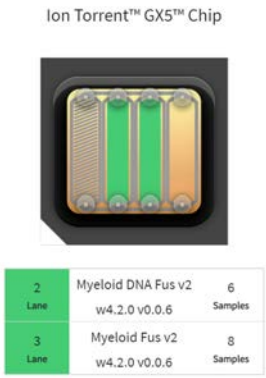
- Identify the system-installed assay or the custom assay to use in the run.
- Enter sample information into Genexus™ Software. See “Enter samples in the Genexus™ Software” on page 40.
- Quantify the sample concentration. Dilute samples manually to the target concentration of the assay, if desired.

1. In the menu bar, click **Runs** ▸ **Nucleic Acid to Result**.
2. In the **Setup** step, enter or make the following selections.
   a. In the **Plan** section, enter a unique name for the plan.
      The name is limited to 50 characters and no spaces are allowed.
   b. *(Optional)* In the **Reporting (Optional)** section, ensure that **Generate Report** is enabled to generate a **Variant Report** using the default report template.
   c. *(Optional)* In the **Reporting (Optional)** section, enable **Upload BAM files to Server** to upload BAM files to another server.
   d. Click **Next**.
3. In the **Assays** step, select one or more assays that you want to include in the run.
   a. Use the **(Filter)** tools in table column headings to find assays of interest, if desired.
   b. In the **Application Type** column for the assay of interest, select one or more application types, such as **DNA and Fusions** or **DNA**, to include each selected application type for the assay in the run plan.
      After selecting an assay and the research application for the assay, the list is filtered to show compatible assays that can be selected and run at the same time.
   c. If more assays are included in the run, repeat substep 3b for each extra assay.
   d. Click **Next**.

4. In the **Samples** step, select the samples that you want to run with each application type of each assay.
   a. Select the checkbox next to each sample that you want to assign to the application type of an assay, then in the **Selected Assays** pane, for the assay and application type that you want to use for the selected samples, click **Assign**.

      The **Chip View** updates to show the lanes used in the run. Lane usage is calculated based on the number of samples (including a no template control, if selected) and the minimum read counts per sample for the assay. Green denotes a chip lane in the run containing assigned samples within lane capacity. If the `minimum reads per sample` × `number of samples` exceeds the chip or lane well capacity, a dialog box appears after you click **Assign** asking you to confirm that you want to continue. After confirmation, the **Chip View** updates and shows the lane color as red instead of green. The run is allowed if the lane capacity is exceeded, but you may not achieve the required reads per sample to pass QC metrics.

      If the number of selected barcodes or samples exceed the limit for an assay, the **Total number of max barcode limit exceeded** message appears. If needed, remove extra samples from the run as described in substep 4c.



Green lane color denotes lane usage and sample assignment within lane capacity. In this example, lane 1 was used in a previous run and is not available.

   b. If you selected more than one application type or assay, repeat substep 4a for each application type for each assay in the run plan.

   c. If needed, edit samples in one of the following ways.
      - Click **View & Remove**, make the selections, then click **Update**.
      - Click **Remove All**, to remove all sample assignments for all assays.

   d. If desired, for each application type of each assay in the run plan, select **NTC** to include a no template control.

      The **Chip View** updates to show the lanes used in the run for the included no template controls.

   e. Click **Next**.

5. In the **Sample Plate** step, review position assignments in the sample plate. If applicable, drag-and-drop samples and no template controls to edit the location of samples and controls.
   a. If desired, enter the extraction kit barcode for one or more samples or controls. For a single sample, in the row of the sample of interest, in the **Kit Barcodes** column, enter the extraction kit barcode or control kit barcode, if applicable. For multiple samples or controls, select the samples and controls, then click **Assign Kit Barcodes**. In the **Assign Kit Barcodes** dialog box, enter the extraction kit barcode for the samples, and if applicable, enter the barcode for the no template control.

   b. Enter the sample concentration. The recommended target concentration is 1.11 ng/µL for DNA samples and 0.95 ng/µL for RNA samples. For a single sample, in the row of the sample of interest, click in the **Conc. (ng/µL)** column, then edit the concentration.

      To modify the concentration of multiple samples, select the samples of interest, then click **Edit Concentration**. In the **Bulk Edit** dialog box, enter the concentration for all selected samples, then click **Submit**. The concentration for each selected sample is updated to the new value.

      If a sample concentration is within 1–1,024X of the target concentration, the sequencer dilutes the sample to the target concentration during the run. Sample concentrations cannot be higher than 1,024X of the target concentration. If a sample concentration is >1,024X of the target concentration, manually dilute the sample to the target concentration before loading on the sample plate.

      Note: The sample volume that is required for library preparation is not adjustable. The volume depends on the number of primer pools in the assay, sample type, and library chemistry. For specific sample volumes to load onto the sample plate, see the relevant assay user guide for guidance.

      ---

   c. Ensure that sample plate information is correct, then click **Next**.

6. In the **Review** step, review the run plan summary, then click **Save & Print** to print the run setup guide, if desired. Click **Save** to save the run without printing.

   After saving, the run appears in the **Manage Runs** screen in the run list with the name you specified.

After you select the run and load the sequencer, the run starts on the sequencer screen.

When the sequencing run is complete, you can recover the leftover volume from each library that was prepared in the run. For more information to find, recover, and purify the leftover library preparations, see the *Genexus™ Integrated Sequencer User Guide* (Pub. No. MAN0017910).

5 Genexus™ FFPE DNA and RNA Purification protocol

Genexus™ FFPE DNA and RNA Purification workflow

5 min

Plan a purification run (page 49)

IMPORTANT! If performing a **Sample to Result** run, plan the run in the Genexus™ Software. See "Plan a Sample to Result run" on page 41.

To purify samples for use in **Nucleic Acid to Result** runs or other nonsequencing applications, run the Genexus™ Purification Instrument in standalone configuration. Add a new purification run plan or copy-edit an existing purification run plan that best represents your experiment. Purification run plans contain instrument settings that are used in sample purification.

3 hr

Prepare samples from FFPE curls (page 55)

OR

Prepare samples from FFPE slides (page 57)

Samples are deparaffinized and digested with protease in preparation for isolation of DNA and RNA.

5 min

Load the Genexus™ Purification Instrument (page 59)

The purification run plan is selected, and the run is initiated. The instrument performs a UV cleaning, then reagents and consumables are loaded onto the instrument.

2 hr

Start the run (page 69)

After the sample plate, reagents, and consumables are loaded, the instrument door is closed, and the run is started.

Depending on the number of samples purified, sample quantification adds up to 2.5 hours to the run time.

Genexus™ FFPE DNA and RNA Purification workflow

5 min

Unload the purified nucleic acids (page 70)

If performing a **Sample to Result** run, remove the 96-Well Nucleic Acid Output Plate and proceed to sequence the purified sample. Remove and seal the 48-Well Nucleic Acid Archive Plate, then store as directed.

If performing a **Nucleic Acid to Result** run or purifying nucleic acids in standalone configuration for use in other downstream applications, remove and seal the 48-Well Nucleic Acid Archive Plate, then store as directed or proceed to sequence the purified sample.

Used reagents and consumables are removed from the instrument and the instrument performs a UV cleaning.

Plan a purification run (standalone configuration)

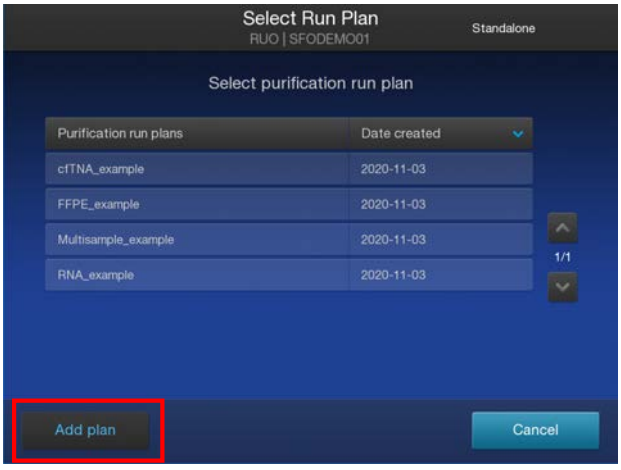
Note: If running the Genexus™ Purification System in integrated configuration, see "Plan a Sample to Result run" on page 41 to plan a **Sample to Result** run in the Genexus™ Software.

In standalone configuration, plan a purification-only run through the instrument touchscreen. After purification is complete, all purified samples are transferred to an archive plate for storage.

Add a purification run plan (standalone configuration)

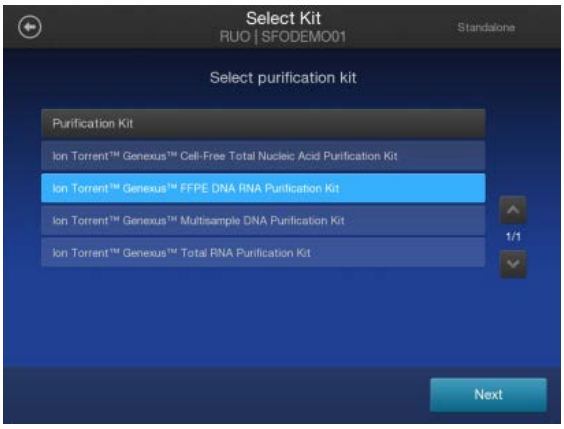
Plan the run before you prepare samples and load the samples into the FFPE DNA and RNA Purification Plate 1. However, experienced users can save time if you plan the purification run during the protease digestion step of sample preparation.

1. Enter your username and password to sign in to the instrument.
2. Tap **Run**, then tap **Add plan**.

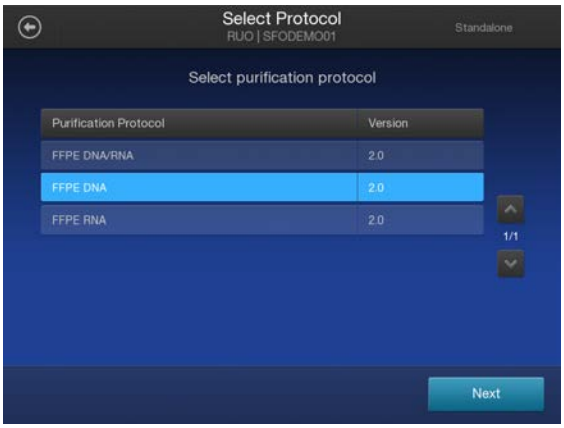


3. Tap in the entry box, enter a unique name for the run plan, then tap **Done** ▸ **Next**.

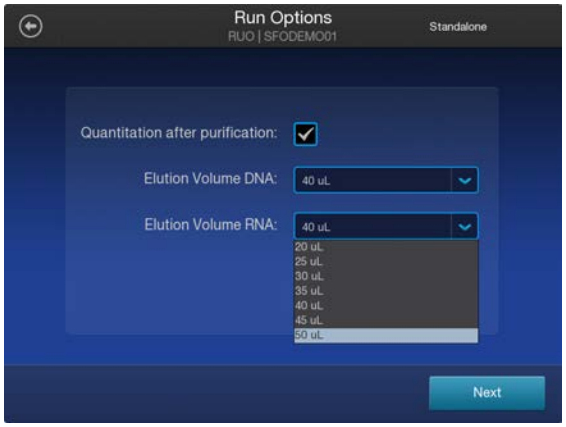
4. Select the **Ion Torrent™ Genexus™ FFPE DNA and RNA Purification Kit**, then tap **Next**.



5. Select the appropriate purification protocol and software version in use, then tap **Next**.
   - If sequentially purifying DNA and RNA, select **FFPE DNA RNA**.
   - If purifying DNA only, select **FFPE DNA**.
   - If purifying RNA only, select **FFPE RNA**.

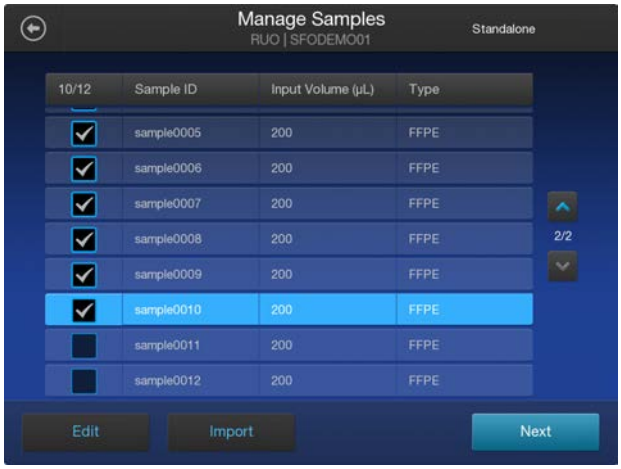


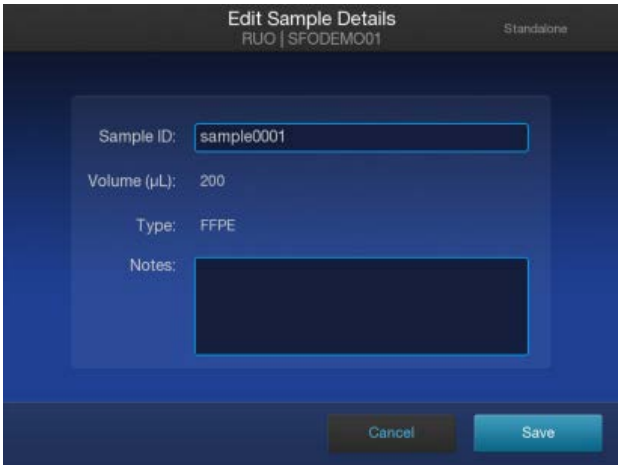
6. Enable or disable **Quantitation after Purification**.
   The Quantitation Plate is required even if **Quantitation after Purification** is disabled.
   Disabling **Quantitation after Purification** may reduce the purification run time by up to 2.5 hours.



7. Accept the default elution volume. If needed, select the desired elution volume from the dropdown list, then tap **Next**.

8. *(Optional)* Change the number of samples and the sample details.
   a. In the **Manage Samples** screen, deselect extra samples (for example, if you run only 10 samples, deselect samples 11 and 12).
   b. Tap on a sample ID to select the sample.
   c. Tap **Edit**, enter a new **Sample ID** and any **Notes**, then tap **Save**.
   d. Repeat substep 8b and substep 8c for each additional sample.
   e. Click **Next**.





9. *(Optional)* Import sample information.

   Importing sample information overwrites the existing **Sample ID** and **Notes** information for each sample selected.

In standalone configuration, prepare a CSV sample import file and save it to a USB drive to import sample information. See page 161.

a. In the **Manage Samples** screen, select the samples to import the sample information, then tap **Import**.

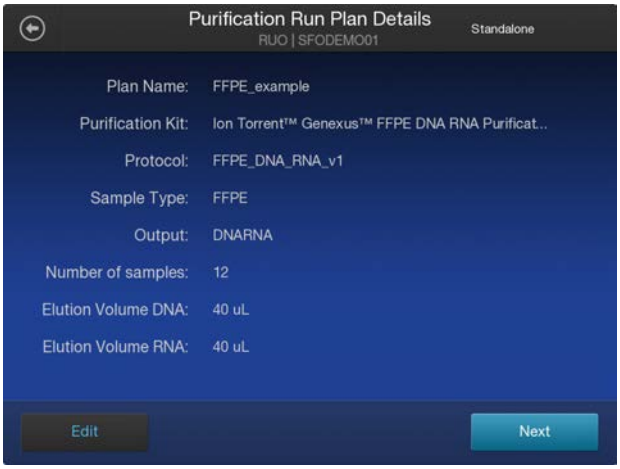
b. In the **Sample Import** screen, tap **Import** to proceed.

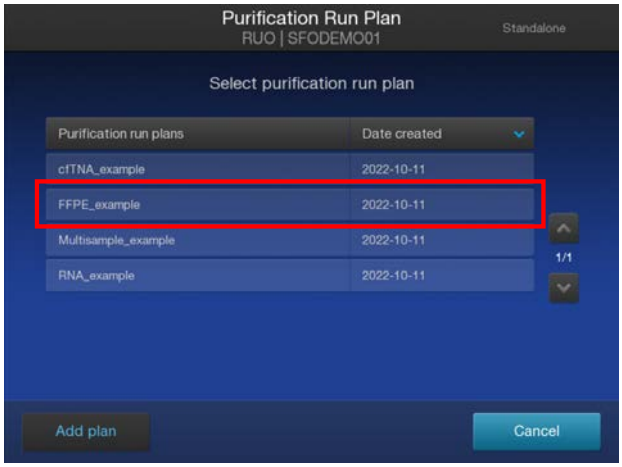
c. Insert the USB drive that contains the sample import CSV file into the USB port on the front of the purification instrument. In the **Sample Import** screen, select the USB drive, then navigate to and select the sample import file.

d. *(Optional)* Tap **Details** to view the CSV file that lists the sample names to be imported.

e. Tap **Import**, then in the **Import Successful** screen, tap **OK**.
The imported sample information is shown in the **Manage Samples** screen. If needed, edit imported sample information as described in step 8.

10. Review the **Purification Run Plan Details**. Tap **Edit** to change any of your selections, otherwise tap **Next**.





The new purification run plan appears in the list of available **Purification Run Plans**.

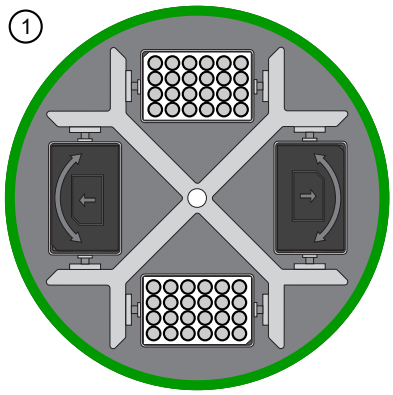
To delete an existing run plan, see “Delete a run plan (standalone configuration)” on page 161.

Prepare samples

Procedural guidelines

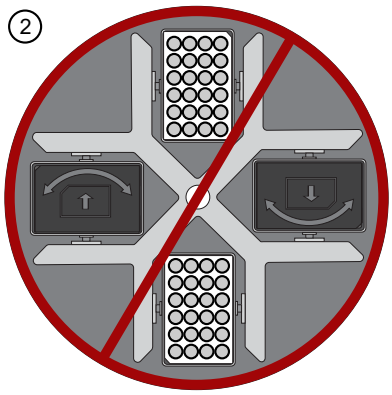
IMPORTANT! Store all kit components containing liquid in the upright orientation.

- Perform all steps at room temperature (20°C–25°C) unless otherwise noted.
- Thawing or storing on ice can be substituted with thawing or storing at 4°C (2–8°C refrigerator or prechilled benchtop cold block).
- When mixing samples by pipetting up and down, avoid creating bubbles.
- Wear clean gloves and a clean laboratory coat.
- Change gloves whenever you suspect that they are contaminated.
- Open and close all sample tubes carefully. Avoid splashing or generating aerosols of the samples.
- When working with RNA:
  - Use a positive-displacement pipettor and RNase-free pipette tips.
  - Clean laboratory benches and equipment periodically with an RNase decontamination solution, such as RNase*Zap*™ RNase Decontamination Solution (Cat. No. AM9780).
  - Store RNA at –90°C to –70°C.
- Volumes for reagent mixes are given per sample. We recommend that you prepare master mixes for larger sample numbers. To calculate volumes for master mixes, see the per-well volume and add 5–10% overage.
- Incubation at 60°C can be extended 1 hour (2 hr total time) to increase DNA yields followed by the 90°C incubation for 1 hour.
- We recommend using a plate centrifuge that holds the AutoLys M Tube Rack in "landscape" orientation.



① Landscape orientation—recommended

Note: Place AutoLys M Tube Rack in the centrifuge with the arrow on the cover pointing outward as shown.



② Portrait orientation—not recommended

- The plate chiller shuts off 60 minutes after run completion. Remove the 96-Well Nucleic Acid Output Plate and 48-Well Nucleic Acid Archive Plate with purified nucleic acids from the instrument within 1 hour of run completion. Proceed immediately to sequencing or properly store the nucleic acids until use.
- The Quantitation Plate requires equilibration to room temperature for at least 30 minutes before use.

Before each use of the kit

- We recommend the use of incubators when using AutoLys M Tubes.
- Preheat incubators to 60°C and 90°C.
- Prepare Protease Digestion and DNase Digestion solutions immediately before use.
- Centrifuge purification plates for 30 seconds at 1,000 x *g* to collect the contents.

Materials required

- Genexus™ FFPE DNA and RNA Purification (Part. No. A45532)
  - FFPE DNA and RNA Purification Plate 1
  - Proteinase K (red cap)
  - FFPE Protease Buffer
- AutoLys M TubeLifter or Pliers
- AutoLys M Tubes and Caps
- AutoLys M Tube Rack
- Plate centrifuge
- Incubators (see “Recommended materials not supplied for use with the Genexus™ Purification System” on page 25 for a list of recommended incubators)

Recommended input amount

Sample type	Input range	Recommended input amount
FFPE tumor resections	1 x 5 µm curl/slide to 4 x 10 µm curls/slides	1 x 10 µm curl/slide
FFPE fine needle aspirate (FNA) FFPE core needle biopsy (CNB)	1 x 5 µm curl/slide to 6 x 10 µm curls/slides	4 x 10 µm curls/slides

Prepare 1X Protease Digestion Master Mix

Prepare the 1X Protease Digestion Master Mix immediately before use.

1. Invert the FFPE Protease Buffer and Proteinase K tubes supplied in the kit 5X each, then briefly centrifuge.

2. In a 1.5-mL low-retention microcentrifuge tube, prepare a 1X Protease Digestion Master Mix as indicated, where `n` is the number of tissue samples.

Component	Volume per reaction
FFPE Protease Buffer	(n + 1) × 225 µL
Proteinase K (red cap)	(n + 1) × 10 µL
Total volume	**(n + 1) × 235 µL**

3. Vortex for ~5 seconds to mix, then briefly centrifuge to collect the contents.

Prepare FFPE curl samples with AutoLys M Tubes

Use AutoLys M Tubes to prepare FFPE samples. Alternatively, CitriSolv™ Clearing Agent, xylene, or an equivalent method for removal of paraffin from the FFPE samples can be used to prepare samples. See Appendix B, “Supplemental information”.

Digest with Protease in AutoLys M Tubes

Note: To minimize the amount of time between protease digestion and starting the purification run on the instrument, prepare the reagents and consumables that are required by the instrument during the 90°C incubation (step 6).

1. Label an AutoLys M Tube for each FFPE tissue sample.

2. Add each FFPE section curl to a separate labeled tube.

3. Place AutoLys M Tubes in an AutoLys M Tube Rack, then centrifuge at 2,000 × *g* for 1 minute to collapse the curl before the addition of buffer.

4. Pipet 235 µL 1X Protease Digestion Master Mix into each labeled tube.

   Ensure that the samples are submerged in the Protease Digestion Master Mix.

5. Cap each tube securely to limit evaporation, then incubate at 60°C for ≥60 minutes in an AutoLys M Tube Rack.

   Incubation at 60°C can be extended to 2 hours to increase DNA yields. We recommend that you incubate low yielding samples such as core needle biopsy and fine needle aspirate samples for 2 hours to maximize yield.

6. Incubate at 90°C for 60 minutes.
   - If using a single incubator, keep the sample in the incubator while the temperature increases. Start timing when the temperature reaches 90°C.
   - Set up the FFPE DNA and RNA Purification Plate 1 during the incubation.
   - Prepare the reagents and consumables that are required by the instrument during the incubation. See “Prepare the consumables” on page 60.
   - Equilibrate the Quantitation Plate to room temperature during the incubation.

7. Allow samples to cool to room temperature for 5 minutes before proceeding to lift the tubes.

8. Lift the tubes.

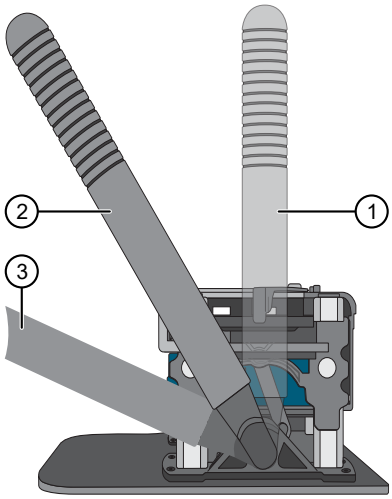
   The following steps describe use of the AutoLys M TubeLifter to process up to 24 samples simultaneously. Alternatively, AutoLys M Tube Pliers can be used to process tubes individually.

   For more information about use of the AutoLys M TubeLifter see the *AutoLys M TubeLifter User Guide* (Pub. No. MAN0017676).

   a. Ensure that the AutoLys M TubeLifter lever is in Position A (straight up) and the slider is in Position 1.

   b. Slide the 24-well AutoLys M Tube Rack containing the lysed samples into the AutoLys M TubeLifter.

   c. Press the lever down from Position A to Position B, then remove the rack from the lifter.



① Position A
② Position B
③ Position C

9. Slide the AutoLys M Tube Locking Lid onto the rack, then centrifuge the samples at 2,000 × *g* for 10 minutes.

   IMPORTANT! Ensure that the embossed arrow of the AutoLys M Tube Locking Lid points away from the center of rotation (landscape orientation) when placed in the centrifuge. See “Procedural guidelines” on page 53.

10. Separate the filter from the outer tube.
    a. Adjust the position of the AutoLys M TubeLifter slider to position 2.

    b. Remove the AutoLys M Tube Locking Lid, then slide the rack into the AutoLys M TubeLifter.

    c. Press the lever down from Position B to Position C.

    Keep the samples on ice or at 4°C.

Proceed to “Load the Genexus™ Purification Instrument and start the run” on page 59.

STOPPING POINT If needed, samples can be stored overnight at 4°C or frozen at –30°C to –10°C.

Prepare FFPE slide samples with AutoLys M Tubes

Use AutoLys M Tubes for the preparation of FFPE samples. Alternatively, CitriSolv™ Clearing Agent, xylene, or an equivalent method for removal of paraffin from the FFPE samples can be used to prepare samples. See Appendix B, “Supplemental information”.

Collect the tissue

1. Label an AutoLys M Tube for each FFPE tissue sample.

   Label each tube (cap and side) with its Sample ID using a marker that is resistant to xylene and ethanol.

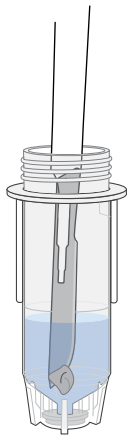
2. Pipet 235 µL 1X Protease Digestion Master Mix into each labeled tube.

3. Pipet 2–4 µL of 1X Protease Digestion Master Mix from the labeled tube evenly across the fixed tissue section on the slide to pre-wet the tissue section.

   Larger sections may need an additional 2–4 µL of 1X Protease Digestion Master Mix.

4. Use a sterile disposable scalpel or clean razor blade to scrape the tissue in a single direction, then collect the tissue into a cohesive mass on the tip of the scalpel blade.

5. Carefully insert the scalpel blade with the tissue mass into the 1X Protease Digestion Master Mix in the AutoLys M Tube. Rinse the tissue from the blade into the buffer, then ensure that the entire mass is in solution.



6. Remove and inspect the blade to ensure that no tissue remains on it.

7. Inspect the slide to ensure that all the tissue is removed (the slide should be translucent). Discard the scalpel in a waste container for sharp objects.

8. Gently flick the tube to mix and to immerse the tissue.

   If the tissue adheres to the sides of the tube, use a pipette tip to push the tissue into the solution or centrifuge briefly to immerse the tissue in the solution.

Digest with protease

To minimize the amount of time between protease digestion and starting the purification run on the instrument, prepare the reagents and consumables that are needed by the instrument during the 90°C incubation (step 2).

1. Incubate at 60°C for ≥60 minutes in an AutoLys M Tube Rack.

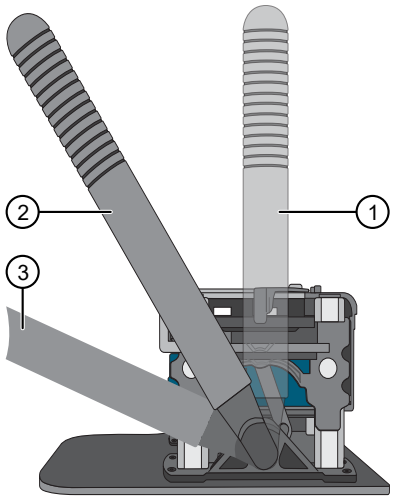
   Incubation at 60°C can be extended to 2 hours to increase DNA yields.

2. Incubate at 90°C for 60 minutes.
   - If using a single incubator, keep the sample in the incubator while the temperature increases. Start timing when the temperature reaches 90°C.
   - Set up the FFPE DNA and RNA Purification Plate 1 during the incubation.
   - Prepare the reagents and consumables that are needed by the instrument during the incubation. See “Prepare the consumables” on page 60.
   - Equilibrate the Quantitation Plate to room temperature during the incubation.

3. Allow samples to cool to room temperature for 5 minutes before proceeding to lift the tubes.

4. Lift the tubes. The following steps describe use of the AutoLys M TubeLifter to process up to 24 samples simultaneously. Alternatively, AutoLys M Tube Pliers can be used to process tubes individually.
   a. Ensure that the AutoLys M TubeLifter lever is in Position A (straight up) and the slider is in Position 1.
   b. Slide the 24-well AutoLys M Tube Rack that contains the lysed samples into the AutoLys M TubeLifter.
   c. Press the lever down from Position A to Position B, then remove the rack from the lifter.

   For more information about use of the AutoLys M TubeLifter, see the *AutoLys M TubeLifter User Guide* (Pub. No. MAN0017676).



① Position A
② Position B
③ Position C

5. Slide the AutoLys M Tube Locking Lid onto the rack, then centrifuge the samples at 2,000 × *g* for 10 minutes.

   IMPORTANT! Ensure that the embossed arrow of the AutoLys M Tube Locking Lid points away from the center of rotation (landscape orientation) when placed in the centrifuge (see “Procedural guidelines” on page 53).

6. Separate the filter from the outer tube.
   a. Adjust the position of the AutoLys M TubeLifter slider to position 2.

b. Remove the AutoLys M Tube Locking Lid, then slide the rack into the AutoLys M TubeLifter.

c. Press the lever down from Position B to Position C.

Keep the samples on ice or at 4°C.

Proceed to "Load the Genexus™ Purification Instrument and start the run" on page 59.

STOPPING POINT If needed, samples can be stored overnight at 4°C or frozen at –30°C to –10°C.

Load the Genexus™ Purification Instrument and start the run

This section describes how to perform the following procedures.

- Set up the instrument for use by loading all of the required reagents and consumables.
- Start a Genexus™ Purification Instrument run.

Note: Do NOT load any consumables onto the instrument until after the instrument has performed the prerun UV cleaning.

Materials required

- Genexus™ FFPE DNA and RNA Purification (Part. No. A45532)
  - FFPE DNA and RNA Purification Plate 1
  - FFPE DNA and RNA Purification Plate 2
  - DNase (yellow cap)
  - DNase Buffer (blue cap)
  - 12-Well Tip Comb
- Genexus™ Nucleic Acid Quantitation (Part. No. A45538)
  - Quantitation Plate
  - Quantitation Tube
- Genexus™ Purification Supplies 2 (Part. No. A45574)
  - 2 Purification Tip Cartridges
  - 48-Well Nucleic Acid Archive Plate
  - 48-Well Nucleic Acid Archive Plate Seal
- 96-Well Nucleic Acid Output Plate
- P200 pipette and filtered tips

Prepare the consumables

Note: Consumables can be prepared during the protease digestion 90°C incubation step to save time.

Remove all cartridges and consumables from their packaging, then place them on the bench at room temperature. Prepare the following cartridges and consumables.

- Genexus™ Purification Supplies 2
  - 2 Purification Tip Cartridges
  - 48-Well Nucleic Acid Archive Plate
  - 48-Well Nucleic Acid Archive Plate Seal
- 12-Well Tip Comb

Equilibrate the Quantitation Plate

IMPORTANT! Allow at least 30 minutes for the Quantitation Plate to equilibrate to room temperature.

The Quantitation Plate is required even if your run plan does not include sample quantitation.

The Quantitation Plate can be equilibrated to room temperature during the protease digestion to save time.

Centrifuge the Quantitation Plate at 1,000 × *g* for 30 seconds to collect the contents.

Add 1X DNase Digestion Master Mix to the FFPE DNA and RNA Purification Plate 2

Note: Addition of DNase is not required if purifying only DNA (purification protocol **FFPE DNA** is selected for the run). Proceed directly to "Add samples to FFPE DNA and RNA Purification Plate 1" on page 61.

The FFPE DNA and RNA Purification Plate 2 contains magnetic beads in row H.

1. Vortex the DNase Buffer and DNase supplied in the kit for ~5 seconds each, then briefly centrifuge to collect the contents.

2. In a 1.5-mL low-retention microcentrifuge tube, prepare a 1X DNase Digestion Master Mix as indicated, where `n` is the number of tissue samples.

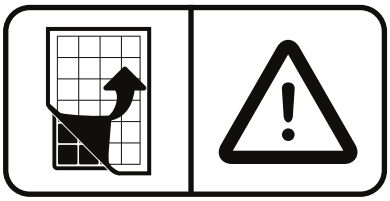
Component	Volume per reaction[1]
DNase Buffer	(n + 1) × 99 µL
DNase	(n + 1) × 1.0 µL
Total volume	**(n + 1) × 100 µL**

[1] Include a 5–10% overage to accommodate pipetting errors.

3. Vortex for ~5 seconds to mix, then briefly centrifuge to collect the contents.

4. Centrifuge the FFPE DNA and RNA Purification Plate 2 at 1,000 x *g* for 30 seconds to collect the contents.

5. Carefully remove the plate seal without disturbing the contents.



6. Pipet 100 µL 1X DNase Digestion Master Mix into each well that is used in Row A of the FFPE DNA and RNA Purification Plate 2.

Add samples to FFPE DNA and RNA Purification Plate 1

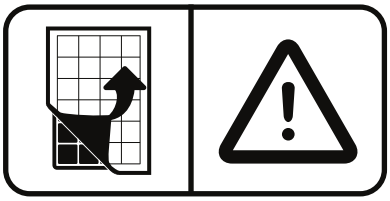
The FFPE DNA and RNA Purification Plate 1 contains magnetic beads in row B.

1. Centrifuge the plate at 1,000 x *g* for 30 seconds to collect the contents.

   IMPORTANT! Do not create bubbles when preparing the plate.

2. Inspect the plate to ensure that the contents of all rows are at the bottom of the wells.

3. Carefully remove the plate seal without disturbing the contents.



4. Transfer 200 µL of each sample to an individual well in row A of the prefilled FFPE DNA and RNA Purification Plate 1.

   Add samples to consecutive wells starting with sample 1 in well A1, through sample 12 in well A12 as defined in the run plan. Do not skip wells.

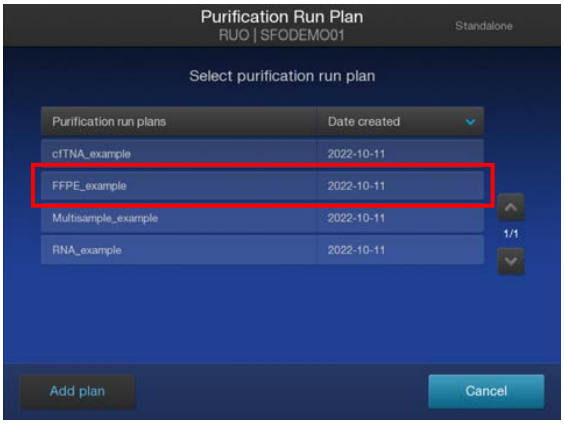
   A precipitate can form, but this does not interfere with the DNA binding. Proceed directly to the next step.

   Reagent consumables cannot be reused.

   You can add the samples to the FFPE DNA and RNA Purification Plate 1 and load the plate in the Genexus™ Purification Instrument as the final steps of loading the instrument. This can be done to ensure that other components are successfully loaded and accepted by the instrument before adding samples of possibly limited supply to the purification plate.

Start the purification run

1. In the instrument touchscreen, tap **Run**, then tap to select the run plan that you created for this run.



2. Ensure that the run plan selected is correct, then tap **Next**.

3. *(Optional, standalone configuration)* Import sample information.

   The import overwrites the existing **Sample ID** and **Notes** information for each sample. That is, if the run plan has 6 samples, the sample import file must include information for at least 6 samples.

   To import sample information, prepare a CSV sample import file and save it to a USB drive. See “Create a template for importing samples in standalone configuration purification run plans” on page 161.

   a. In the **Sample Assignment** screen, tap **Manage Samples**.

   b. In the **Manage Samples** screen, tap **Import**.

   c. In the **Sample Import** screen, tap **Import** to proceed.

   d. Insert the USB drive that contains the sample import CSV file into the USB port on the front of the purification instrument. In the **Sample Import** screen, select the USB drive, then navigate to and select the sample import file.

   e. *(Optional)* Tap **Details** to view the CSV file that lists the sample names to be imported.

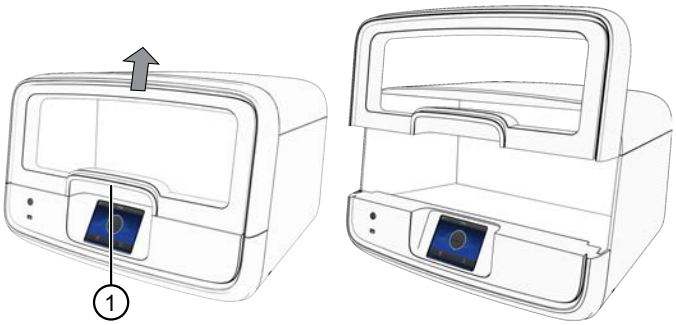
   f. Tap **Import**, then in the **Import Successful** screen, tap **OK**.

      The imported sample information is shown in the **Manage Samples** screen. If needed, select a sample, then tap **Edit** to modify the **Sample ID** or **Notes**.

4. Tap **Next**.

   The instrument performs a 2-minute UV cleaning, then unlocks the door.

5. Lift the instrument door to the stop.



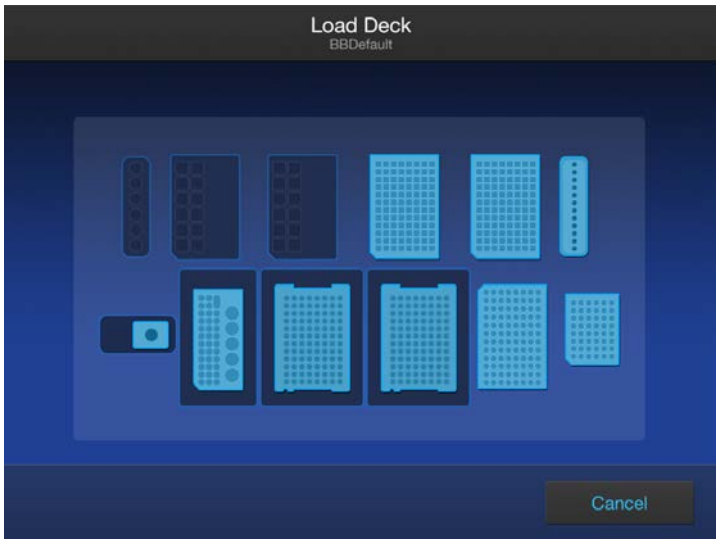
① Hold here, then lift.

Load the Genexus™ Purification Instrument

IMPORTANT!

- Do NOT load any consumables onto the instrument until after the instrument has performed the prerun UV cleaning.
- Ensure that all components are clean and dry before loading them onto the instrument.
- Ensure that the reagent and quantitation station compartments are free of condensate before loading components. If needed, use a lint-free wipe to dry the compartment.

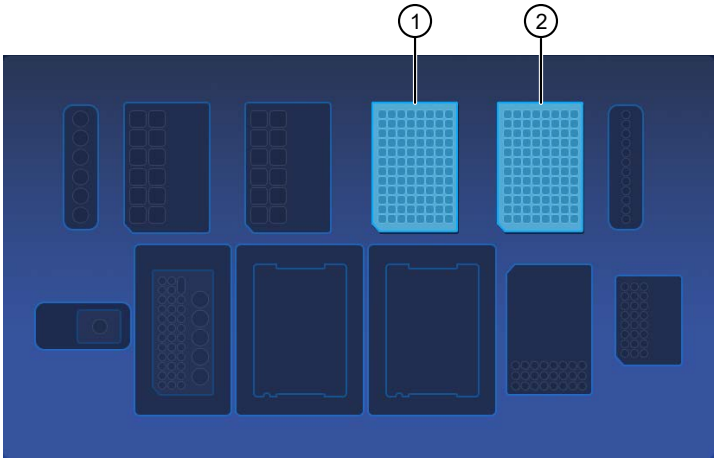
Follow the on-screen prompts to load the instrument.



Load FFPE DNA and RNA Purification Plate 1 & 2

1. Load the FFPE DNA and RNA Purification Plate 1 (DNA plate) prepared in step 4 of "Add samples to FFPE DNA and RNA Purification Plate 1" on page 61.

2. Load the FFPE DNA and RNA Purification Plate 2 (RNA plate) prepared in step 6 of "Add 1X DNase Digestion Master Mix to the FFPE DNA and RNA Purification Plate 2" on page 60.

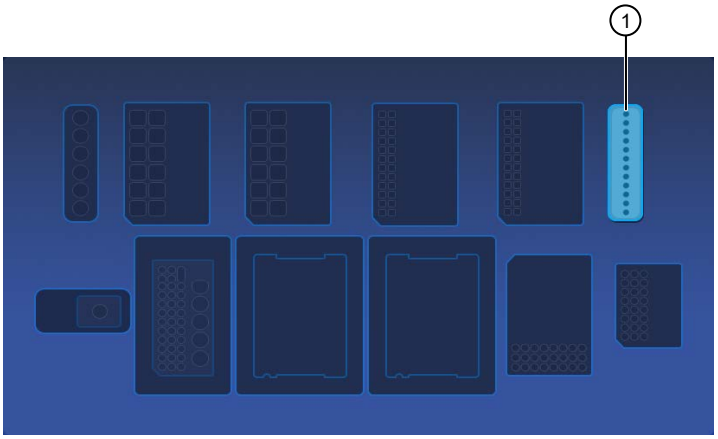


① FFPE DNA and RNA Purification Plate 1 position
② FFPE DNA and RNA Purification Plate 2 position

Load the 12-Well Tip Comb, Purification Tip Cartridges, 96-Well Nucleic Acid Output Plate, and 48-Well Nucleic Acid Archive Plate

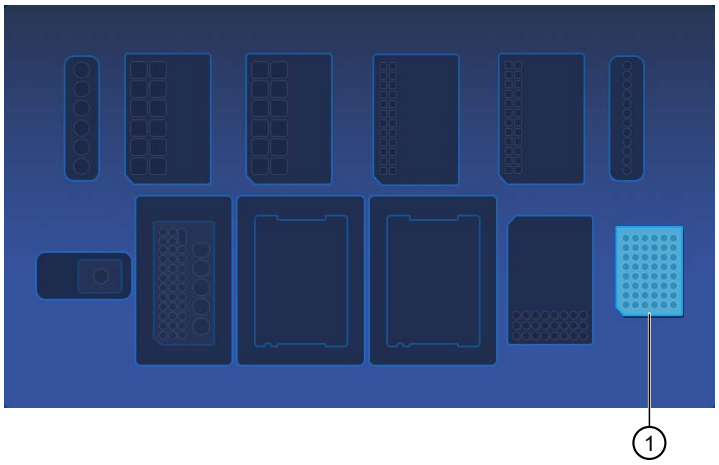
1. Unwrap, then load a new 12-Well Tip Comb.

   Ensure that the 12-Well Tip Comb is straight and that the tabs are not bent or broken. If needed, gently bend the tip comb in the opposite direction to the curvature to straighten the tip comb before installing it.



① 12-Well Tip Comb position

2. Unwrap, then load a new 48-Well Nucleic Acid Archive Plate.

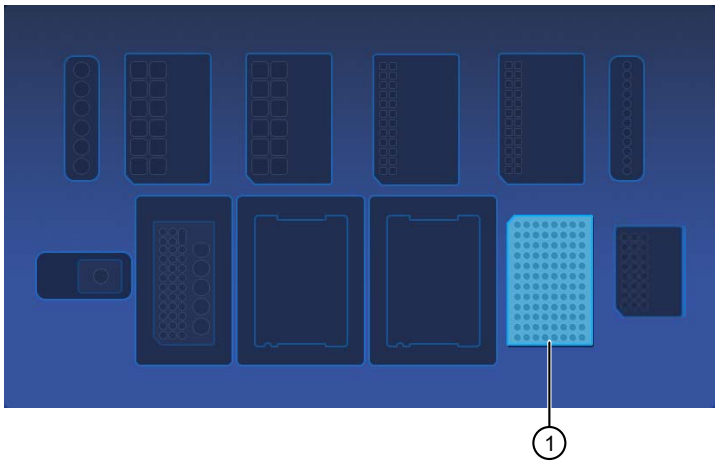


① 48-Well Nucleic Acid Archive Plate position

3. *(Integrated configuration)* Load a new 96-Well Nucleic Acid Output Plate into the output plate position.

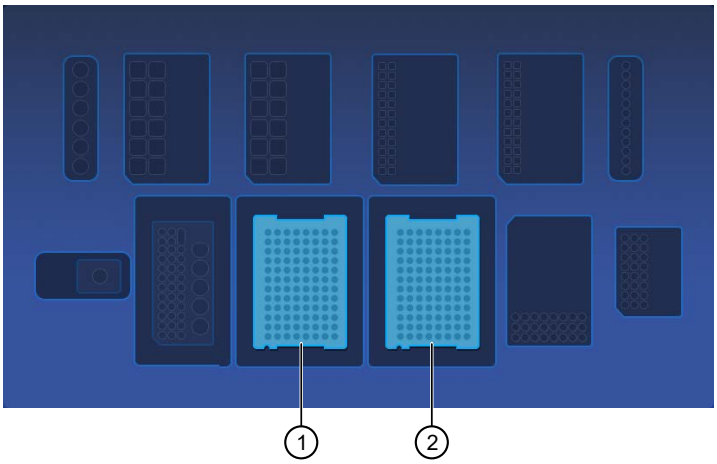
   The 96-Well Nucleic Acid Output Plate is not required when performing the purification in standalone configuration. The samples are in the 48-Well Nucleic Acid Archive Plate on completion of the purification run.

   After a **Sample to Result** purification run, the 96-Well Nucleic Acid Output Plate becomes the sample plate to be loaded in the Genexus™ Integrated Sequencer.



① 96-Well Nucleic Acid Output Plate position

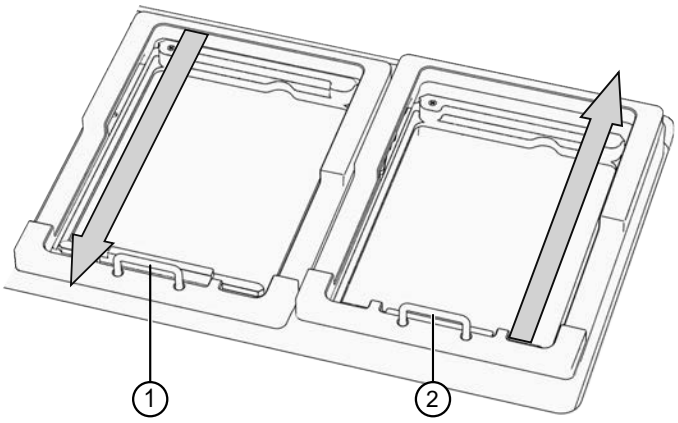
4. Unwrap two new Purification Tip Cartridges, remove the cover to expose the pipette tips, then load the cartridges in positions 1 and 2.



① Purification Tip Cartridges position 1
② Purification Tip Cartridges position 2

   a. Pull the locking mechanism handle forward (callout 1), then place the tip box in the open position.

   b. Push the locking mechanism handle back (callout 2) to lock the tip box in place.



① Unlocked (forward)

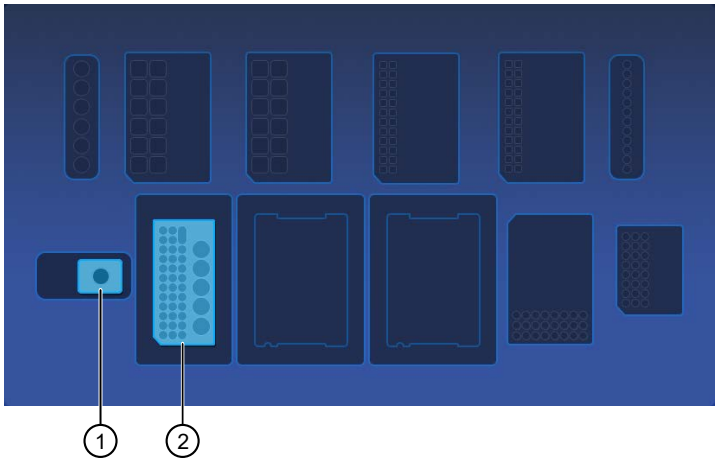
② Locked (back)

Load the quantitation reagents and consumables

Note:

- Protect the Quantitation Plate from light to prevent photobleaching of the preloaded reagents.
- The Quantitation Plate is required even if your run plan does not include sample quantitation.
- The Quantitation Tube is not required if your run plan does not include sample quantitation.

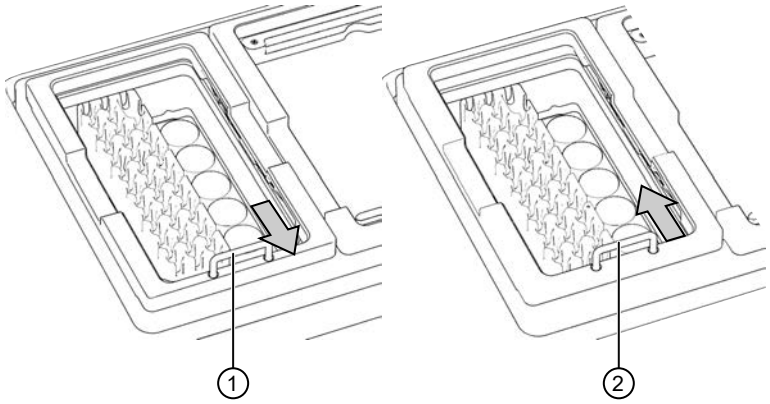
1. Centrifuge the Quantitation Plate at 1,000 × *g* for 30 seconds to collect the contents.
2. Load the Quantitation Plate in position 2.



① Quantitation Tube position
② Quantitation Plate position

   a. Pull the locking mechanism handle forward, then place the Quantitation Plate in the open position.

   b. Push the locking mechanism handle back to lock the plate in place.

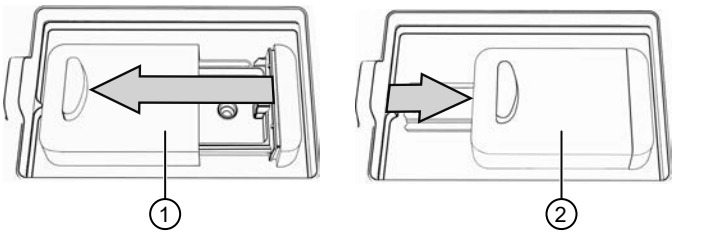


① Unlocked (forward)

② Locked (back)

3. *(If needed)* Slide and hold the quantitation module cover to the left, then insert the Quantitation Tube. **Press down firmly** to properly seat the tube, then allow the module cover to close.

WARNING! Do not force the module cover closed. Forcing the module cover closed can damage the instrument.



① Open ② Closed

Confirm that consumables are installed correctly

IMPORTANT! To ensure correct and safe instrument operation, confirm that all consumables are installed correctly on the deck before you start a run. The instrument vision system confirms that required reagents are in place, no reagents are expired, and foil seals are removed. The vision system does not verify all aspects of the consumable setup before beginning each run.

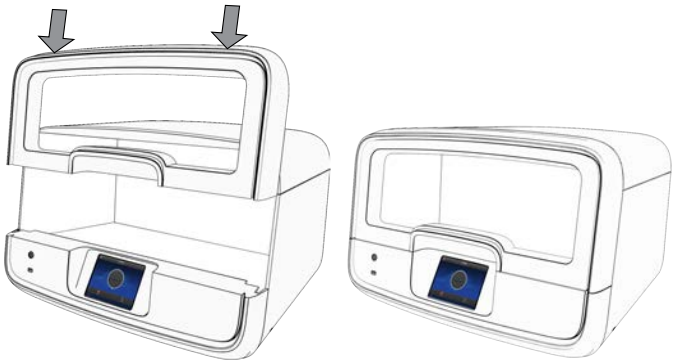
1. Confirm the following.
   - Foil seals are removed from the purification plates. Do not remove foil seal from the Quantitation Plate.
   - Each component is at the correct location and in the correct orientation. Press down on all plates and cartridges to ensure that they are firmly seated in place.
   - The Tip Combs are in place.
   - The Quantitation Plate is in the correct location, is in the correct orientation, and is locked in place.
   - *(If needed)* The Quantitation Tube is firmly seated in the quantitation module.
   - Each Purification Tip Cartridge is in the correct location, in the correct orientation, and locked in place.

   If the vision system detects an error, the location indicator does not turn gray in the touchscreen.

2. If needed, tap **Help**, then accept each warning message appropriately to proceed.

Start the run

1. When all reagents and consumables are loaded in the Genexus™ Purification Instrument, tap **Next**.
2. Close the instrument door by pressing down on both top corners. Ensure that the door is locked after closing it.



   The instrument vision system confirms that all reagents are in place and are not expired.

3. Tap **Start**.

   The time remaining until the purification is complete is displayed and the interior lighting turns green.

   - If you need to stop the run for any reason, tap **Cancel**, then tap **Yes** to confirm the cancellation. A canceled run cannot be resumed. You must restart a run from the beginning.
   - The interior lighting turns off during quantitation, then turns blue when the run is complete.
   - If the instrument encounters a problem during the run, it aborts the run and displays the error on the instrument touchscreen. The interior lighting turns red.

When the run is complete, the interior light turns blue, and the touchscreen displays **Run Complete**. Quantitation results are available immediately. See “View and export quantitation results” on page 72.

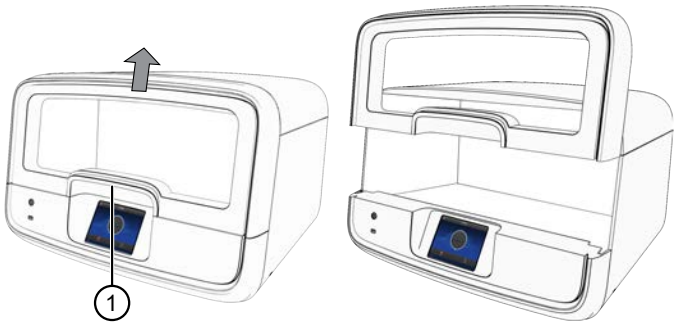
Unload purified DNA and RNA

IMPORTANT! Do not allow purified nucleic acids to sit on the instrument. Store as directed or use in sequencing reactions within 60 minutes.

1. In the touchscreen, tap **Unload**.

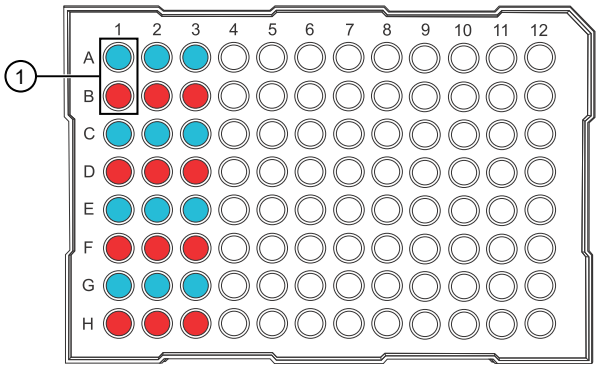
The door unlocks.

2. Lift the instrument door to access the instrument deck.



① Hold here, then lift.

3. ***(Sample to Result** run)* Remove the 96-Well Nucleic Acid Output Plate that contains the purified sample DNA and RNA that is ready for the addition of positive or nontemplate sample sequencing controls. Store on ice or at 4°C. If quantitation was performed, the sample concentration information is visible in the Genexus™ Software. Alternatively, determine sample concentrations manually, if needed.



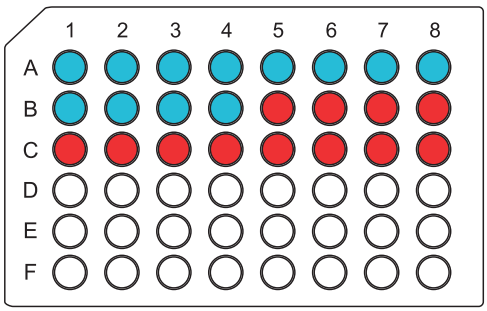
① Paired purified DNA-A1 and RNA-B1 from sample 1.
C1 + D1 = sample 2,
E1 + F1 = sample 3,
and so on.

DNA

RNA

STOPPING POINT If not sequencing immediately, seal the plate with an Adhesive PCR Plate Foil (Cat. No. AB0626), then store the plate at –20°C for up to 1 week. For long term storage (>1 week), transfer the samples to labeled low-retention tubes, then store the DNA samples at –30°C to –10°C and the RNA samples at –90°C to –70°C for up to 36 months.

4. Remove the 48-Well Nucleic Acid Archive Plate that contains the purified sample DNA and RNA.



DNA is in wells A1–B4. DNA samples always start in well A1.

RNA is in wells B5–C8. RNA samples always start in well B5 regardless of how many samples are purified.

Note: *(Purification configuration only)* If using the purified DNA or RNA immediately, transfer the sample to a sample input plate for sequencing. To determine the sample concentrations, see “View and export quantitation results” on page 72.

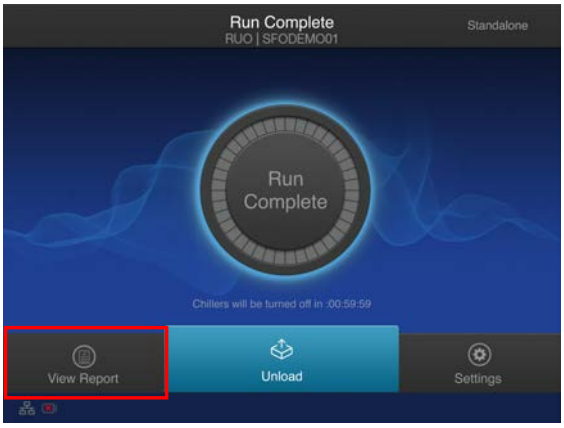
5. For short-term storage, seal the plate with a 48-Well Nucleic Acid Archive Plate Seal. Store the plate at –20°C for up to 3 months. For long-term storage (>3 months), transfer samples to labeled low-retention tubes, then store the DNA samples at –30°C to –10°C and the RNA samples at –90°C to –70°C for up to 36 months.

   If the archive plate is thawed during short-term storage, transfer the DNA and RNA into labeled low-retention tubes. Do not reseal the archive plate with the used plate seal.

View and export quantitation results

Purification runs that include sample quantitation produce sample concentration results that can be accessed after the run is complete. In integrated configuration, view the **Run Report** that is available in the Genexus™ Software to see the sample concentrations. In standalone configuration, sample concentration results can be accessed from the **Run Complete** screen or the **Home** screen as described here.

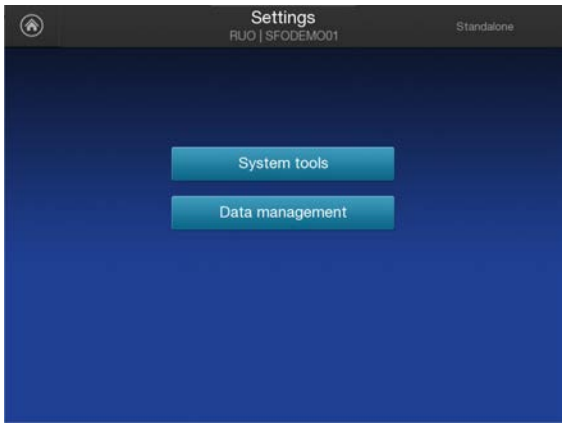
1. In the **Run Complete** screen, tap **View report**.



   The **Saved Experiment Reports** screen opens. See step 4.

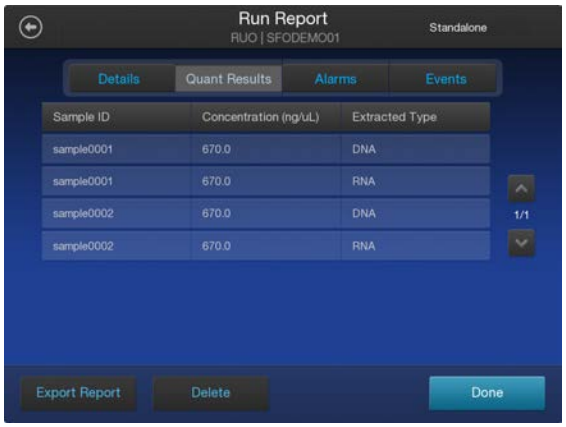
2. At any time after unloading and UV cleaning the instrument, sample concentration results can be accessed through the **Home** screen. Tap ⚙ (**Settings**).

3. In the **Settings** screen, tap **Data Management**.



4. In the **Saved Experiment Reports** screen, tap ⌄ or ⌃ to page through the list. Locate the **Experiment Name** of interest, tap in the row to select the experiment, then tap **View Report**.

5. In the **Run Report** screen, tap **Quant Results** to view the sample concentration results.



6. Insert a USB drive into the USB port on the front of the instrument, then tap **Export Report**. Navigate to the file destination, then tap **Save**.

Dispose of used consumables and UV clean the instrument

Unload purified nucleic acid samples before disposal of used consumables.

IMPORTANT! Do not allow purified nucleic acids to sit on the instrument. Store as directed or use in sequencing reactions within 60 minutes.

1. Remove and discard the deep-well sample input plates.
   a. Remove the FFPE DNA and RNA Purification Plate 1 from the instrument.
   b. Dispose of the liquid waste by tipping the deep-well plate on one corner and pouring the waste into an appropriate liquid biohazardous waste container.

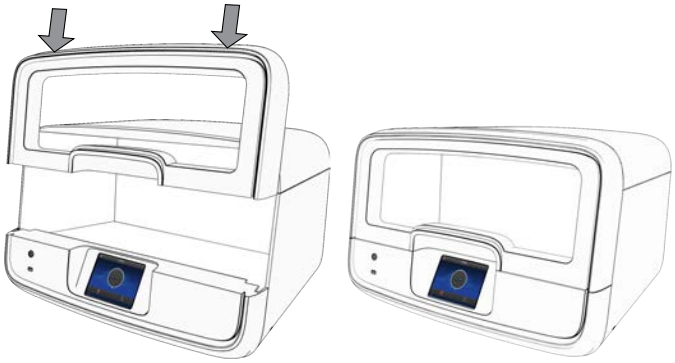
WARNING! Liquid waste contains guanidine thiocyanate, dispose of properly.

   c. Dispose of the deep-well plate in an appropriate waste container.
   d. Repeat substep 1a through substep 1c to discard the FFPE DNA and RNA Purification Plate 2.
2. Unlock, then remove and dispose of the Purification Tip Cartridges in an appropriate waste container.
3. Unlock, then remove and dispose of the Quantitation Plate.
   a. Dispose of the liquid waste by tipping the deep-well plate on one corner and pouring the waste into an appropriate liquid biohazardous waste container.

WARNING! No data are currently available that address the mutagenicity or toxicity of the Qubit™ RNA BR Reagent (Component A). This reagent is known to bind nucleic acid and is provided as a solution in DMSO. Treat the Qubit™ RNA BR Reagent with the same safety precautions as all other potential mutagens and dispose of the dye in accordance with local regulations.

   b. Dispose of the deep-well plate in an appropriate waste container.
4. Open the quantitation module cover, remove and discard the Quantitation Tube, then allow the module cover to close.

5. Close and lock the instrument door by pressing down on both top corners, then tap **Start UV Clean**.



The time remaining in the UV cleaning is displayed. When complete, the instrument is ready to start a new purification run.

6 Genexus™ Cell-Free Total Nucleic Acid Purification protocol

Genexus™ Cell-Free Total Nucleic Acid Purification workflow

5 min

Plan a purification run (page 78)

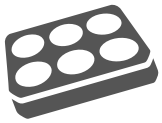
IMPORTANT! If performing a **Sample to Result** run, plan the run in the Genexus™ Software. See "Plan a Sample to Result run" on page 41.

To purify samples for use in **Nucleic Acid to Result** runs or other nonsequencing applications, run the Genexus™ Purification Instrument in standalone configuration. Add a new purification run plan or copy-edit an existing purification run plan that best represents your experiment. Purification run plans contain instrument settings that are used in sample purification.

30 min

Equilibrate the Quantitation Plate to room temperature (page 81)

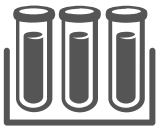
The Quantitation Plate requires equilibration to room temperature for at least 30 minutes before use. To save time, experienced users can take the Quantitation Plate out of 4°C storage before creating a run plan and preparing samples.



45 min

Prepare cell-free plasma from whole blood samples (page 81)

Whole blood samples are centrifuged to separate plasma from other components.



2 min

Load the Genexus™ Purification Instrument (page 83)

The purification run plan is selected, and the run is initiated. The instrument performs a UV cleaning, then samples, reagents, and consumables are loaded onto the instrument.

Genexus™ Cell-Free Total Nucleic Acid Purification workflow

2 hr

Start the run (page 94)

After the sample plate, reagents, and consumables are loaded, the instrument door is closed, and the run is started.

Depending on the number of samples purified, quantification adds ~45 minutes to the run time.

5 min

Unload the purified nucleic acids (page 95)

In integrated configuration, remove the 96-Well Nucleic Acid Output Plate and proceed to sequence the purified sample.

In standalone configuration, remove and seal the 48-Well Nucleic Acid Archive Plate, then store as directed, or proceed to sequence the purified sample.

Used reagents and consumables are removed from the instrument and the instrument performs a UV cleaning.

Plan a purification run (standalone configuration)

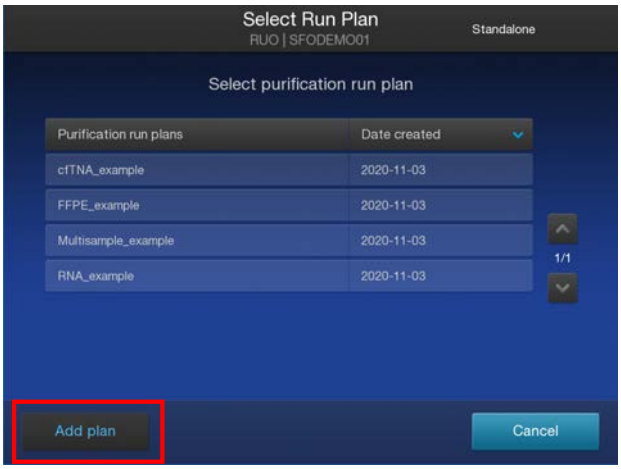
Note: If running the Genexus™ Purification System in integrated configuration, see “Plan a Sample to Result run” on page 41 to plan a **Sample to Result** run in the Genexus™ Software.

In standalone configuration, plan a purification-only run through the instrument touchscreen. After purification is complete, all purified samples are transferred to an archive plate for storage.

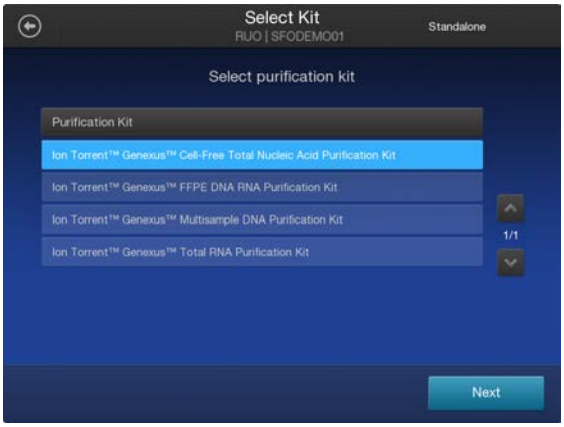
Add a run plan

Create a run plan before you prepare samples and load the samples into the Cell-Free Total Nucleic Acid Purification Plate 1. However, experienced users can save time by creating the run plan during the centrifugation steps of sample preparation.

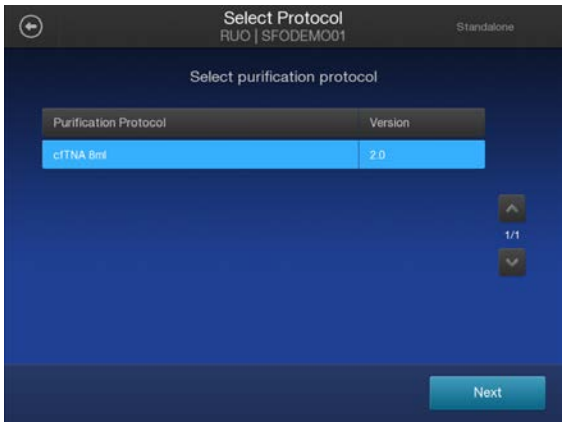
1. Enter your username and password to sign in to the instrument.
2. Tap **Run**, then tap **Add plan**.



3. Tap in the entry box, enter a unique name for the run plan, then tap **Done** ▸ **Next**.
4. Select the Ion Torrent™ Genexus™ Cell-Free Total Nucleic Acid Purification Kit, then tap **Next**.



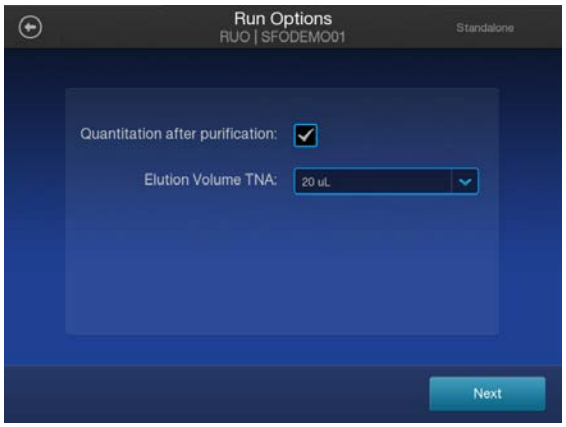
5. Select the appropriate purification protocol, then tap **Next**.



6. Enable or disable **Quantitation after Purification**.

   The Quantitation Plate is required even if **Quantitation after Purification** is disabled.

   Disabling **Quantitation after Purification** can reduce the purification run time by up to 45 minutes. Quantitation requires up to 5 µL of the eluted sample. If the expected sample yield is limiting, manual sample quantitation using less volume may be preferred to preserve sample.



7. Select the desired elution volume from the dropdown list, then tap **Next**.

8. *(Optional)* Change the number of samples and the sample details.

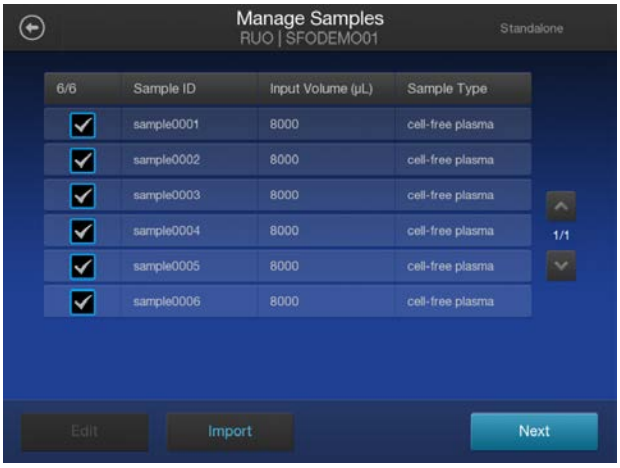
   a. In the **Manage Samples** screen, deselect extra samples (for example, if you run only 5 samples, deselect sample 6). Do not deselect samples from in the middle of the range (for example, if you run only 5 samples, do not deselect sample 2, 3, 4, or 5)

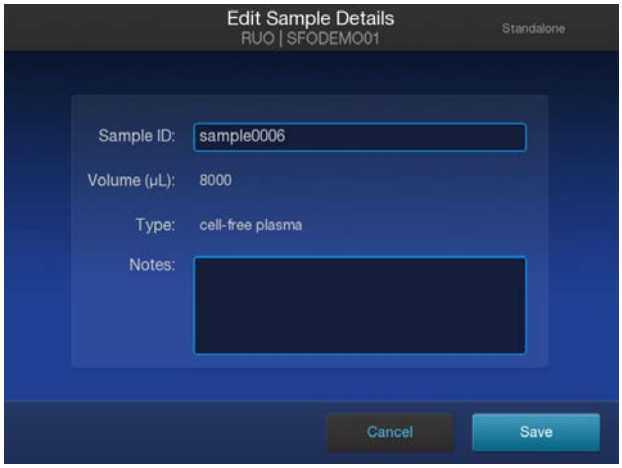
   b. In the **Manage Samples** screen, tap on a sample ID to select the sample.

   c. Tap **Edit**, enter a new **Sample ID** and any **Notes**, then tap **Save**.

   d. Repeat substep 8b and substep 8c for each additional sample.

   e. Tap **Next**.





9. *(Optional)* Import sample information.

   The import overwrites the existing **Sample ID** and **Notes** information for each sample selected.

   In standalone configuration, prepare a CSV sample import file and save it to a USB drive to import sample information. See page 161.

   a. In the **Manage Samples** screen, select the samples to import sample information, then tap **Import**.

   b. In the **Sample Import** screen, tap **Import** to proceed.

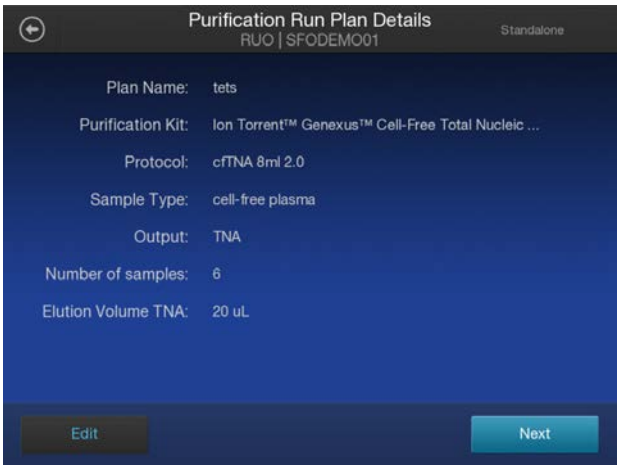
   c. Insert the USB drive containing the sample import CSV file into the USB port on the front of the purification instrument. In the **Sample Import** screen, select the USB drive, then navigate to and select the sample import file.

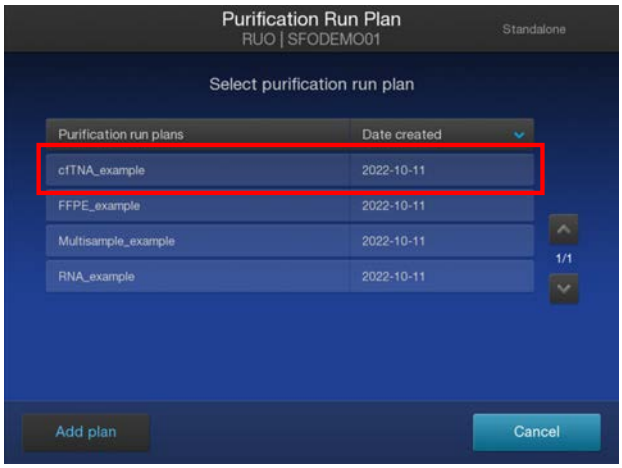
   d. *(Optional)* Tap **Details** to view the CSV file that lists the sample names to be imported.

   e. Tap **Import**, then in the **Import Successful** screen, tap **OK**.

      The imported sample information is shown in the **Manage Samples** screen. If needed, edit imported sample information as described in step 8.

10. Review the **Purification Run Plan Details**. Tap **Edit** to change selections. Otherwise tap **Next**.





The new **Run Plan** appears in the list of available **Purification Run Plans**.

Prepare the Quantitation Plate

Prepare the following cartridges and consumables:

- Genexus™ Nucleic Acid Quantitation (Part No. A45538)
  - Quantitation Plate
  - Quantitation Tube

Equilibrate the Quantitation Plate

The Quantitation Plate is required even if your run plan does not include sample quantitation.

IMPORTANT!

- Protect the Quantitation Plate from light to prevent photobleaching of the preloaded reagents.
- Allow at least 30 minutes for the Quantitation Plate to equilibrate to room temperature.
- Experienced users can save time by isolating cell-free plasma from whole blood while the Quantitation Plate equilibrates.

1. Centrifuge the Quantitation Plate at 1,000 × *g* for 30 seconds to collect the contents.
2. Place the plate and Quantitation Tube on the bench next to the Genexus™ Purification Instrument.

Prepare cell-free plasma from whole blood samples

Procedural guidelines

IMPORTANT! Store all kit components that contain liquid in the upright orientation.

- Perform all steps at room temperature (20–25°C) unless otherwise noted.
- Thawing or storing on ice can be substituted with thawing or storing at 4°C (2–8°C refrigerator or prechilled benchtop cold block).
- Blood specimens must be collected in K_2EDTA blood collection tubes.
- When mixing samples by pipetting up and down, avoid creating bubbles.
- When working with whole blood, observe these guidelines.
  - Wear clean gloves and a clean laboratory coat.
  - Change gloves whenever you suspect that they are contaminated.
  - Open and close all sample tubes carefully. Avoid splashing or spraying samples.
  - Use a positive-displacement pipettor and RNase-free pipette tips.
  - Clean laboratory benches and equipment periodically with 10% bleach solution and rinse with 70% isopropanol.

- When working with cell-free RNA, observe these guidelines.
  - Wear clean gloves and a clean laboratory coat.
  - Change gloves whenever you suspect that they are contaminated.
  - Open and close all sample tubes carefully. Avoid splashing or spraying samples.
  - Use a positive-displacement pipettor and RNase-free pipette tips.
  - Clean laboratory benches and equipment periodically with an RNase decontamination solution, such as RNase*Zap*™ RNase Decontamination Solution (Cat. No. AM9780) or RNase *AWAY*™ Decontamination Reagent (Cat. No. 7005-11).
- The plate chiller shuts off 60 minutes after run completion. Remove the 96-Well Nucleic Acid Output Plate (integrated configuration) or 48-Well Nucleic Acid Archive Plate (standalone configuration) with purified nucleic acids from the instrument within 1 hour of run completion. Proceed immediately to sequencing, or properly store the nucleic acids until use.

Before each use of the kit

- Thaw plasma samples—stored at –90°C to –70°C—at room temperature, then store on ice or at 4°C until use.
- Keep fresh plasma samples on ice or at 4°C until use.
- Centrifuge purification plates at 1,000 × *g* for 30 seconds to collect the contents.

Isolate cell-free plasma from whole blood

1. Centrifuge the blood sample at 2,000 × *g* for 10 minutes at 4°C.

   Up to 8 mL of plasma can be used as sample input. One 10 mL tube of whole blood yields approximately 4 mL plasma.

   Centrifuge the sample within 2 hours of blood draw. Ensure that the sample is centrifuged no later than 6 hours after blood draw.

   If a refrigerated centrifuge is not available, chill the sample on ice or in a prechilled 4°C cold block for 10 minutes, centrifuge at 2,000 × *g* for 10 minutes at room temperature, then immediately place the centrifuged sample on ice or 4°C cold block.

2. Transfer the plasma to a new 15-mL or 50-mL conical centrifuge tube. Volume should be 3–5 mL.

   IMPORTANT! Do not disturb the buffy coat layer when transferring the plasma layer.

   A 1X centrifuged plasma sample can be stored overnight at 4°C, or long term at –90°C to –70°C.

3. Centrifuge the plasma sample at 6,000 × *g* for 30 minutes at 4°C.

   Alternatively, centrifuge the plasma sample at 16,000 × *g* for 10 minutes at 4°C.

4. Transfer the supernatant to a fresh tube, note the volume of cell-free plasma, then keep on ice or at 4°C until use.

   Store cell-free plasma samples at –90°C to –70°C for long term storage.

Load the Genexus™ Purification Instrument and start the run

This section describes how to perform the following procedures.

- Set up the Genexus™ Purification Instrument for use by loading all required reagents and consumables.
- Start a Genexus™ Purification Instrument run.

Note: Do NOT load any consumables onto the instrument until after the instrument has performed the prerun UV cleaning.

Materials required

- Genexus™ Cell-Free Total Nucleic Acid Purification (Part No. A45535)
  - Cell-Free Total Nucleic Acid Purification Plate 1
  - Cell-Free Total Nucleic Acid Purification Plate 2
  - Cell-Free Total Nucleic Acid Purification Plate 3
  - 6-Well Tip Comb
  - 12-Well Tip Comb
  - Proteinase K (red cap)
  - cfTNA Lysis/Binding Solution
- Genexus™ Nucleic Acid Quantitation (Part No. A45538)
  - Quantitation Plate
  - Quantitation Tube
- Genexus™ Purification Supplies 1 (Part No. A45529)
  - Purification Tip Cartridge
  - 48-Well Nucleic Acid Archive Plate (not required for integrated configuration)
  - 48-Well Nucleic Acid Archive Plate Seal (not required for integrated configuration)
- MicroAmp™ EnduraPlate™ Optical 96-Well Clear Reaction Plates with Barcode (96-Well Nucleic Acid Output Plate, integrated configuration only)
- 200- and 1000-µL pipettors, and filtered tips
- 1000-µL multichannel pipettor and reagent reservoir (recommended)

Prepare the consumables

Remove all cartridges and consumables from their packaging, then place them on the bench at room temperature.

Prepare the following cartridges and consumables:

- Genexus™ Purification Supplies 1
  - Purification Tip Cartridge
  - 48-Well Nucleic Acid Archive Plate
  - 48-Well Nucleic Acid Archive Plate Seal

- 12-Well Tip Comb
- 6-Well Tip Comb
- MicroAmp™ EnduraPlate™ Optical 96-Well Clear Reaction Plates with Barcode (96-well output plate)

Add cfTNA Lysis/Binding Solution to Cell-Free Total Nucleic Acid Purification Plate 1 & 3

To prepare the Cell-Free Total Nucleic Acid Purification Plate 1 and the Cell-Free Total Nucleic Acid Purification Plate 3 for use, add cfTNA Lysis/Binding Solution to the plates.

1. Remove the plate seal from Cell-Free Total Nucleic Acid Purification Plate 1.

2. Add 2.5 mL of cfTNA Lysis/Binding Solution to each well in the plate, A1 through D6.
   a. Attach six 1,000 µL pipette tips on a 1,000 µL multichannel pipettor, then set the volume on the pipettor to 833 µL.

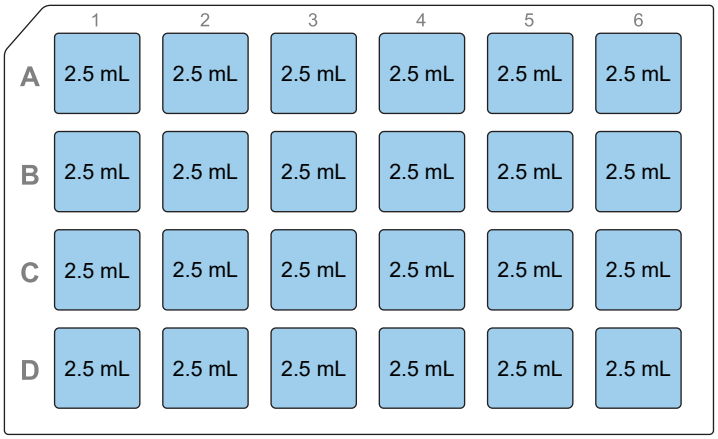
      If the tip spacing of the multichannel pipettor is not adjustable, attach tips into alternate channels to fit into plate 1 wells.

   b. Transfer ~70 mL of the cfTNA Lysis/Binding Solution to a 50–100-mL reagent reservoir.

      Use one bottle per run to avoid cross-contamination between runs.

   c. Use the multichannel pipettor to dispense 833 µL cfTNA Lysis/Binding Solution to each well A1–A6, then B1–B6, and so on. Well A1 is located at the notched corner of the plate.

   d. Repeat substep 2c two more times to load a total volume of 2.5 mL into each of the 24 wells.

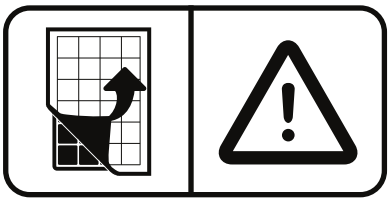


cfTNA Lysis/Binding Solution loaded in 24 wells of plate 1

e. Visually inspect the plate to ensure that the wells are uniformly filled to 2.5 mL, then set the plate aside until you are ready to add samples. See “Add samples to Cell-Free Total Nucleic Acid Purification Plate 1” on page 92.

- If you are purifying fewer than 6 samples, add cfTNA Lysis/Binding Solution to wells in each row of the plate columns for the number of samples that you have, but start with wells A1, B1, and so on.
- If a multichannel pipettor is not available, use a single-channel pipettor or repeat pipettor to add cfTNA Lysis/Binding Solution to the plates. We do not recommend the use of serological pipettes.
- To prevent contaminants from falling into wells after adding the solution, cover the plate loosely with the original plate seal, or cover with a clean object such as a 96-well plate cover.

3. Carefully remove the plate seal from Cell-Free Total Nucleic Acid Purification Plate 3 without disturbing the contents of the plate.



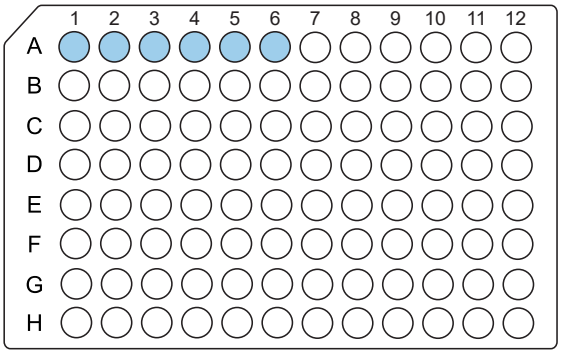
4. Add 440 µL of cfTNA Lysis/Binding Solution to wells A1 through A6.

a. Attach six 1,000 µL pipette tips on a 1,000 µL multichannel pipettor, then set the volume on the pipettor to 440 µL.

b. If needed, transfer additional cfTNA Lysis/Binding Solution from the bottle into the reagent reservoir. Use the remaining solution from substep 2b.

Use one bottle per run to avoid cross-contamination between runs.

c. Use the multichannel pipettor to dispense 440 µL cfTNA Lysis/Binding Solution to each well A1–A6.



cfTNA Lysis/Binding Solution loaded in wells A1–A6 of plate 3 (440 µL/well)

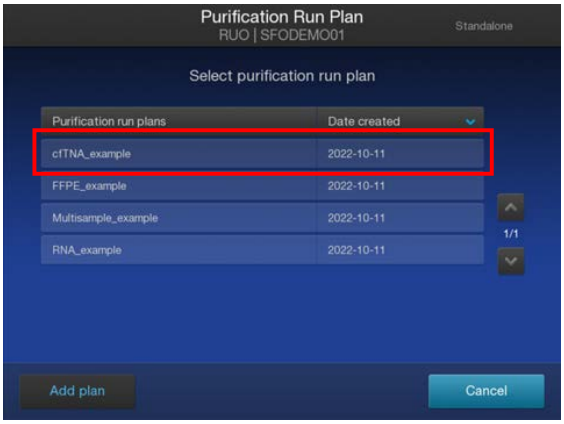
- If you are purifying fewer than 6 samples, add cfTNA Lysis/Binding Solution to row A wells of the plate columns for the number of samples to purify, but start with well A1.
- If a multichannel pipettor is not available, use a single-channel pipettor or repeat pipettor to add cfTNA Lysis/Binding Solution to the plates. We do not recommend the use of serological pipettes.

5. Discard excess cfTNA Lysis/Binding Solution into an appropriate liquid biohazardous waste container.

WARNING! Liquid waste contains guanidine thiocyanate. Dispose of waste appropriately.

Start the purification run

1. In the instrument touchscreen, tap **Run**, then tap to select the run plan that you created for this run.



2. Ensure that the run plan selected is correct, then tap **Next**.

3. *(Optional, standalone configuration)* Import sample information.

   The import overwrites the existing **Sample ID** and **Notes** information for each sample. That is, if the run plan has 6 samples, the sample import file must include information for at least 6 samples.

   To import sample information, prepare a CSV sample import file and save it to a USB drive. See “Create a template for importing samples in standalone configuration purification run plans” on page 161.

   a. In the **Sample Assignment** screen, tap **Manage Samples**.

   b. In the **Manage Samples** screen, tap **Import**.

   c. In the **Sample Import** screen, tap **Import** to proceed.

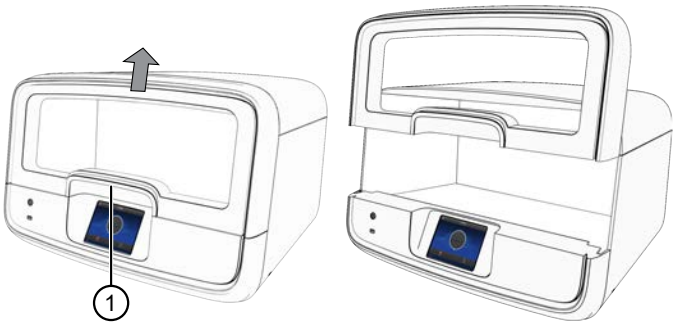
   d. Insert the USB drive that contains the sample import CSV file into the USB port on the front of the purification instrument. In the **Sample Import** screen, select the USB drive, then navigate to and select the sample import file.

   e. *(Optional)* Tap **Details** to view the CSV file listing the sample names that are to be imported.

   f. Tap **Import**, then in the **Import Successful** screen, tap **OK**.
   The imported sample information is shown in the **Manage Samples** screen. If needed, select a sample then tap **Edit** to modify the **Sample ID** or **Notes**.

4. Tap **Next**.
   The instrument performs a 2-minute UV cleaning, then unlocks the door.

5. Lift the instrument door to the stop.



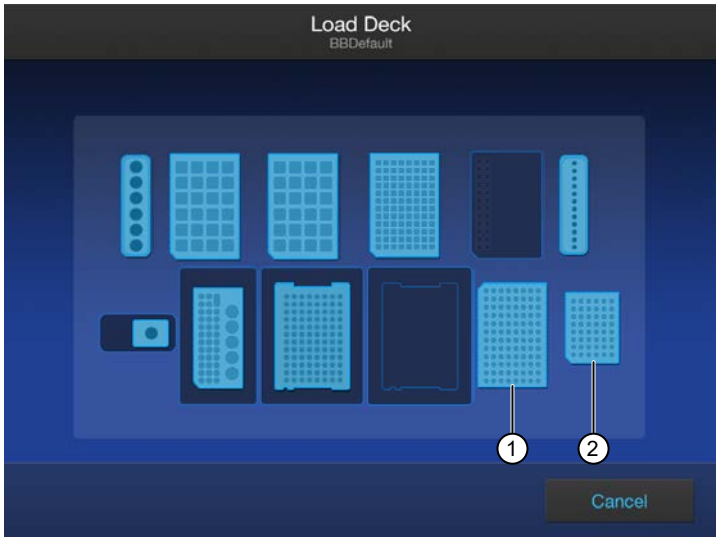
① Hold here, then lift.

Load the Genexus™ Purification Instrument

IMPORTANT!

- Do NOT load any consumables onto the instrument until after the instrument has performed the prerun UV cleaning.
- Ensure that all components are clean and dry before loading them onto the instrument.
- Ensure that the reagent and quantitation station compartments are free of condensate before loading components. If needed, use a lint-free wipe to dry the compartment.

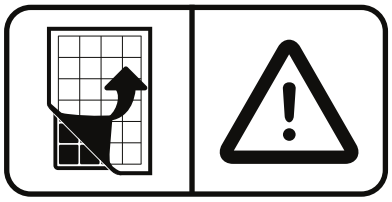
Follow the on-screen prompts to load the instrument.



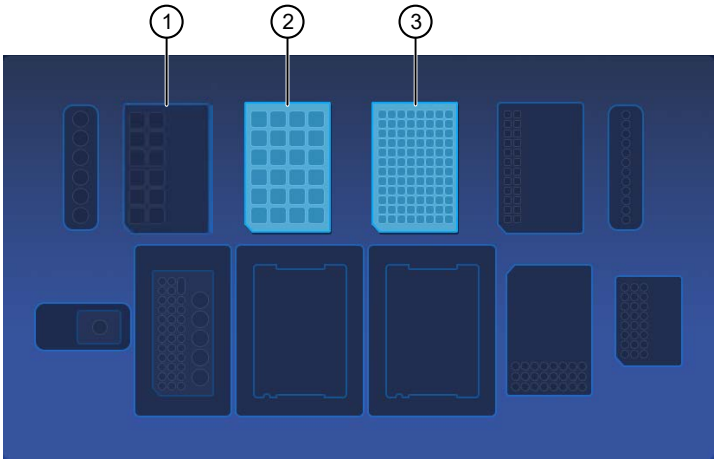
① 96-Well Nucleic Acid Output Plate, not needed when performing the purification in standalone configuration.
② 48-Well Nucleic Acid Archive Plate, not needed when performing the purification in integrated configuration.

Load Cell-Free Total Nucleic Acid Purification Plate 2 & 3

1. Carefully remove the plate seal from Cell-Free Total Nucleic Acid Purification Plate 2 without disturbing the contents of the plate.



2. Load the 24 deep-well Cell-Free Total Nucleic Acid Purification Plate 2 in position 2.



① Cell-Free Total Nucleic Acid Purification Plate 1 position (do not load yet)
② Cell-Free Total Nucleic Acid Purification Plate 2 position
③ Cell-Free Total Nucleic Acid Purification Plate 3 position

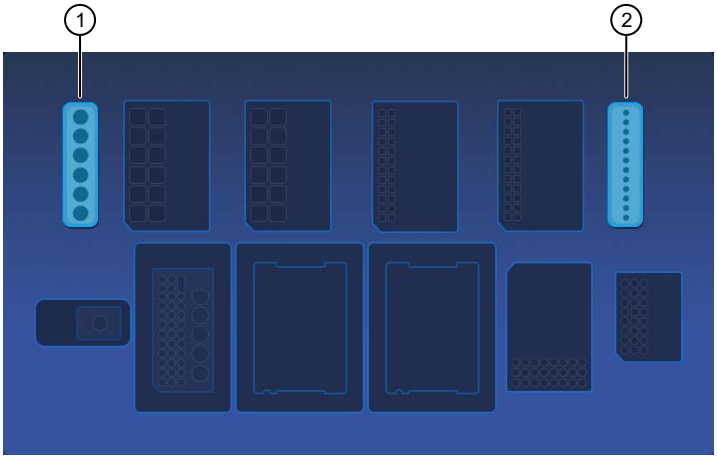
3. Load the 96 deep-well Cell-Free Total Nucleic Acid Purification Plate 3 in position 3.

Note: Ensure that the plate has 440 µL cfTNA Lysis/Binding Solution manually loaded in wells A1–D6.

Load the tip combs, Purification Tip Cartridge, 96-Well Nucleic Acid Output Plate, and 48-Well Nucleic Acid Archive Plate

1. Unwrap, then load a new 6-Well Tip Comb and 12-Well Tip Comb.

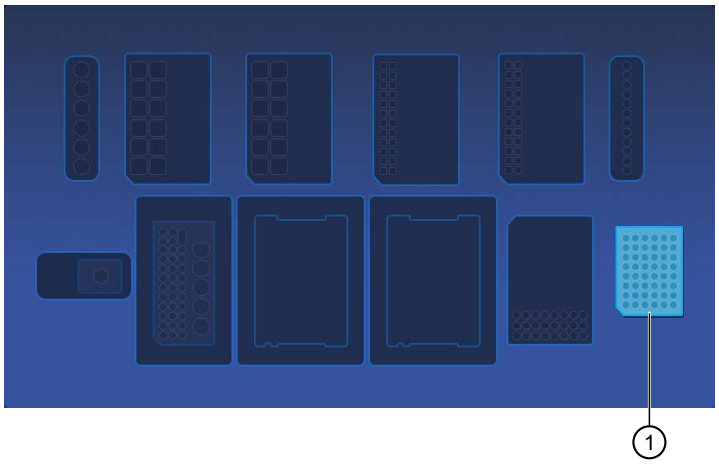
   Ensure that each tip comb is straight and that the tabs are not bent or broken. If needed, gently bend the tip comb in the opposite direction to the curvature to straighten the tip comb before installing it.



① 6-Well Tip Comb position
② 12-Well Tip Comb position

2. *(Standalone configuration only)* Unwrap, then load a new 48-Well Nucleic Acid Archive Plate.

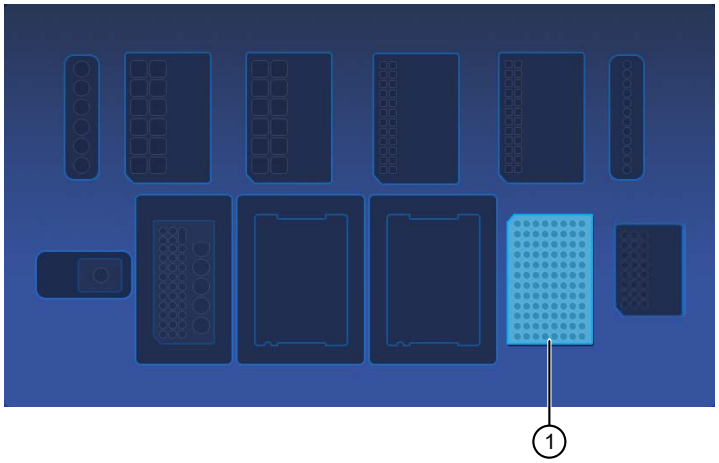
   The 96-Well Nucleic Acid Output Plate is not required when performing the purification in standalone configuration.



① 48-Well Nucleic Acid Archive Plate position

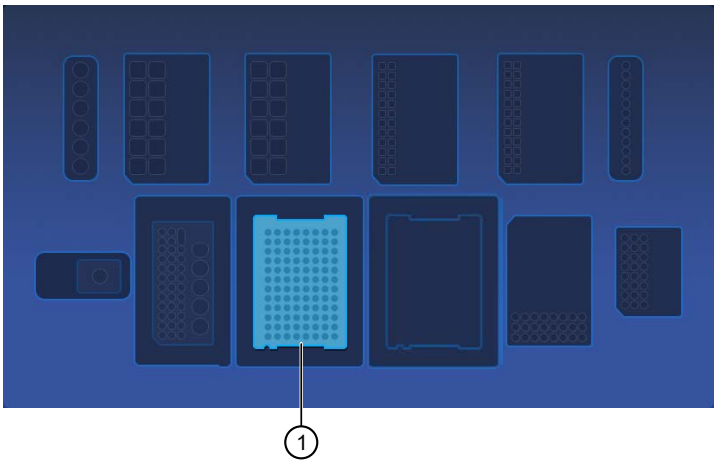
3. *(Integrated configuration only)* Load a new 96-Well Nucleic Acid Output Plate into the output plate position.

   After a purification run, the 96-Well Nucleic Acid Output Plate becomes the sample plate to be loaded in the Genexus™ Integrated Sequencer. The 48-Well Nucleic Acid Archive Plate is not required when performing the purification in integrated configuration.



① 96-Well Nucleic Acid Output Plate position

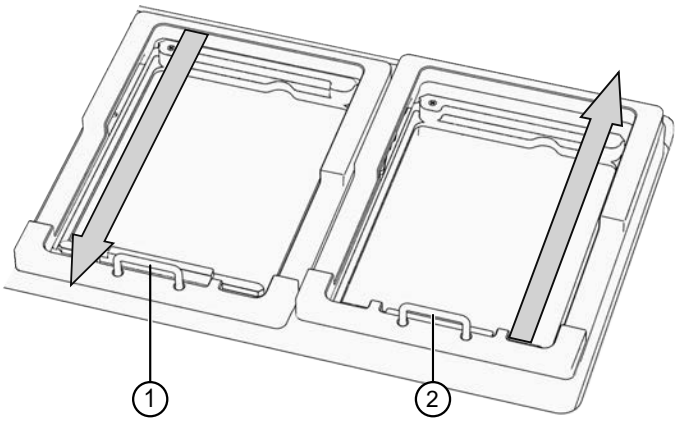
4. Unwrap a Purification Tip Cartridge, remove the cover to expose the pipette tips, then load it in position 1.



① Purification Tip Cartridge position 1

   a. Pull the locking mechanism handle forward (callout 1, below), then place the tip box in the open position.

   b. Push the locking mechanism handle back (callout 2) to lock the tip box in place.



① Unlocked (forward)

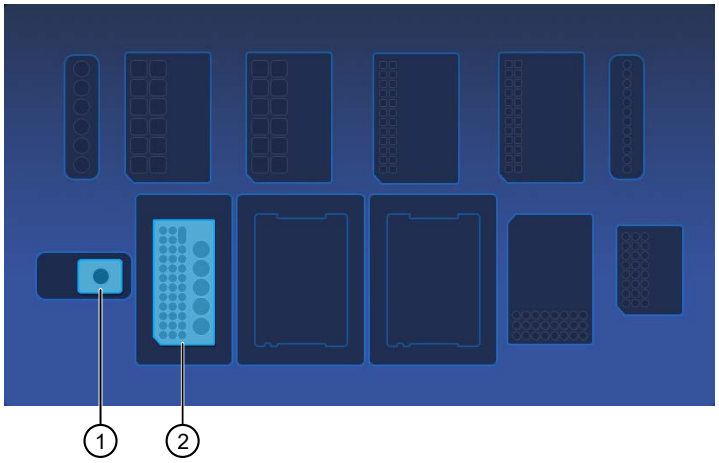
② Locked (back)

Load the quantitation reagents and consumables

Note:

- Protect the Quantitation Plate from light to prevent photobleaching of the preloaded reagents.
- The Quantitation Plate is required even if your run plan does not include sample quantitation.
- The Quantitation Tube is not required if your run plan does not include sample quantitation.

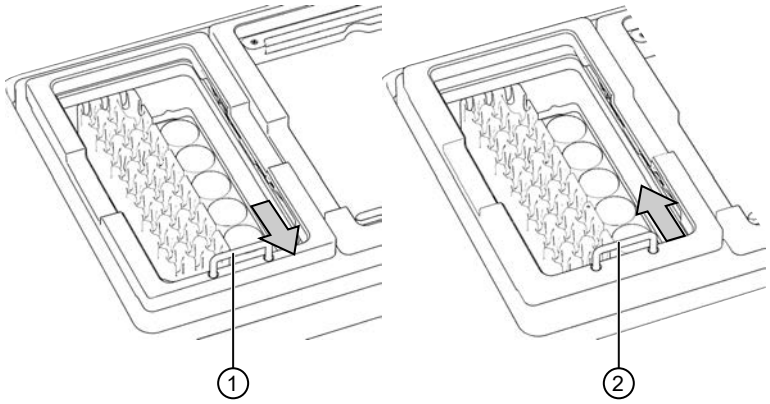
1. Centrifuge the Quantitation Plate at 1,000 × *g* for 30 seconds to collect the contents.
2. Load the Quantitation Plate in position 2.



① Quantitation Tube position
② Quantitation Plate position

   a. Pull the locking mechanism handle forward, then place the Quantitation Plate in the open position.

   b. Push the locking mechanism handle back to lock the plate in place.

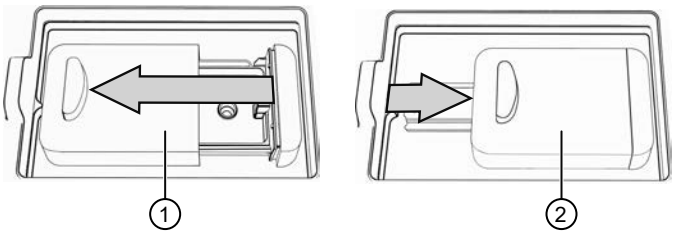


① Unlocked (forward)

② Locked (back)

3. *(If needed)* Slide and hold the quantitation module cover to the left, then insert the Quantitation Tube. **Press down firmly** to properly seat the tube, then allow the module cover to close.

WARNING! Do not force the module cover closed. Forcing the module cover closed can damage the instrument.



① Open ② Closed

Add samples to Cell-Free Total Nucleic Acid Purification Plate 1

IMPORTANT!

- Before adding samples, ensure that cfTNA Lysis/Binding Solution is added to the Cell-Free Total Nucleic Acid Purification Plate 1.
- Prepare and load all reagents and consumables, except the Cell-Free Total Nucleic Acid Purification Plate 1, on the instrument, before adding Proteinase K to the samples to avoid overdigestion.
- Do not create bubbles when preparing the plate.
- During the wash steps, the Wash Solution may develop inert white or brown particulates that float in solution. This is not a cause for concern and does not negatively affect performance.

1. Inspect the plate to ensure that the contents of all rows are at the bottom of the tubes. If needed, centrifuge the plate at 1,000 × *g* for 30 seconds to collect the contents.

   Alternatively, gently flick or tap the plate on the bench to force the reagents to the bottoms of the tubes.

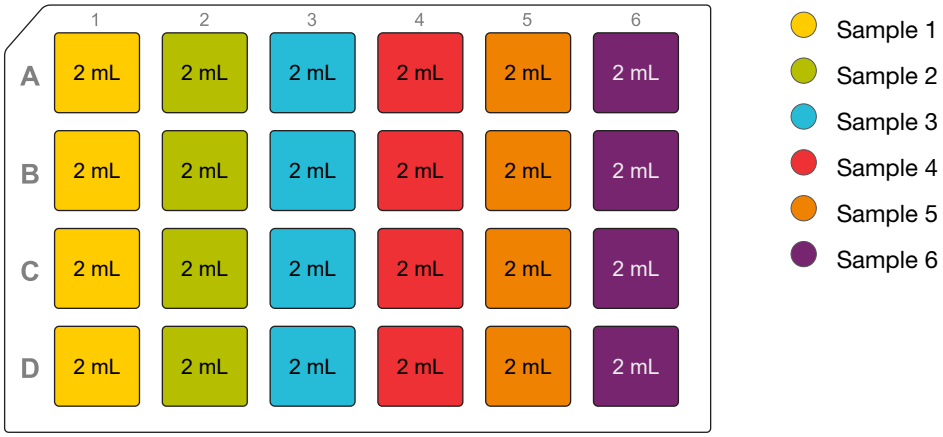
2. If the plasma sample volume is less than 8 mL, add 1X PBS to a final volume of 8 mL.

   Plasma sample volumes less than 8 mL can result in suboptimal performance.

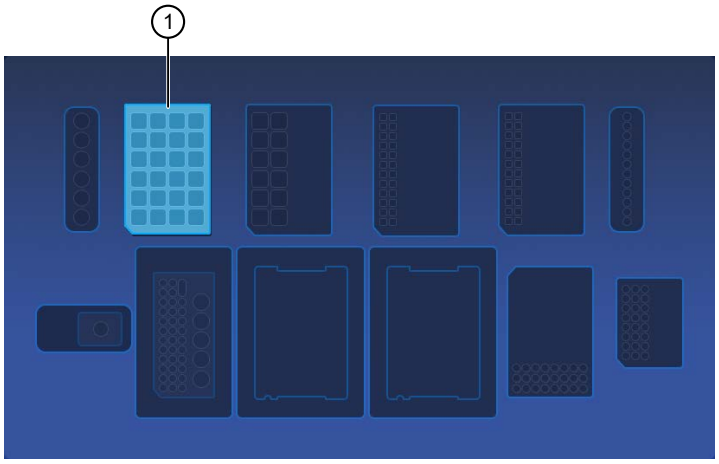
3. Add 50 µL Proteinase K to each sample, then mix by inverting the tube 5–10 times.

4. Transfer each sample into the 4 wells of a single column (2 mL per well) in the prefilled 24 deep-well Cell-Free Total Nucleic Acid Purification Plate 1.

   Add samples to consecutive columns beginning with sample 1 in column 1, through sample 6 in column 6. Do not skip wells.



5. Load the Cell-Free Total Nucleic Acid Purification Plate 1 with the samples in position 1.



① Cell-Free Total Nucleic Acid Purification Plate 1 position

Confirm that consumables are installed correctly

IMPORTANT! To ensure correct and safe instrument operation, confirm that all consumables are installed correctly on the deck before you start a run. The instrument vision system confirms that required reagents are in place, no reagents are expired, and foil seals are removed. The vision system does not verify all aspects of the consumable setup before beginning each run.

1. Confirm the following.
   - Foil seals are removed from the purification plates. Do not remove foil seal from the Quantitation Plate.
   - Each component is at the correct location and in the correct orientation. Press down on all plates and cartridges to ensure that they are firmly seated in place.
   - The Tip Combs are in place.
   - The Quantitation Plate is in the correct location, is in the correct orientation, and is locked in place.
   - *(If needed)* The Quantitation Tube is firmly seated in the quantitation module.

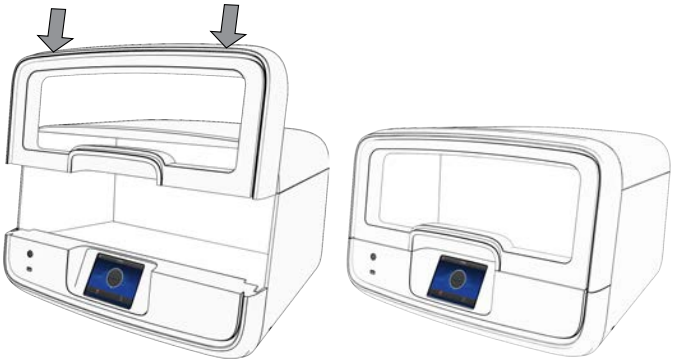
- Each Purification Tip Cartridge is in the correct location, in the correct orientation, and locked in place.

If the vision system detects an error, the location indicator does not turn gray in the touchscreen.

2. If needed, tap **Help**, then accept each warning message appropriately to proceed.

Start the run

1. When all reagents and consumables are loaded in the Genexus™ Purification Instrument, tap **Next**.
2. Close the instrument door by pressing down on both top corners. Ensure that the door is locked after closing it.



The instrument vision system confirms that all reagents are in place and are not expired.

3. Tap **Start**.

   The time remaining until the purification is complete is displayed and the interior lighting turns green.

   - (Integrated configuration) Quantitation is turned off by default to preserve sample.
   - If you have to stop the run for any reason, tap **Cancel**, then tap **Yes** to confirm the cancellation. A canceled run cannot be resumed. You must restart a run from the beginning.
   - The interior lighting turns off during quantitation, then turns blue when the run is complete.
   - If the instrument encounters a problem during the run, it aborts the run and displays the error on the instrument touchscreen. The interior lighting turns red.

When the run is complete, the interior light turns blue, and the touchscreen displays **Run Complete**. Quantitation results are available immediately. See “View and export quantitation results” on page 97.

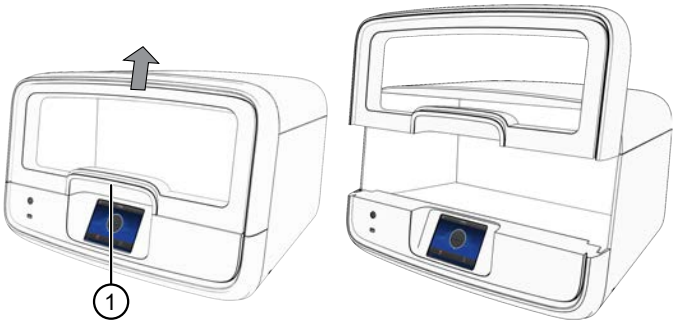
Unload purified cell-free TNA

IMPORTANT! Do not allow purified nucleic acids to sit on the instrument. Store as directed or use in sequencing reactions within 60 minutes.

1. In the touchscreen, tap **Unload**.

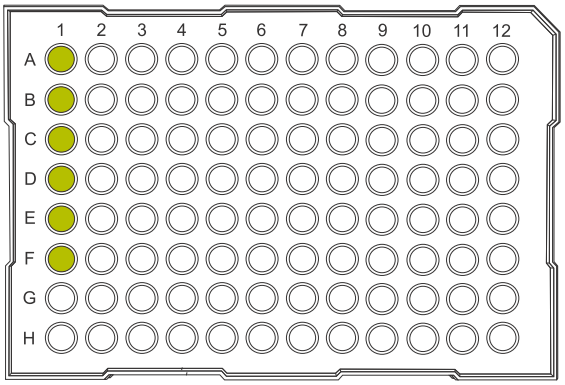
The door unlocks.

2. Lift the instrument door to access the instrument deck.



① Hold here, then lift.

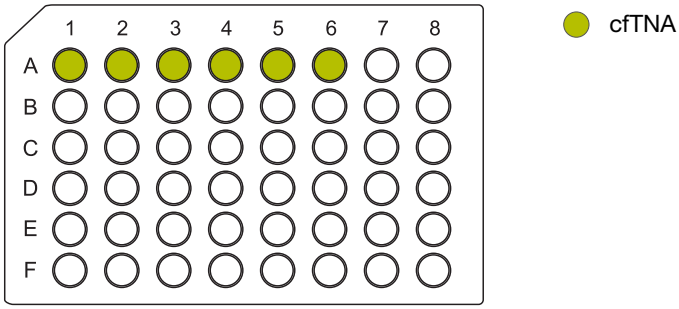
3. *(Integrated configuration)* Remove the 96-Well Nucleic Acid Output Plate that contains the purified sample cfTNA that is ready for the addition of positive or nontemplate sample sequencing controls. Store on ice or at 4°C. Quantitation is turned off by default to preserve the sample. Determine sample concentrations manually, if needed.



The 48-Well Nucleic Acid Archive Plate is not used.

STOPPING POINT If not sequencing immediately, seal the plate with an Adhesive PCR Plate Foil (Cat. No. AB0626), then store the plate at –20°C for up to 1 week. For long term storage (>1 week), transfer the samples to labeled low-retention tubes, then store at –90°C to –70°C for up to 12 months.

4. *(Standalone configuration)* Remove the 48-Well Nucleic Acid Archive Plate, containing the purified sample cell-free TNA in row A.



If using the purified cfTNA immediately, transfer the sample to a sample input plate for sequencing. To determine the sample concentrations, see "View and export quantitation results" on page 97 if quantitation was performed. Alternatively, determine sample concentrations manually, if needed. For more information, see the relevant assay user guide for **Nucleic Acid to Result** guidance.

5. For short term storage, seal the plate with a 48-Well Nucleic Acid Archive Plate Seal. Store the plate at –20°C for up to 3 months. For long-term storage (>3 months), transfer samples to labeled low-retention tubes, then store cfTNA samples at –90°C to –70°C for up to 12 months.

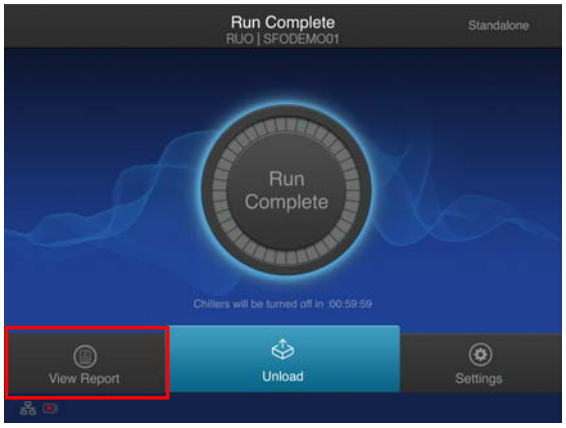
   If the archive plate is thawed during short-term storage, transfer the cfTNA into labeled low-retention tubes. Do not reseal the archive plate with the used plate seal.

View and export quantitation results

Purification runs that include sample quantitation produce sample concentration results that can be accessed after the run is complete. In standalone configuration, sample concentration results can be accessed from the **Run Complete** screen or the **Home** screen as described here.

Note: (Integrated configuration) Quantitation is turned off by default to preserve the sample.

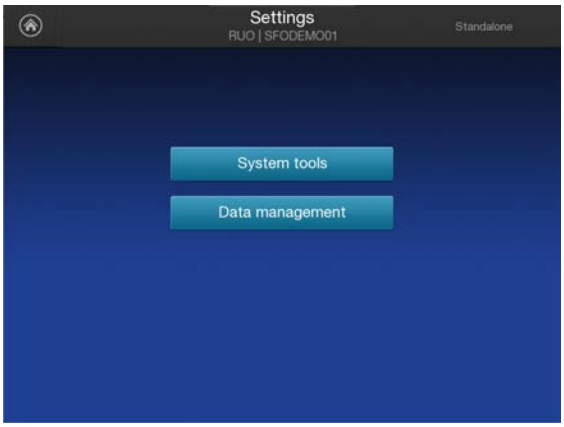
1. In the **Run Complete** screen, tap **View report**.



   The **Saved Experiment Reports** screen opens. See step 4.

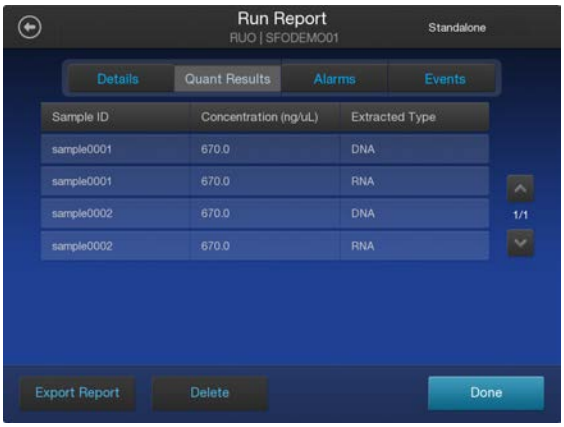
2. At any time after unloading and UV cleaning the instrument, sample concentration results can be accessed through the **Home** screen. Tap ⚙ (**Settings**).

3. In the **Settings** screen, tap **Data Management**.



4. In the **Saved Experiment Reports** screen, tap ⌄ or ⌃ to page through the list. Locate the **Experiment Name** of interest, tap in the row to select the experiment, then tap **View Report**.

5. In the **Run Report** screen, tap **Quant Results** to view the sample concentration results.



6. Insert a USB drive into the USB port on the front of the instrument, then tap **Export Report**. Navigate to the file destination, then tap **Save**.

Dispose of used consumables and UV clean the instrument

Unload purified nucleic acid samples before disposal of used consumables.

IMPORTANT! Do not allow purified nucleic acids to sit on the instrument. Store as directed or use in sequencing reactions within 60 minutes.

1. Remove and discard the deep-well sample input plates.
   a. Remove the Cell-Free Total Nucleic Acid Purification Plate 1 from the instrument.
   b. Dispose of the liquid waste by tipping the deep-well plate on one corner and pouring the waste into an appropriate liquid biohazardous waste container.

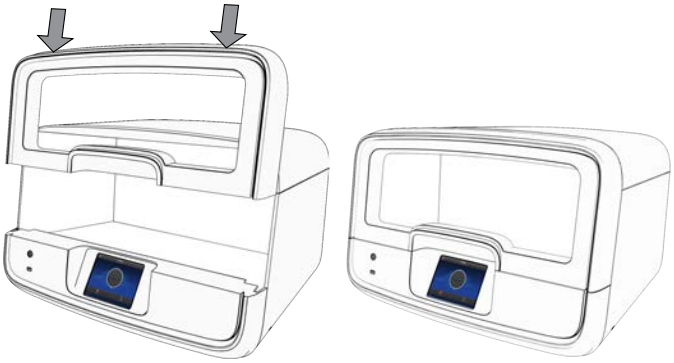
WARNING! Liquid waste contains guanidine thiocyanate, dispose of properly.

   c. Dispose of the deep-well plate in an appropriate waste container.
   d. Repeat substep 1a through substep 1c to discard both the Cell-Free Total Nucleic Acid Purification Plate 2 and the Cell-Free Total Nucleic Acid Purification Plate 3.
2. Unlock, then remove and dispose of the Purification Tip Cartridges in an appropriate waste container.
3. Unlock, then remove and dispose of the Quantitation Plate.
   a. Dispose of the liquid waste by tipping the deep-well plate on one corner and pouring the waste into an appropriate liquid biohazardous waste container.

WARNING! No data are currently available that address the mutagenicity or toxicity of the Qubit™ RNA BR Reagent (Component A). This reagent is known to bind nucleic acid and is provided as a solution in DMSO. Treat the Qubit™ RNA BR Reagent with the same safety precautions as all other potential mutagens and dispose of the dye in accordance with local regulations.

   b. Dispose of the deep-well plate in an appropriate waste container.
4. *(If needed)* Open the quantitation module cover, remove and discard the Quantitation Tube, then allow the module cover to close.

5. Close and lock the instrument door by pressing down on both top corners, then tap **Start UV Clean**.



The time remaining in the UV cleaning is displayed. When complete, the instrument is ready to start a new purification run.

7 Genexus™ Multisample DNA Purification protocol

Genexus™ Multisample DNA Purification workflow

5 min

Plan a purification run (page 103)

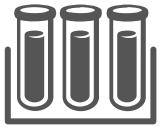
IMPORTANT! If performing a **Sample to Result** sequencing run, create a run plan in the Genexus™ Software. See “Plan a Sample to Result run” on page 41.

To purify samples for use in **Nucleic Acid to Result** runs or other nonsequencing applications, run the Genexus™ Purification Instrument in standalone configuration. Add a new purification run plan or copy-edit an existing purification run plan that best represents your experiment. Purification run plans contain instrument settings that are used in sample purification.

5–30 min

Prepare samples (page 107)

Samples are processed based on the sample type before adding to the Multisample DNA Purification Plate and loading on to the instrument for purification of DNA.



2 min

Load the Genexus™ Purification Instrument (page 114)

The purification run plan is selected, and the run is initiated. The instrument performs a UV cleaning, then consumables are loaded on to the instrument. DNA Enhancer Solution, sample, and Proteinase K are added to the Multisample DNA Purification Plate, then immediately loaded on to the instrument for purification of DNA.

1 hr

Start the run (page 120)

After the sample plate, reagents, and consumables are loaded, the instrument door is closed, and the run is started.

Depending on the number of samples, quantification adds ~1 hour to the run time.

Genexus™ Multisample DNA Purification workflow

5 min

Unload the purified nucleic acids (page 121)

If performing a **Sample to Result** run, remove the 96-Well Nucleic Acid Output Plate and proceed to sequence the purified sample. Remove and seal the 48-Well Nucleic Acid Archive Plate, then store as directed.

If performing a **Nucleic Acid to Result** run or purifying nucleic acids in standalone configuration for use in other downstream applications, remove and seal the 48-Well Nucleic Acid Archive Plate, then store as directed or proceed to sequence the purified sample.

Used reagents and consumables are removed from the instrument and the instrument performs a UV cleaning.

The Quantitation Plate requires equilibration to room temperature for at least 30 minutes before use. To save time, experienced users can take the Quantitation Plate out of 4°C storage before creating a purification run plan and preparing samples.

Plan a purification run (standalone configuration)

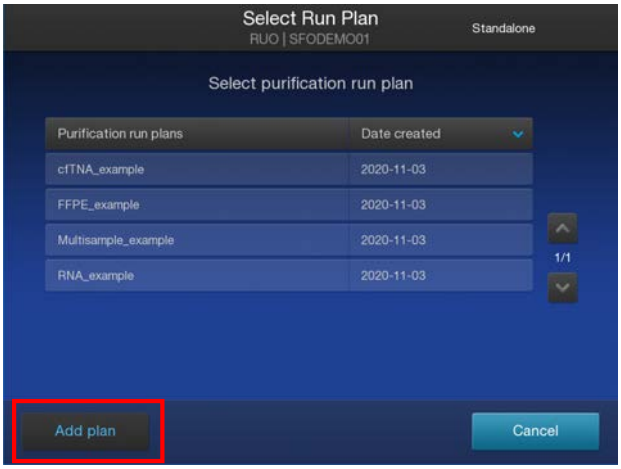
Note: If running the Genexus™ Purification System in integrated configuration, see "Plan a Sample to Result run" on page 41 to plan a **Sample to Result** run in the Genexus™ Software.

In standalone configuration, plan a purification run through the instrument touchscreen. After purification is complete, all purified samples are transferred to an archive plate for storage.

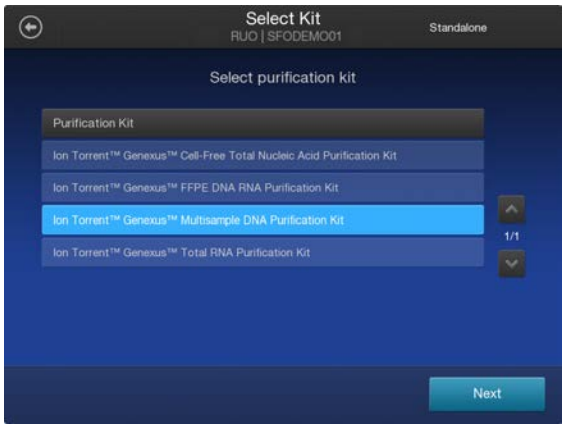
Add a purification run plan (standalone configuration)

We recommend that you create the run plan before preparing your samples and loading into the Multisample DNA Purification Plate.

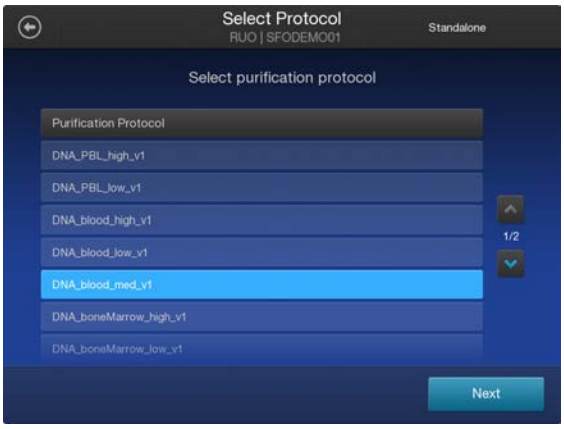
1. Enter your username and password to sign in to the instrument.
2. Tap **Run**, then tap **Add plan**.



3. Tap in the entry box, enter a unique name for the run plan, then tap **Done** ▸ **Next**.
4. Select the **Ion Torrent™ Genexus™ Multisample DNA Purification Kit**, then tap **Next**.



5. Select the appropriate purification protocol and software version in use, then tap **Next**.

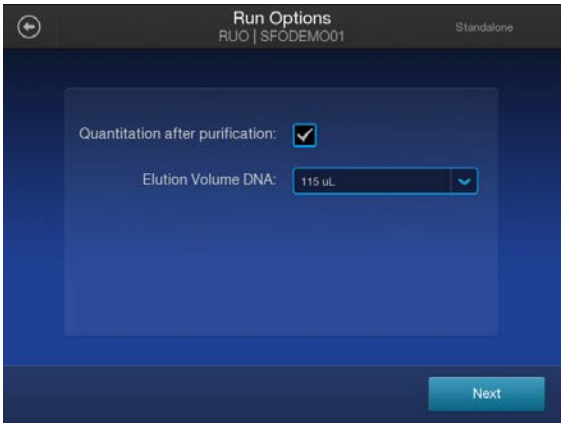


Sample type	Input volume	Select
Whole blood	50–400 µL	**DNA_blood_high_vX**
Peripheral blood leukocytes (PBL/buffy coat)	50–200 µL	**DNA_PBL_high_vX**
Bone marrow	50–200 µL	**DNA_boneMarrow_high_vX**
Tissue	400 µL lysate from up to 10 mg low-yield tissue	**DNA_tissue_low_vX**
	400 µL from up to 5 mg high-yield tissue (for example, spleen, thymus, pancreas)	**DNA_tissue_high_vX**
Cell lysates (for example, BMMC, PBMC, cell lines)	400 µL	**DNA_blood_high_vX**

6. Enable or disable **Quantitation after Purification**.

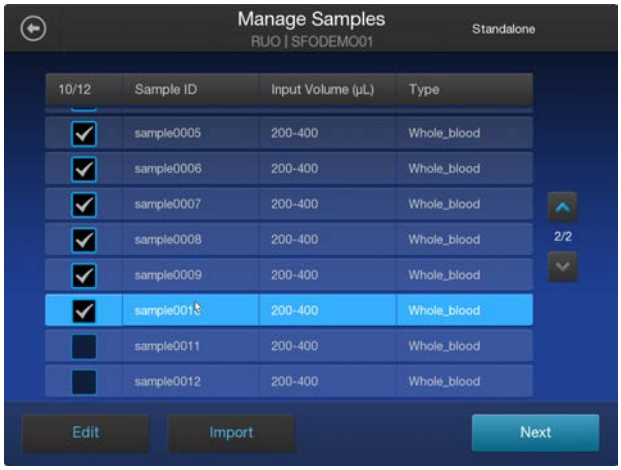
   The Quantitation Plate is required even if **Quantitation after Purification** is disabled.

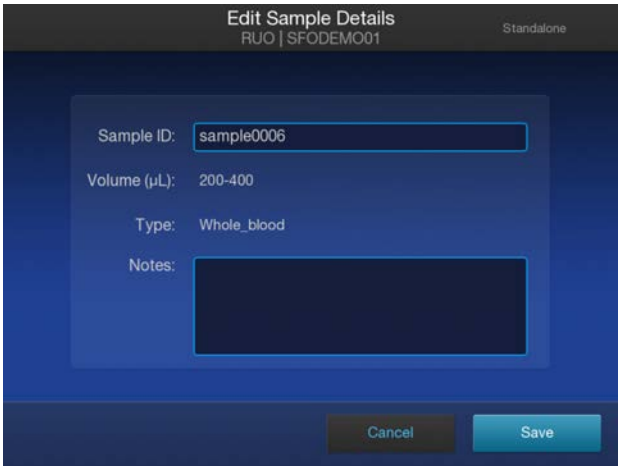
   Disabling **Quantitation after Purification** may reduce the purification run time by up to 1 hour.



7. Accept the default elution volume. If needed, select the desired elution volume from the dropdown list, then tap **Next**.

8. *(Optional)* Change the number of samples and the sample details.
   a. In the **Sample Details** screen, deselect extra samples (for example, if you run only 11 samples, deselect sample 12).
   b. In the **Sample Details** screen, tap on a sample ID to select the sample.
   c. Tap **Edit**, enter a new **Sample ID** and any **Notes**, then tap **Save**.
   d. Repeat substep 8b and substep 8c for each additional sample.
   e. Click **Next**.





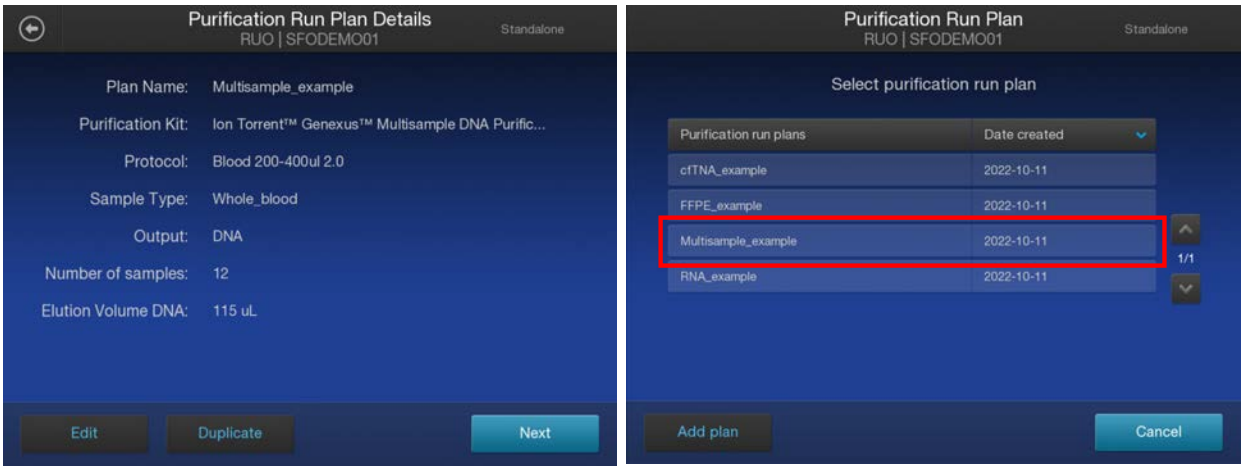
9. *(Optional)* Import sample information.

   The import overwrites the existing **Sample ID** and **Notes** information for each sample selected.

   In standalone configuration, to import sample information, prepare a CSV sample import file and save it to a USB drive. See page 161.

   a. In the **Manage Samples** screen, select the samples to import sample information, then tap **Import**.
   b. In the **Sample Import** screen, tap **Import** to proceed.
   c. Insert the USB drive that contains the sample import CSV file into the USB port on the front of the purification instrument. In the **Sample Import** screen, select the USB drive, then navigate to and select the sample import file.
   d. *(Optional)* Tap **Details** to view the CSV file that lists the sample names to be imported.
   e. Tap **Import**, then in the **Import Successful** screen, tap **OK**.
      The imported sample information is shown in the **Manage Samples** screen. If needed, edit imported sample information as described in step 8.

10. Review the **Purification Run Plan Details**. Tap **Edit** to change selections. Otherwise tap **Next**.



The new run plan appears in the list of available **Purification Run Plans**.

Prepare the Quantitation Plate and consumables

Cartridges and consumables needed:

- Genexus™ Multisample DNA Purification (Part. No. A45533)
  - Multisample DNA Purification Plate
  - 12-Well Tip Comb
- Genexus™ Nucleic Acid Quantitation, Broad Range (Part. No. A45537)
  - Quantitation Plate Broad Range
  - Quantitation Tube
- Genexus™ Purification Supplies 1 (Part. No. A45529)
  - Purification Tip Cartridge
  - 48-Well Nucleic Acid Archive Plate
  - 48-Well Nucleic Acid Archive Plate Seal
- P200 pipet and filtered tips
- 96-Well Nucleic Acid Output Plate

Equilibrate the Quantitation Plate

Note: The Quantitation Plate is required even if your run plan does not include sample quantitation.

IMPORTANT!

- Protect the Quantitation Plate from light to prevent photobleaching of the preloaded reagents.
- Allow at least 30 minutes for the Quantitation Plate to equilibrate to room temperature.

1. Centrifuge the Quantitation Plate at 1,000 × *g* for 30 seconds to collect the contents.
2. Place the plate and Quantitation Tube on the bench next to the Genexus™ Purification Instrument.

Prepare the consumables

IMPORTANT! Store all kit components containing liquid in the upright orientation.

Remove all cartridges and consumables from their packaging, then place them on the bench at room temperature.

Prepare the following cartridges and consumables:

- Genexus™ Purification Supplies 1
  - Purification Tip Cartridge
  - 48-Well Nucleic Acid Archive Plate
  - 48-Well Nucleic Acid Archive Plate Seal
- 12-Well Tip Comb

Prepare samples

Procedural guidelines

IMPORTANT! Store all kit components that contain liquid in the upright orientation.

- Perform all steps at room temperature (20–25°C) unless otherwise noted.
- Thawing or storing on ice can be substituted with thawing or storing at 4°C (2–8°C refrigerator or prechilled benchtop cold block).
- Blood specimens must be collected in K_2EDTA blood collection tubes.
- When mixing samples by pipetting up and down, avoid creating bubbles.
- When working with whole blood, observe these guidelines.
  - Wear clean gloves and a clean laboratory coat.
  - Change gloves whenever you suspect that they are contaminated.
  - Open and close all sample tubes carefully. Avoid splashing or spraying samples.
  - Use a positive-displacement pipettor and RNase-free pipette tips.
  - Clean laboratory benches and equipment periodically with 10% bleach solution and rinse with 70% isopropanol.
  - When freezing whole blood or bone marrow aspirate samples for later use. We recommend that you freeze samples in aliquots up to 400 µL at –90°C to –70°C such that the entire sample is used for one purification.

- When working with cell-free RNA, observe these guidelines.
  - Wear clean gloves and a clean laboratory coat.
  - Change gloves whenever you suspect that they are contaminated.
  - Open and close all sample tubes carefully. Avoid splashing or spraying samples.
  - Use a positive-displacement pipettor and RNase-free pipette tips.
  - Clean laboratory benches and equipment periodically with an RNase decontamination solution, such as RNase*Zap*™ RNase Decontamination Solution (Cat. No. AM9780) or RNase *AWAY*™ Decontamination Reagent (Cat. No. 7005-11).
- The plate chiller shuts off 60 minutes after run completion. Remove the 96-Well Nucleic Acid Output Plate (integrated configuration) or 48-Well Nucleic Acid Archive Plate (standalone configuration) with purified nucleic acids from the instrument within 1 hour of run completion. Proceed immediately to sequencing, or properly store the nucleic acids until use.

Before each use of the kit

- Keep samples on ice or at 4°C until use.
- Centrifuge purification plates for 30 seconds at 1,000 × *g* to collect the contents.

Materials required

Genexus™ Multisample DNA Purification (Part No. A45535)

- Multisample DNA Purification Plate
- Enhancer solution
- Proteinase K

Fisherbrand™ Bead Mill 24 Homogenizer

Whole Blood Samples

1. Determine the volume (≥50–400 µL) of each whole blood sample.
2. To each sample, add DNA Homogenization Buffer to a total volume of 400 µL.
   For example, to 200 µL whole blood add 200 µL DNA Homogenization Buffer. To 400 µL whole blood do not add DNA Homogenization Buffer.

   IMPORTANT! For frozen samples, add DNA Homogenization Buffer directly to the frozen sample to help in thawing.
3. Vortex, or pipet up and down at least 10 times, to thoroughly mix.

Proceed directly to “Start the purification run” on page 113. Samples are loaded in step 4 of “Add samples to Multisample DNA Purification Plate” on page 118.

Prepare bone marrow aspirate samples

IMPORTANT! Use of frozen bone marrow samples is not recommended.

1. Add ≥50–200 µL of bone marrow aspirate sample to a 1.5 mL low-retention tube on ice or at 4°C.
2. Centrifuge the sample at 200 × *g* for 10 minutes at room temperature.
3. Carefully remove the supernatant containing the unpelleted debris and fatty layer.

   IMPORTANT! Do not disturb the lightly pelleted cells. Leave a small amount of supernatant behind to ensure that you do not disturb the cell pellet.
4. To the cell pellet, add DNA Homogenization Buffer up to a final volume of 200 µL.
5. Vortex, or pipet up and down at least 10 times, to thoroughly mix.

Proceed to "Start the purification run" on page 113. Samples are loaded in step 4 of "Add samples to Multisample DNA Purification Plate" on page 118.

Prepare tissue samples

Fresh or frozen tissue DNA yields can vary based on the tissue type. Use the amounts suggested in Table 2. For more information on expected DNA yield by tissue type, see "Example tissue yields" on page 111. Adjust input amount based on your results.

Use a bead mill homogenizer when processing small amounts of tissue and use a rotor-stator tissue homogenizer when processing larger amounts of tissue. Alternate methods of cell disruption can also be used. Do not exceed 5 mg of homogenized tissue for high yielding tissues or 10 mg of homogenized tissue for low yielding tissues as sample input to the Multisample DNA Purification Plate.

Table 2 Recommended input amount based on tissue type

Tissue type	Recommended tissue:DNA Homogenization Buffer (mg:µL) ratio[1]	Maximum Multisample DNA Purification Plate tissue input amount[2]
Low-yield tissue	1:40	10 mg
High-yield tissue	1:80	5 mg

[1] Do not exceed the indicated ratio when homogenizing the sample before loading on the purification plate.
[2] Do not exceed the indicated amount as input into the sample purification plate.

1. Cut the sample into appropriately sized pieces. For larger samples, we recommend cutting the material into long, thin strips for faster homogenization.
2. Weigh the tissue sample, then calculate and add the recommended volume of DNA Homogenization Buffer.
   For example, for 5.0 mg high-yield tissue add 400 µL DNA Homogenization Buffer or for 25 mg low-yield tissue add 1.0 mL DNA Homogenization Buffer.
   Maintain the recommended tissue-to-buffer ratio if using more or less tissue.

3. Homogenize the samples following manufacturer instructions for your homogenizer.

   When homogenizing large amounts of tissue, use a rotator-stator tissue homogenizer in 10 second pulses on ice or at 4°C.

   Visually inspect the samples. If homogenization is incomplete, repeat step 3.

4. Transfer the lysate to a new tube. Ensure that no beads are carried over if using a bead mill homogenizer.

   Keep homogenized samples on ice or at 4°C until use.

   Proceed to "Start the purification run" on page 113. Samples are loaded in step 4 of "Add samples to Multisample DNA Purification Plate" on page 118.

STOPPING POINT If not proceeding directly to sample loading, store homogenized samples at –90°C to –70°C.

Prepare peripheral blood leukocytes (PBL/buffy coat) samples

1. Pipet 2–5 mL fresh whole blood into 15-mL conical tubes.
2. Weigh each tube, then, if needed, adjust volume to properly balance tubes before centrifugation.
3. Centrifuge the samples in a swinging bucket rotor at 2,000 × *g* for 10 minutes at 4°C (Brake = 0–5). Keep samples on ice or at 4°C when complete.
4. Use a P1000 pipettor to transfer the plasma to a new 15-mL conical centrifuge tube.

   IMPORTANT! Leave a small amount of plasma behind. Do not disturb the buffy coat layer when transferring the plasma layer.

5. Transfer the buffy coat layer to a 1.5-mL Eppendorf™ LoBind™ tube on ice or at 4°C.

   You should recover ~20% of the starting volume as buffy coat (for example, ~1 mL buffy coat from 5 mL whole blood).

6. Centrifuge the buffy coat layer at 100 × *g* for 5 minutes at 4°C, then carefully remove the remaining supernatant without disturbing the buffy coat layer.
7. Determine the volume of the buffy coat layer, then add DNA Homogenization Buffer up to a final volume of 200 µL.
8. Vortex, or pipet up and down at least 10 times, to thoroughly mix.

Proceed to "Start the purification run" on page 113. Samples are loaded in step 4 of "Add samples to Multisample DNA Purification Plate" on page 118.

Prepare cultured cell samples

Up to 4 × 10^6 cultured cells can be processed per sample.

1. Centrifuge cells in culture media at 100 × *g* for 5 minutes at 4°C, then carefully remove the supernatant without disturbing the cell pellet.

   Thaw previously frozen cell pellets on ice or at 4°C, then remove as much culture media as possible without disturbing the cell pellet.

2. *(Optional)* Wash the cell pellet.
   a. Resuspend the cell pellet in 1/2 volume of 1X PBS.
   b. Centrifuge cells at 100 × *g* for 5 minutes at 4°C, then carefully remove the supernatant without disturbing the cell pellet.

3. Add 400 µL of DNA Homogenization Buffer (provided) to each sample cell pellet, set a P1000 pipettor to 300 µL, then slowly pipet up and down 10–15 times.

   IMPORTANT! The sample can be viscous. Pipet up and down thoroughly to ensure complete mixing.

Proceed to "Start the purification run" on page 113. Samples are loaded in step 4 of "Add samples to Multisample DNA Purification Plate" on page 118.

Example tissue yields

Table 3 Recommended input amount based on tissue type

Tissue type	Recommended tissue:DNA Homogenization Buffer (mg:µL) ratio[1]	Maximum Multisample DNA Purification Plate tissue input amount[2]	Potential yield[3]
High yielding tissues			
High-yield tissue (25 mg)	1:80	5 mg	10–30 µg
Liver (25 mg)	1:80	5 mg	10–30 µg
Brain (25 mg)	1:80	5 mg	15–30 µg
Thymus (25 mg)	1:80	5 mg	15–30 µg
Kidney (25 mg)	1:80	5 mg	15–30 µg
Spleen (25 mg)	1:80	5 mg	15–75 µg
Mouse tail (1.2 cm tip)	1:80	5 mg	10–25 µg
Low yielding tissues			
Low-yield tissue (25 mg)	1:40	10 mg	5–10 µg
Lung (25 mg)	1:40	10 mg	5–10 µg

Table 3 Recommended input amount based on tissue type *(continued)*

Tissue type	Recommended tissue:DNA Homogenization Buffer (mg:µL) ratio[1]	Maximum Multisample DNA Purification Plate tissue input amount[2]	Potential yield[3]
Heart (25 mg)	1:40	10 mg	5–10 µg
Breast (25 mg)	1:40	10 mg	5–10 µg

[1] Do not exceed the indicated ratio when homogenizing the sample before loading on the purification plate.
[2] Do not exceed the indicated amount as input into the sample purification plate.
[3] All yields are approximate and not indicative of purification performance.

Load the Genexus™ Purification Instrument and start the run

This section describes how to perform the following procedures.

- Set up the instrument for use by loading all of the required reagents and consumables.
- Start a Genexus™ Purification Instrument run.

Note: Do NOT load any consumables onto the instrument until after the instrument has performed the prerun UV cleaning.

Prepare the consumables

IMPORTANT! Store all kit components containing liquid in the upright orientation.

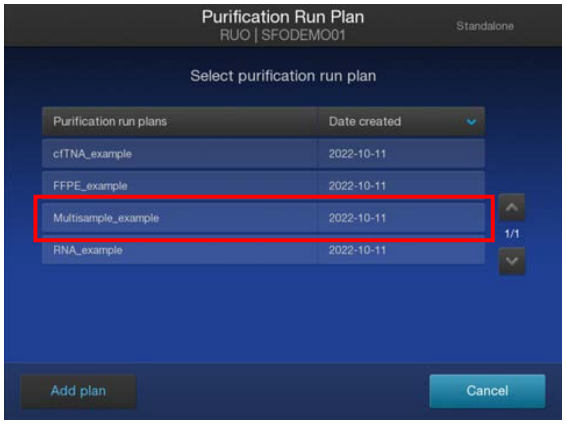
Remove all cartridges and consumables from their packaging, then place them on the bench at room temperature.

Prepare the following cartridges and consumables:

- Genexus™ Purification Supplies 1
  - Purification Tip Cartridge
  - 48-Well Nucleic Acid Archive Plate
  - 48-Well Nucleic Acid Archive Plate Seal
- 12-Well Tip Comb

Start the purification run

1. In the instrument touchscreen, tap **Run**, then tap to select the run plan that you created for this run.



2. Ensure that the run plan selected is correct, then tap **Next**.

3. *(Optional, standalone configuration)* Import sample information.
   - The import overwrites the existing **Sample ID** and **Notes** information for each sample. That is, if the run plan has 6 samples, the sample import file must include information for at least 6 samples.
   - To import sample information, prepare a CSV sample import file and save it to a USB drive. See “Create a template for importing samples in standalone configuration purification run plans” on page 161.

   a. In the **Sample Assignment** screen, tap **Manage Samples**.

   b. In the **Manage Samples** screen, tap **Import**.

   c. In the **Sample Import** screen, tap **Import** to proceed.

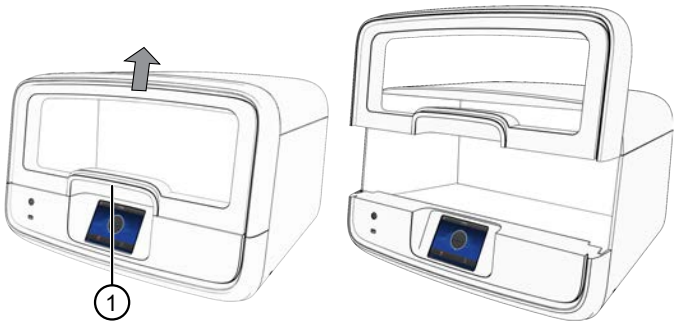
   d. Insert the USB drive that contains the sample import CSV file into the USB port on the front of the purification instrument. In the **Sample Import** screen, select the USB drive, then navigate to and select the sample import file.

   e. *(Optional)* Tap **Details** to view the CSV file that lists the sample names to be imported.

   f. Tap **Import**, then in the **Import Successful** screen, tap **OK**.
   The imported sample information is shown in the **Manage Samples** screen. If needed, select a sample, then tap **Edit** to modify the **Sample ID** or **Notes**.

4. Tap **Next**.
   The instrument performs a 2-minute UV cleaning, then unlocks the door.

5. Lift the instrument door to the stop.



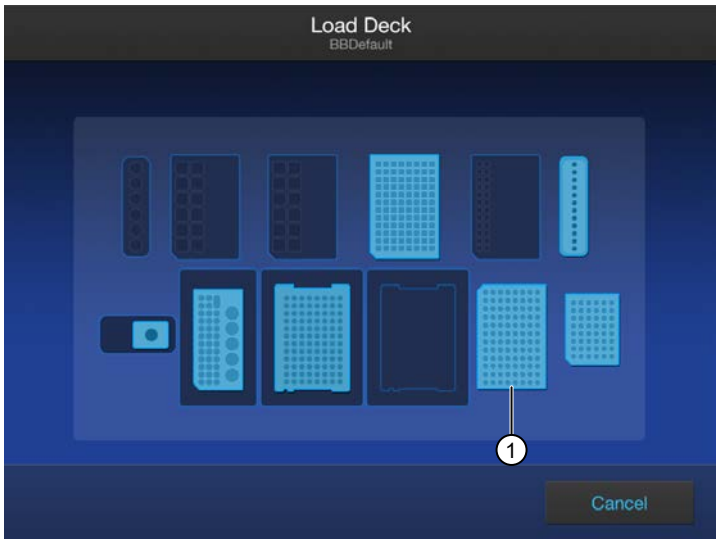
① Hold here, then lift.

Load the Genexus™ Purification Instrument

IMPORTANT!

- Do NOT load any consumables onto the instrument until after the instrument has performed the prerun UV cleaning.
- Ensure that all components are clean and dry before loading them onto the instrument.
- Ensure that the reagent and quantitation station compartments are free of condensate before loading components. If needed, use a lint-free wipe to dry the compartment.

Follow the on-screen prompts to load the instrument.

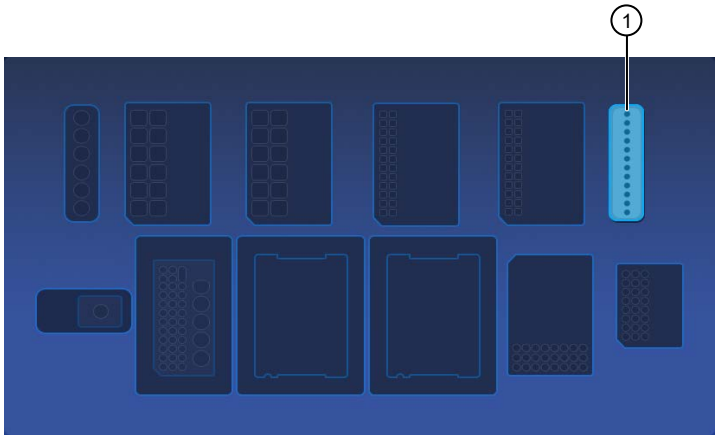


① 96-Well Nucleic Acid Output Plate, only needed when performing the purification in integrated configuration.

Load the 12-Well Tip Comb, Purification Tip Cartridge, 96-Well Nucleic Acid Output Plate, and 48-Well Nucleic Acid Archive Plate

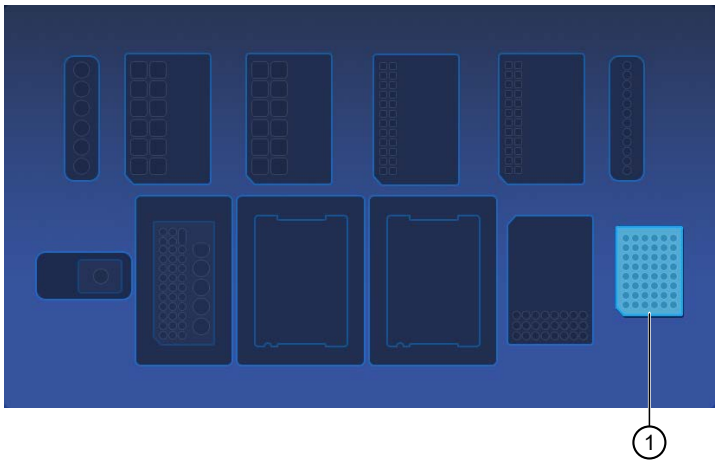
1. Unwrap, then load a new 12-Well Tip Comb.

   Ensure that the tip comb is straight and that the tabs are not bent or broken. If needed, gently bend the tip comb in the opposite direction to the curvature to straighten the tip comb before installing it.



① 12-Well Tip Comb position

2. Unwrap, then load a new 48-Well Nucleic Acid Archive Plate.

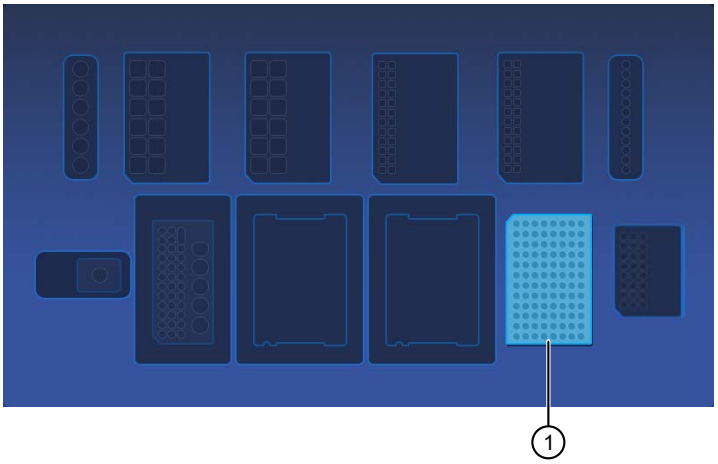


① 48-Well Nucleic Acid Archive Plate position

3. *(Integrated configuration only)* Load a new 96-Well Nucleic Acid Output Plate into the output plate position.

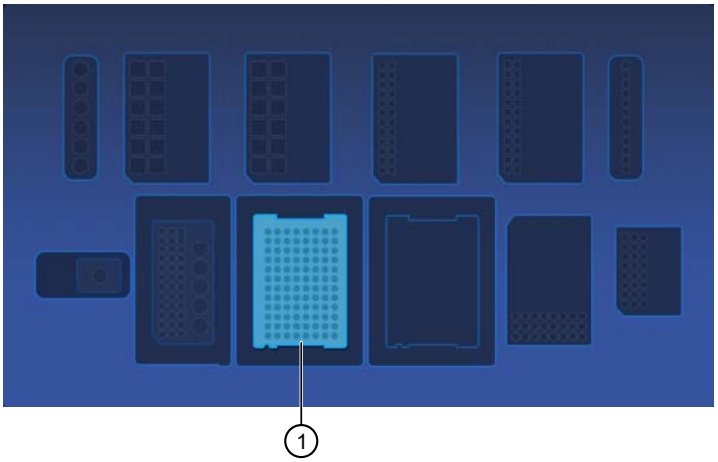
   The 96-Well Nucleic Acid Output Plate is not required when performing the purification in standalone configuration.

   After a purification run, the 96-Well Nucleic Acid Output Plate becomes the sample plate to be loaded in the Genexus™ Integrated Sequencer.



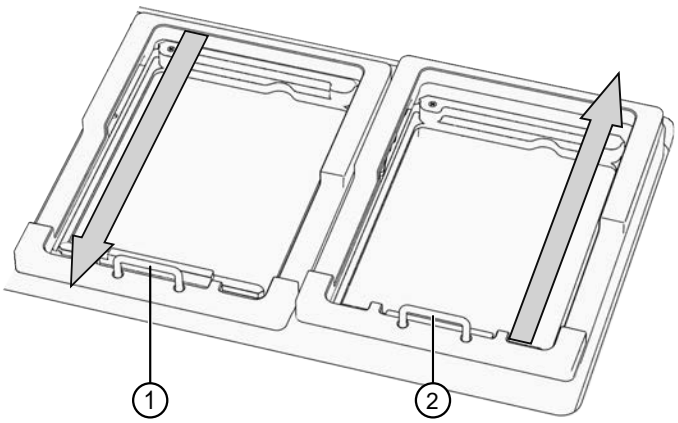
① 96-Well Nucleic Acid Output Plate position

4. Unwrap a Purification Tip Cartridge, remove the cover to expose the pipette tips, then load it in position 1.



① Purification Tip Cartridge position 1

a. Pull the locking mechanism handle forward, then place the tip box in the open position.



① Unlocked (forward) ② Locked (back)

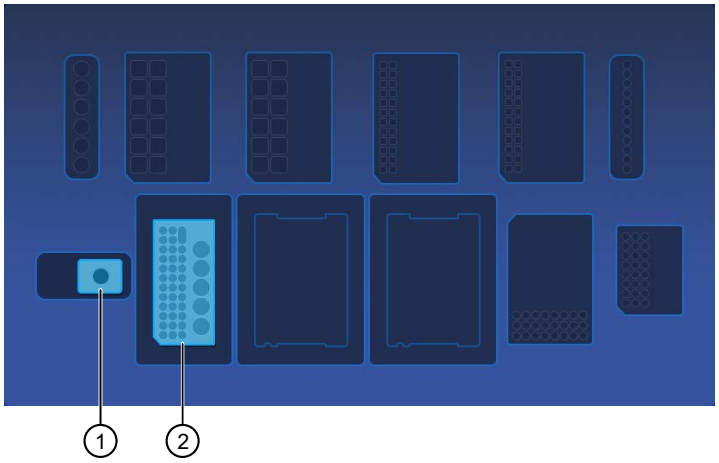
b. Push the locking mechanism handle back to lock the tip box in place.

Load the quantitation reagents and consumables

Note:

- Protect the Quantitation Plate from light to prevent photobleaching of the preloaded reagents.
- The Quantitation Plate is required even if your run plan does not include sample quantitation.
- The Quantitation Tube is not required if your run plan does not include sample quantitation.

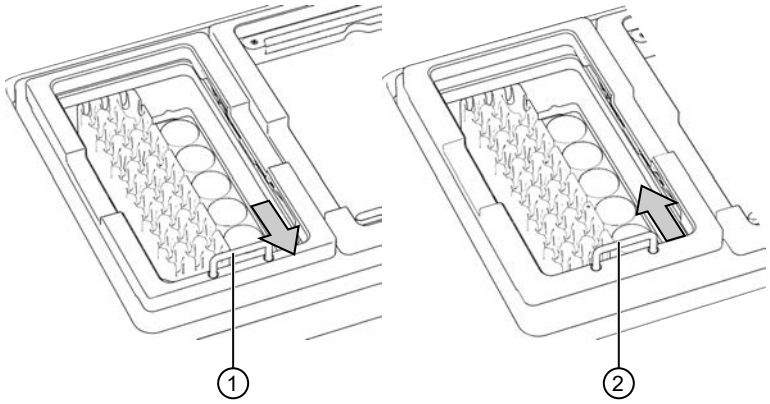
1. Centrifuge the Quantitation Plate at 1,000 × *g* for 30 seconds to collect the contents.
2. Load the Quantitation Plate in position 2.



① Quantitation Tube position
② Quantitation Plate position

   a. Pull the locking mechanism handle forward, then place the Quantitation Plate in the open position.

   b. Push the locking mechanism handle back to lock the plate in place.

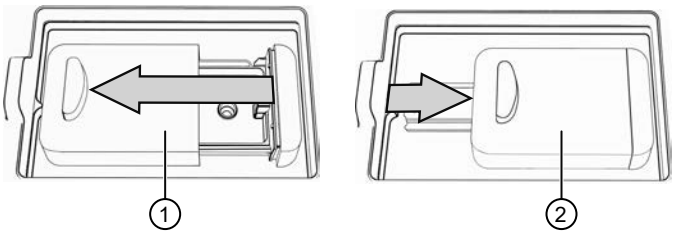


① Unlocked (forward)

② Locked (back)

3. *(If needed)* Slide and hold the quantitation module cover to the left, then insert the Quantitation Tube. **Press down firmly** to properly seat the tube, then allow the module cover to close.

WARNING! Do not force the module cover closed. Forcing the module cover closed can damage the instrument.



① Open ② Closed

Add samples to Multisample DNA Purification Plate

The Multisample DNA Purification Plate contains magnetic beads in row D.

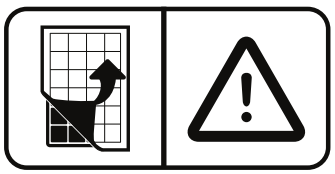
1. Briefly centrifuge the sealed Multisample DNA Purification Plate at 1,000 × *g* for 30 seconds to collect the contents.

   Alternatively, gently flick or tap the plate on the bench to force the reagents to the bottoms of the tubes.

IMPORTANT! Do not create bubbles when preparing the plate.

2. Inspect the plate to ensure that the contents of all rows are at the bottom of the wells. If needed repeat step 1.

3. Carefully remove the plate seal without disturbing the contents.



4. Add the samples to the Multisample DNA Purification Plate as indicated in the table.

IMPORTANT!

- Do not premix the DNA Enhancer Solution and Proteinase K.
- Do not change the order of pipetting.
- Add samples to consecutive wells beginning with sample 1 in well A1, through sample 12 in well A12. Do not skip wells.
- When all components are added, proceed immediately to the instrument processing. There is no need for manual mixing beforehand.

Table 4 Multisample DNA Purification Plate loading volumes

DNA Enhancer Solution (X µL)	Sample volume (Y µL)	Proteinase K volume (Z µL)
Sample type: whole blood		
40	400	40

Table 4 Multisample DNA Purification Plate loading volumes *(continued)*

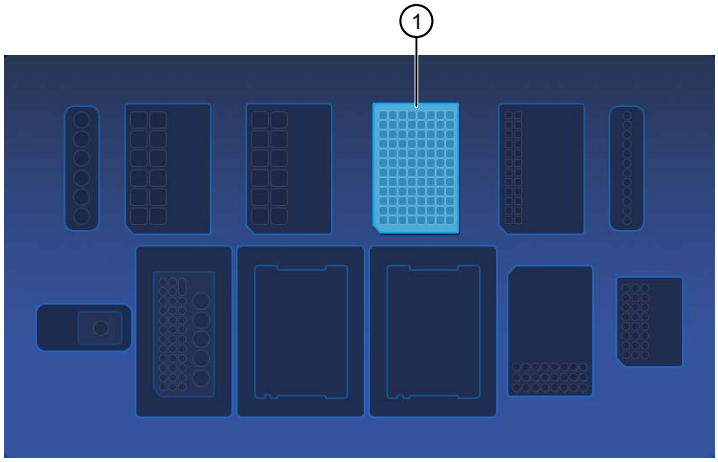
DNA Enhancer Solution (X µL)	Sample volume (Y µL)	Proteinase K volume (Z µL)
Sample type: bone marrow aspirate		
20	200	20
Sample type: fresh frozen tissue		
—	400	—
Sample type: peripheral blood leukocytes / buffy coat		
20	200	40
Sample type: cell lines		
40	400	40

a. Add X µL DNA Enhancer Solution to each well in Row A of the Multisample DNA Purification Plate.

b. Add Y µL sample to each well in Row A.

c. Add Z µL Proteinase K solution to each well in Row A.

5. Immediately load the 96 deep-well Multisample DNA Purification Plate with the samples in position 1.



① Multisample DNA Purification Plate position

Confirm that consumables are installed correctly

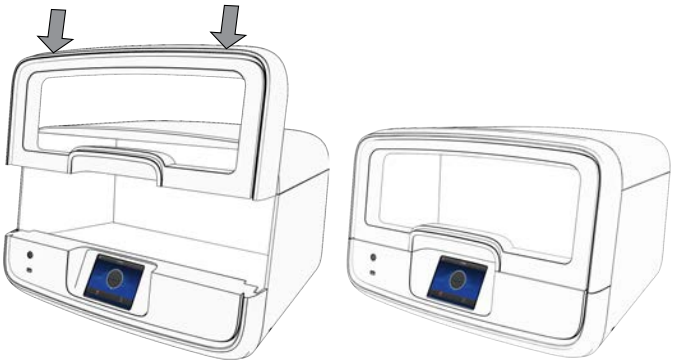
IMPORTANT! To ensure correct and safe instrument operation, confirm that all consumables are installed correctly on the deck before you start a run. The instrument vision system confirms that required reagents are in place, no reagents are expired, and foil seals are removed. The vision system does not verify all aspects of the consumable setup before beginning each run.

1. Confirm the following.
   - Foil seals are removed from the purification plates. Do not remove foil seal from the Quantitation Plate.
   - Each component is at the correct location and in the correct orientation. Press down on all plates and cartridges to ensure that they are firmly seated in place.
   - The Tip Comb is in place.
   - The Quantitation Plate is in the correct location, is in the correct orientation, and is locked in place.
   - *(If needed)* The Quantitation Tube is firmly seated in the quantitation module.
   - The Purification Tip Cartridge is in the correct location, in the correct orientation, and locked in place.

   If the vision system detects an error, the location indicator does not turn gray in the touchscreen.
2. If needed, tap **Help**, then accept each warning message appropriately to proceed.

Start the run

1. When all reagents and consumables are loaded in the Genexus™ Purification Instrument, tap **Next**.
2. Close the instrument door by pressing down on both top corners. Ensure that the door is locked after closing it.



The instrument vision system confirms that all reagents are in place and are not expired.

3. Tap **Start**.

   The time remaining until the purification is complete is displayed and the interior lighting turns green.

   - If you need to stop the run for any reason, tap **Cancel**, then tap **Yes** to confirm the cancellation.
   - The interior lighting turns off during quantitation, then turns blue when the run is complete.
   - If the instrument encounters a problem during the run, it aborts the run and displays the error on the instrument touchscreen. The interior lighting turns red.

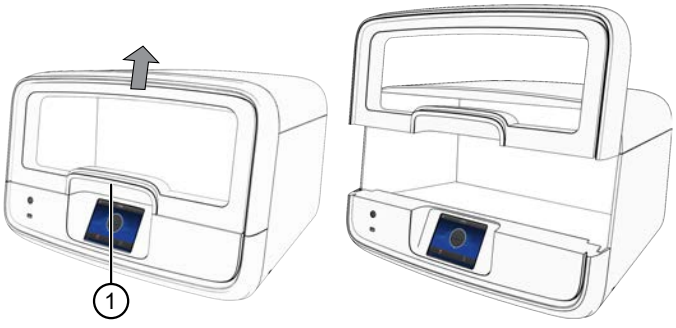
When the run is complete, the interior light turns blue, and the touchscreen displays **Run Complete**. Quantitation results are available immediately. See “View and export quantitation results” on page 123.

Unload purified samples

IMPORTANT! Do not allow purified samples to sit on the instrument. Store as directed or use in sequencing reactions within 60 minutes.

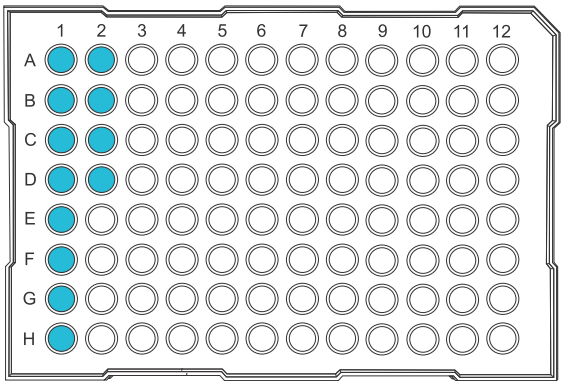
1. In the touchscreen, tap **Unload**. The door unlocks.

2. Lift the instrument door to access the instrument deck.



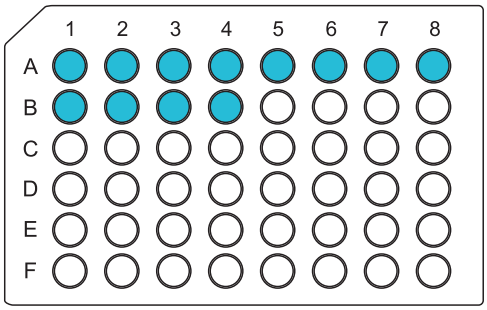
① Hold here, then lift.

3. *(**Sample to Result** run)* Remove the 96-Well Nucleic Acid Output Plate that contains the purified sample DNA that is ready for the addition of positive or nontemplate sample sequencing controls. . Store on ice or at 4°C. If quantitation was performed, the sample concentration information is visible in the Genexus™ Software. Alternatively, use a Qubit™ Fluorometer to accurately measure sample concentration manually, if needed.



STOPPING POINT If not sequencing immediately, for example while waiting for a second purification batch, seal the plate with an Adhesive PCR Plate Foil (Cat. No. AB0626), then store the plate at –20°C for up to 1 week. For long-term storage (>1 week), transfer the samples to labeled low-retention tubes, then store the samples at –30°C to –10°C for up to 36 months.

4. Remove the 48-Well Nucleic Acid Archive Plate that contains the purified sample DNA in rows A1–8 and B1–4.



Note: *(Standalone configuration)* If using the purified DNA immediately, transfer the sample DNA to a sample input plate for sequencing. For more information, see the relevant assay user guide for **Nucleic Acid to Result** run guidance. To determine the sample concentrations, see “View and export quantitation results” on page 123.

5. For short-term storage, seal the plate with a 48-Well Nucleic Acid Archive Plate Seal. Store the plate at –20°C for up to 3 months. For long-term storage (>3 months), transfer samples to labeled low-retention tubes, then store the DNA samples at –30°C to –10°C for up to 36 months.

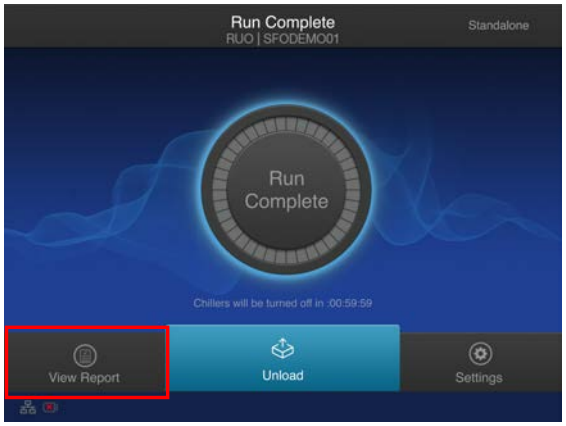
   If the archive plate is thawed during short-term storage, transfer the samples into labeled low-retention tubes. Do not reseal the archive plate with the used plate seal.

View and export quantitation results

Genexus™ Purification Instrument runs that include sample quantitation produce sample concentration results that can be accessed after the run is complete. When integrated with the Genexus™ Software, sample concentration information is automatically available in the software and used for **Sample to Result** runs.

In standalone configuration, results can be accessed from the **Run Complete** screen or the **Home** screen, then exported to a USB for transfer to the Genexus™ Software.

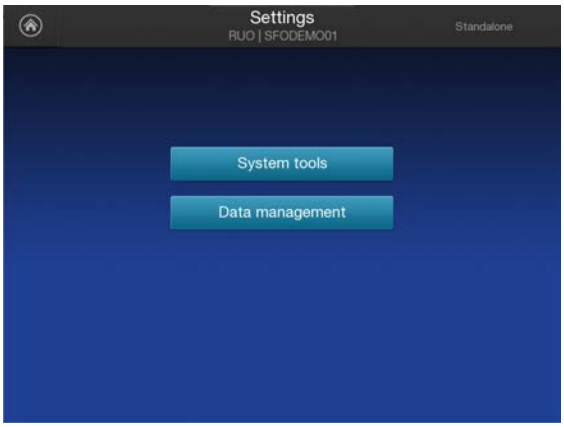
1. In the **Run Complete** screen, tap **View report**.



   The **Saved Experiment Reports** screen opens. See step 4.

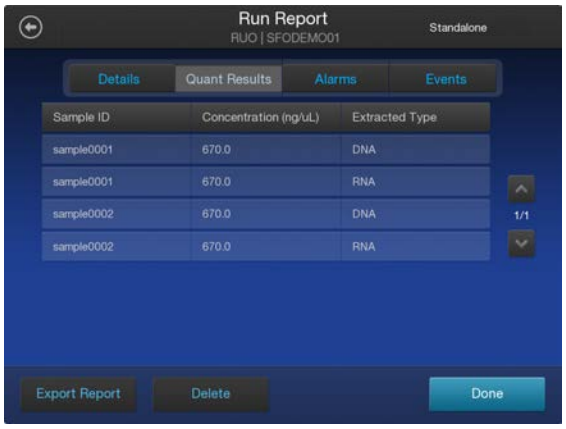
2. At any time after unloading and UV cleaning the instrument, sample concentration results can be accessed through the **Home** screen. Tap ⚙ (**Settings**).

3. In the **Settings** screen, tap **Data Management**.



4. In the **Saved Experiment Reports** screen, tap ⌄ or ⌃ to page through the list. Locate the **Experiment Name** of interest, tap in the row to select the experiment, then tap **View Report**.

5. In the **Run Report** screen, tap **Quant Results** to view the sample concentration results.



6. Insert a USB drive into the USB port on the front of the instrument, then tap **Export Report**. Navigate to the file destination, then tap **Save**.

   Sample concentration information is automatically transferred to the Genexus™ Software and used for **Sample to Result** runs.

Dispose of used consumables and UV clean the instrument

Unload purified DNA samples before disposal of used consumables.

IMPORTANT! Do not allow purified DNA to sit on the instrument. Store as directed or use in sequencing reactions within 60 minutes.

---

1. Remove and discard the deep-well sample input plates.
   a. Remove the Multisample DNA Purification Plate from the instrument.
   b. Dispose of the liquid waste by tipping the deep-well plate on one corner and pouring the waste into an appropriate liquid biohazardous waste container.

WARNING! Liquid waste contains guanidine thiocyanate, dispose of properly.

   c. Dispose of the deep-well plate in an appropriate waste container.

2. Unlock, then remove and dispose of the Purification Tip Cartridge in an appropriate waste container.

3. Unlock, then remove and dispose of the Quantitation Plate.
   a. Dispose of the liquid waste by tipping the deep-well plate on one corner and pouring the waste into an appropriate liquid biohazardous waste container.

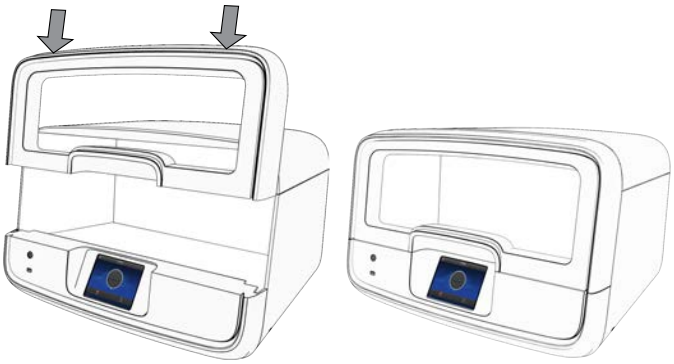
WARNING! No data are currently available that address the mutagenicity or toxicity of the Qubit™ RNA BR Reagent (Component A). This reagent is known to bind nucleic acid and is provided as a solution in DMSO. Treat the Qubit™ RNA BR Reagent with the same safety precautions as all other potential mutagens and dispose of the dye in accordance with local regulations.

   b. Dispose of the deep-well plate in an appropriate waste container.

4. Open the quantitation module cover, remove and discard the Quantitation Tube, then allow the module cover to gently close.

IMPORTANT! Do not allow the module cover to spring shut.

5. Close and lock the instrument door by pressing down on both top corners, then tap **Start UV Clean**.



The time remaining in the UV cleaning is displayed. When complete, the instrument is ready to start a new purification run.

8 Genexus™ Total RNA Purification protocol

Genexus™ Total RNA Purification workflow

5 min

Plan a purification run (page 129)

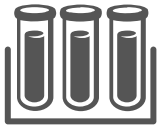
IMPORTANT! If performing a **Sample to Result** run, create a run plan in the Genexus™ Software. For more information see "Plan a Sample to Result run" on page 41.

To purify samples for use in **Nucleic Acid to Result** runs or other nonsequencing applications, run the Genexus™ Purification Instrument in standalone configuration. Add a new purification run plan or copy-edit an existing purification run plan that best represents your experiment. Purification run plans contain instrument settings that are used in sample purification.

3 hr

Prepare samples (page 133)

Samples are processed based on the sample type before adding to the Total RNA Purification Plate and loading on to the instrument for purification of RNA.



5 min

Load the Genexus™ Purification Instrument (page 138)

The purification run plan is selected, and the run is initiated. The instrument performs a UV cleaning, then reagents and consumables are loaded on to the instrument. Preprocessed samples are added to the Total RNA Purification Plate, then immediately loaded on to the instrument for purification of RNA.

2 hr

Start the run (page 147)

After the sample plate, reagents, and consumables are loaded, the instrument door is closed, and the run is started.

Depending on the number of samples purified, sample quantification adds up to 1 hour to the run time.

Genexus™ Total RNA Purification workflow

5 min

Unload the purified total RNA (page 148)

If performing a **Sample to Result** run, remove the 96-Well Nucleic Acid Output Plate and proceed to sequence the purified sample. Remove and seal the 48-Well Nucleic Acid Archive Plate, then store as directed.

If performing a **Nucleic Acid to Result** run or purifying nucleic acids in standalone configuration for use in other downstream applications, remove and seal the 48-Well Nucleic Acid Archive Plate, then store as directed or proceed to sequence the purified sample.

Used reagents and consumables are removed from the instrument and a UV cleaning is performed.

The Quantitation Plate requires equilibration to room temperature for at least 30 minutes before use. To save time, experienced users can take the Quantitation Plate out of 4°C storage before creating a purification run plan and preparing samples.

Plan a purification run (standalone configuration)

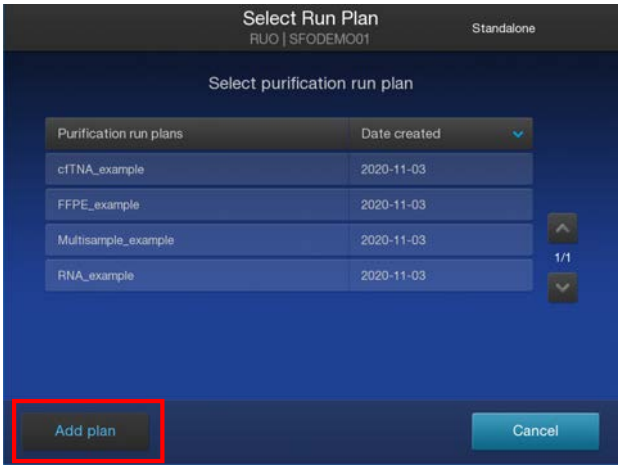
Note: If running the Genexus™ Purification System in integrated configuration, see "Plan a Sample to Result run" on page 41 to plan a **Sample to Result** run in the Genexus™ Software.

In standalone configuration, plan a purification-only run through the instrument touchscreen. After purification is complete, all purified samples are transferred to an archive plate for storage.

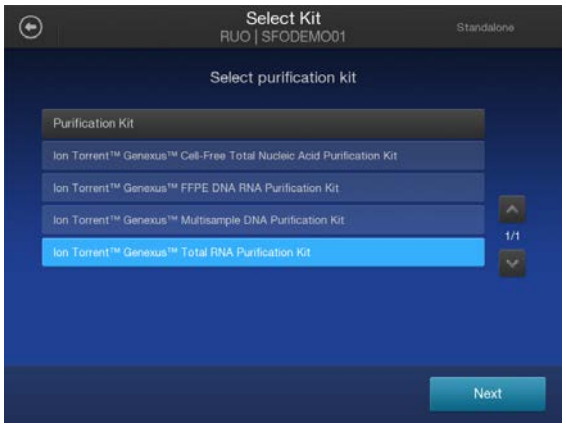
Add a run plan

Create the run plan before preparing samples and loading the samples into the Total RNA Purification Plate.

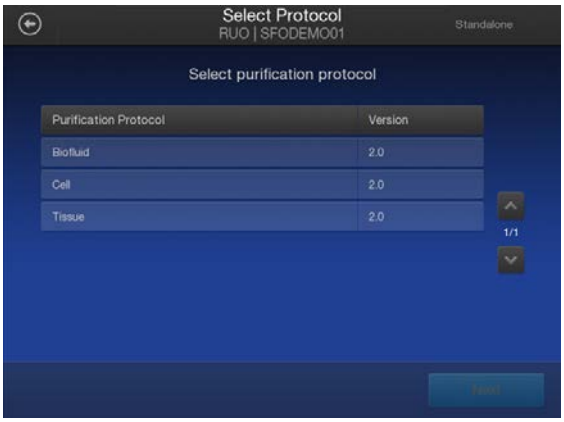
1. Enter your username and password to sign in to the instrument.
2. Tap **Run**, then tap **Add plan**.



3. Tap in the entry box, enter a unique name for the run plan, then tap **Done** ▸ **Next**.
4. Select the **Ion Torrent™ Genexus™ Total RNA Purification Kit**, then tap **Next**.



5. Select the appropriate purification protocol and software version in use, then tap **Next**.

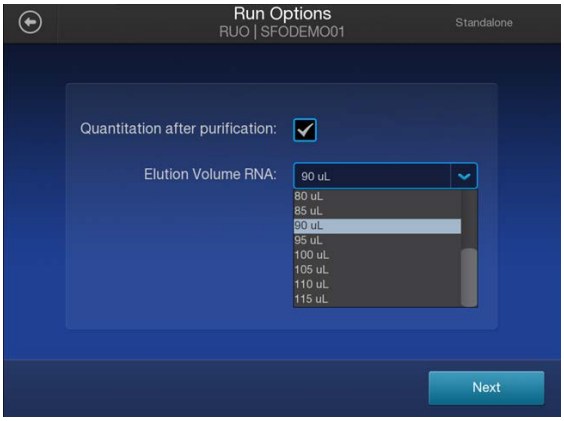


Sample type	Input volume[1]	Purification protocol
Whole blood	50–150 µL	**Biofluids**
Peripheral blood leukocytes (PBL/buffy coat)	50–150 µL	**Biofluids**
Bone marrow	50–150 µL	**Biofluids**
Tissue	up to 10 mg[2]	**Tissue**
Cell lysates (for example: cell lines, bone marrow mononuclear cells (BMMC), peripheral blood mononuclear cells (PBMC))	150 µL (4 × 10^6 cells)	**Cells**

[1] The Total RNA Purification Plate can accommodate a maximum sample input volume of 200 µL. We recommend using 100 µL of sample.

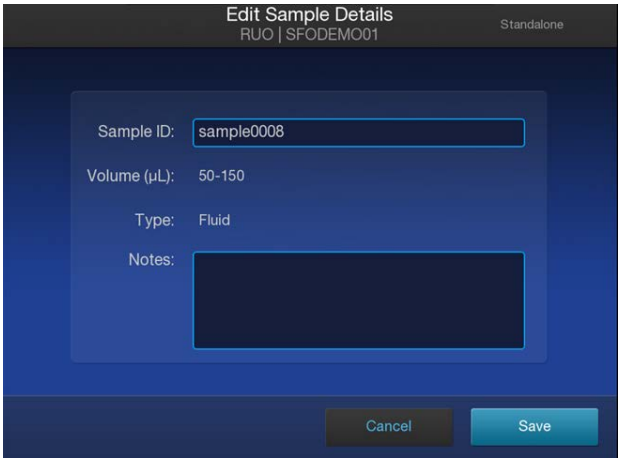
[2] Homogenize tissues in an appropriate volume of homogenization buffer such that the maximum input volume of 200 µL does not exceed 10 mg of input tissue.

6. Enable or disable **Quantitation after Purification**.
   - The Quantitation Plate is required even if **Quantitation after Purification** is disabled.
   - Disabling **Quantitation after Purification** may reduce the purification run time by up to 1 hour.



7. Select the desired elution volume from the dropdown list, then tap **Next**.

8. *(Optional)* Change the number of samples and the sample details.
   a. In the **Manage Samples** screen, deselect extra samples (for example, if you run only 10 samples, deselect samples 11 and 12).
   b. Tap on a sample ID to select the sample.
   c. Tap **Edit**, enter a new **Sample ID** and any **Notes**, then tap **Save**.
   d. Repeat substep 8b and substep 8c for each additional sample.
   e. Click **Next**.



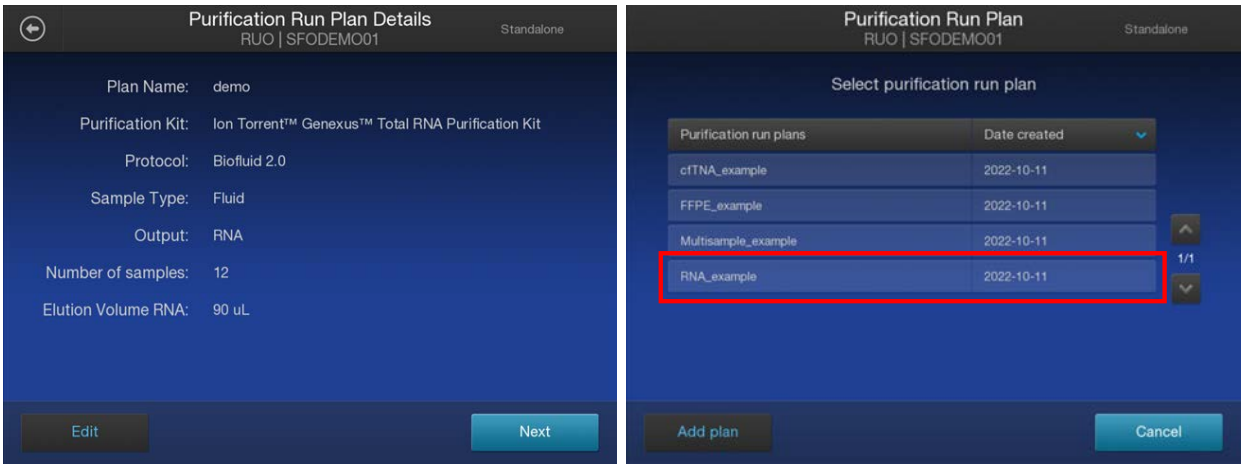
9. *(Optional)* Import sample information.

   The import overwrites the existing **Sample ID** and **Notes** information for each sample selected.

   In standalone configuration, prepare a CSV sample import file and save it to a USB drive to import sample information. See page 161.

   a. In the **Manage Samples** screen, select the samples to import sample information, then tap **Import**.
   b. In the **Sample Import** screen, tap **Import** to proceed.
   c. Insert the USB drive that contains the sample import CSV file into the USB port on the front of the purification instrument. In the **Sample Import** screen, select the USB drive, then navigate to and select the sample import file.
   d. *(Optional)* Tap **Details** to view the CSV file that lists the sample names to be imported.
   e. Tap **Import**, then in the **Import Successful** screen, tap **OK**.
      The imported sample information is shown in the **Manage Samples** screen. If needed, edit imported sample information as described in step 8.

10. Review the **Purification Run Plan Details**. Tap **Edit** to change selections. Otherwise tap **Next**.



The new run plan appears in the list of available **Purification Run Plans**.

Prepare the Quantitation Plate and consumables

Cartridges and consumables needed:

- Genexus™ Total RNA Purification (Part. No. A45534)
  - Total RNA Purification Plate
  - 12-Well Tip Comb
- Genexus™ Nucleic Acid Quantitation, Broad Range (Part. No. A45537)
  - Quantitation Plate Broad Range
  - Quantitation Tube
- Genexus™ Purification Supplies 1 (Part. No. A45529)
  - Purification Tip Cartridge
  - 48-Well Nucleic Acid Archive Plate
  - 48-Well Nucleic Acid Archive Plate Seal
- P200 pipet and filtered tips

Equilibrate the Quantitation Plate

The Quantitation Plate is required even if your run plan does not include sample quantitation.

IMPORTANT!

- Protect the Quantitation Plate from light to prevent photobleaching of the preloaded reagents.
- Allow at least 30 minutes for the Quantitation Plate to equilibrate to room temperature.

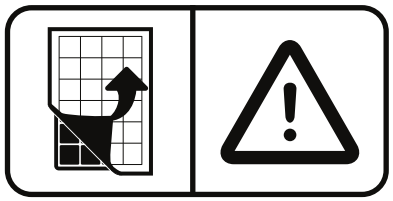
1. Centrifuge the Quantitation Plate at 1,000 × *g* for 30 seconds to collect the contents.
2. Place the plate and Quantitation Tube on the bench next to the Genexus™ Purification Instrument.

Prepare samples

Procedural guidelines

IMPORTANT! Store all kit components containing liquid in the upright orientation.

- Perform all steps at room temperature (20–25°C) unless otherwise noted.
- Thawing or storing on ice can be substituted with thawing or storing at 4°C (2–8°C refrigerator or prechilled benchtop cold block).
- When mixing samples by pipetting up and down, avoid creating bubbles.
- When working with whole blood:
  - Wear clean gloves and a clean laboratory coat.
  - Change gloves whenever you suspect that they are contaminated.
  - Open and close all sample tubes carefully. Avoid splashing or spraying samples.
  - Use a positive-displacement pipettor and RNase-free pipette tips.
  - Clean laboratory benches and equipment periodically with 10% bleach solution and rinse with 70% ethanol.
  - When freezing whole blood or bone marrow aspirate samples for later use, freeze samples in 50–150 µL aliquots at –90°C to –70°C. We recommend 100 µL aliquots in for best results.
  - Freeze samples in tubes large enough to accommodate volumes needed for sample preparation without thawing and transferring the sample to a new tube.
- When working with RNA:
  - Wear clean gloves and a clean laboratory coat.
  - Change gloves whenever you suspect that they are contaminated.
  - Open and close all sample tubes carefully. Avoid splashing or spraying samples.
  - Use a positive-displacement pipettor and RNase-free pipette tips.
  - Clean laboratory benches and equipment periodically with an RNase decontamination solution, such as RNase*Zap*™ RNase Decontamination Solution (Cat. No. AM9780).
- Volumes for reagent mixes are given per sample. We recommend that you prepare master mixes for larger sample numbers. To calculate volumes for master mixes, see the per-well volume and add 5–10% overage.
- Foil seals bearing the warning label must be removed before loading onto the Genexus™ Purification Instrument.



- The plate chiller shuts off 60 minutes after run completion. Remove the 48-Well Nucleic Acid Archive Plate with purified nucleic acids from the instrument within 1 hour of run completion. Proceed immediately to sequencing or properly store the nucleic acids until use.

Note: RNA purifaction protocol scripts indicate sample input volumes up to 150 µL. However, the Total RNA Purification Plate can accommodate up to a maximum of 200 µL sample input volume.

Before each use of the kit

- Keep fresh samples on ice or at 4°C until use.

  IMPORTANT! We recommend fresh unfrozen samples for best RNA integrity.

- Prepare DNase Digestion solution immediately before use.
- Centrifuge purification plates for 30 seconds at 1,000 × *g* to collect the contents.

Materials required

Genexus™ Total RNA Purification (Part No. A45534)

- Total RNA Purification Plate
- DNase
- DNase Buffer
- Proteinase K
- PK Digestion Buffer
- RNA Homogenization Buffer

2-Mercaptoethanol

1X PBS

Isopropanol

Homogenizer

Whole blood samples

Prepare fresh (recommended) or frozen whole blood samples.

IMPORTANT! We recommend fresh unfrozen whole blood for best RNA integrity. If using frozen samples, add the PK Digestion Buffer immediately after removing the sample from the freezer to help in thawing the sample.

1. To each sample, add the indicated volume of PK Digestion Buffer.

Sample volume	PK Digestion Buffer
50–100 µL	Add an equal volume of PK Digestion Buffer
≥100–150 µL[1]	100 µL

[1] Do not use >150 µL sample input volume.

2. *(If needed)* Thaw the sample on ice or at 4°C.

3. Vortex, or pipet up and down at least 10 times, to thoroughly mix.

Keep samples on ice or at 4°C until ready to be added to the Total RNA Purification Plate. For more information, see “Add samples to Total RNA Purification Plate” on page 145.

Prepare bone marrow aspirate samples

IMPORTANT! We recommend fresh unfrozen samples for best RNA integrity.

To prepare fresh (recommended) or frozen bone marrow aspirate samples.

1. To each bone marrow sample, add the indicated volume of PK Digestion Buffer.

Sample volume	PK Digestion Buffer
50–100 µL	Add an equal volume of PK Digestion Buffer
≥100–150 µL[1]	100 µL

[1] Do not use >150 µL sample input volume.

IMPORTANT! Add PK Digestion Buffer immediately after removing the sample from the freezer to help in thawing the sample.

2. Thaw the sample on ice or at 4°C.

3. Vortex, or pipet up and down at least 10 times, to thoroughly mix.

Keep samples on ice or at 4°C until ready to be added to the Total RNA Purification Plate. For more information, see “Add samples to Total RNA Purification Plate” on page 145.

Prepare peripheral blood leukocytes (PBL/buffy coat) samples

1. Pipet 2–5 mL fresh whole blood into 15-mL conical tubes.

2. Weigh each tube, then, if needed, adjust volume to properly balance tubes before centrifugation.

3. Centrifuge the samples in a swinging bucket rotor at 2,000 x *g* for 10 minutes at 4°C (Brake = 0–5). Keep samples on ice or at 4°C when complete.

4. Use a P1000 pipettor to transfer the plasma to a new 15-mL conical centrifuge tube.

   IMPORTANT! Leave a small amount of plasma behind. Do not disturb the buffy coat layer when transferring the plasma layer.

5. Transfer the buffy coat layer to a 1.5-mL Eppendorf™ LoBind™ tube on ice or at 4°C.

   You should recover ~20% of the starting volume as buffy coat (for example, ~1 mL buffy coat from 5 mL whole blood). Some carry over of the red blood cell layer can not be avoided and does not affect sample processing.

6. To each buffy coat sample, add the indicated volume of PK Digestion Buffer.

Sample volume	PK Digestion Buffer
50–100 µL	Add an equal volume of PK Digestion Buffer
≥100–150 µL[1]	100 µL

[1] Do not use >150 µL sample input volume.

IMPORTANT! We recommend fresh unfrozen buffy coat samples for best RNA integrity. If using frozen samples, add the PK Digestion Buffer immediately after removing the sample from the freezer to help in thawing the sample.

7. Vortex, or pipet up and down at least 10 times, to thoroughly mix.

Keep samples on ice or at 4°C until ready to be added to the Total RNA Purification Plate. For more information, see “Add samples to Total RNA Purification Plate” on page 145.

STOPPING POINT If not processing immediately, buffy coat samples can be stored at 4°C for up to 4 days. However, RNA quality can be affected. For long term storage, keep buffy coat samples at –80°C. To minimize RNA degradation, thaw samples stored at –80°C in a 37°C water bath and use immediately.

Prepare cultured cell samples, PBMCs, and BMMCs

Up to 4×10^6 cells can be processed per sample.

If preparing samples from live cell cultures, start at step 3. Depending upon the cell density, a precentrifugation step may be needed to collect the cells.

1. Thaw frozen cells in a 37°C water bath. Remove from the water bath and place on ice or at 4°C just before the last remnant of ice melts.
2. Pipet the tube contents up and down several times to thoroughly disperse the cells into suspension.
3. Count cells using a cell counter or hemocytometer.
4. Based on your cell count, divide the sample equally (up to 4×10^6 cells per tube) into sterile 1.5-mL microcentrifuge tubes.
5. Centrifuge the cell samples at 1,000 × *g* for 5 minutes at 4°C, then carefully remove the supernatant without disturbing the cell pellet.
6. Wash the cell pellet twice in cold 1X PBS.
   a. Resuspend the cell pellet in 1 mL cold 1X PBS.
   b. Centrifuge cells at 1,000 × *g* for 5 minutes at 4°C, then carefully remove the supernatant without disturbing the cell pellet.

IMPORTANT! Keep washed cell pellets on ice or at 4°C until loading into the Total RNA Purification Plate.

7. Prepare sufficient RNA Homogenization Buffer and isopropanol solution for n + 1 samples.
   a. In a 5- or 15-mL tube add (n+1) x 100 µL RNA Homogenization Buffer.
   b. Add (n + 1) x 175 µL isopropanol (100%), then vortex briefly to mix.
8. Resuspend each sample in 275 µL RNA Homogenization Buffer and isopropanol solution.

Keep samples on ice or at 4°C until ready to be added to the Total RNA Purification Plate. For more information, see “Add samples to Total RNA Purification Plate” on page 145.

Prepare tissue samples

Fresh or frozen tissue RNA yields can vary based on the tissue type. Use the amounts recommended in Table 5. Adjust the input amount based on your results. Use a bead mill homogenizer when processing small amounts of tissue. Use a rotator-stator tissue homogenizer when processing larger amounts of tissue. Alternate methods of cell disruption can also be used. Do not exceed 10 mg of homogenized tissue as sample input to the Total RNA Purification Plate.

Preweigh tissue that is cut into small pieces and store immediately in a preservative such as RNA*later*™ Stabilization Solution (for freshly collected samples) or snap freezing in liquid nitrogen or a dry ice bath, and then store at –90°C to –70°C.

Table 5 Recommended input amount based on tissue type

Tissue type	Recommended tissue: RNA Homogenization Buffer ratio[1] (mg:µL)	Maximum Total RNA Purification Plate tissue input amount[2]
Normal RNase level (for example: brain, heart, and liver)	1:20	10 mg
High RNase level (for example: spleen or pancreas)	1:40	5 mg

[1] Do not exceed the indicated ratio when homogenizing the sample before loading on the purification plate.
[2] Do not exceed the indicated amount as input into the sample purification plate.

1. Prepare sufficient RNA Homogenization Buffer to homogenize the tissue samples.
   a. To a 50-mL conical tube add sufficient RNA Homogenization Buffer, include a 10% overage.
   b. Add 14 µL 2-mercaptoethanol per 200 µL RNA Homogenization Buffer.
   c. Cap the conical tube securely, then invert to mix.
2. Cut the sample into appropriately sized pieces. For larger samples, we recommend cutting the material into thin strips for faster homogenization.
3. Weigh the tissue sample, then calculate the recommended volume of prepared RNA Homogenization Buffer needed for homogenization.

   Maintain the recommended tissue to buffer ratio if using more or less tissue. Most mechanical homogenizers require a minimum volume of 200 µL homogenization buffer.

4. Add the calculated amount of prepared RNA Homogenization Buffer (for example, 10.0 mg tissue add 200 µL RNA Homogenization Buffer) to an appropriately sized tube (for example, 15-mL conical tube), then add the weighed tissue.

5. Homogenize the samples following the instructions of the manufacturer for your homogenizer.

   Visually inspect the samples. If homogenization is incomplete, repeat step 5. Keep on ice or at 4°C when complete.

   We recommend using a rotator-stator tissue homogenizer in 10-second pulses on ice or at 4°C, when homogenizing large amounts of tissue.

6. Transfer the lysate to a new tube. Ensure that no beads are carried over if using a bead mill homogenizer.

   Keep homogenized samples on ice or at 4°C until ready to be added to the Total RNA Purification Plate. For more information, see “Add samples to Total RNA Purification Plate” on page 145.

STOPPING POINT Store homogenized samples at –90°C to –70°C if not proceeding directly to sample loading.

Load the Genexus™ Purification Instrument and start the run

This section describes how to perform the following procedures.

- Set up the instrument for use by loading all of the required reagents and consumables.
- Start a Genexus™ Purification Instrument run.

Note: Do NOT load any consumables onto the instrument until after the instrument has performed the prerun UV cleaning.

Prepare the consumables

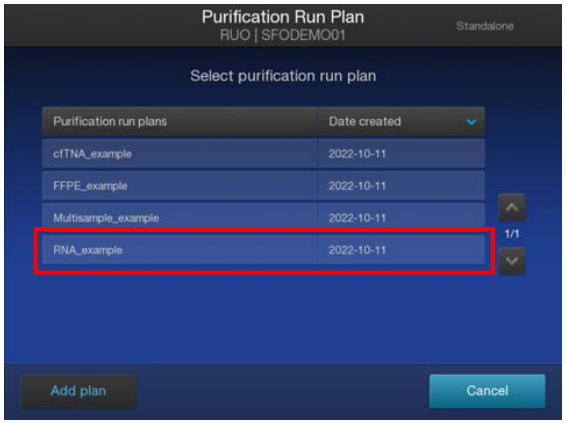
Remove all cartridges and consumables from their packaging, then place them on the bench at room temperature.

Prepare the following cartridges and consumables:

- Genexus™ Purification Supplies 1
  - Purification Tip Cartridge
  - 48-Well Nucleic Acid Archive Plate
  - 48-Well Nucleic Acid Archive Plate Seal
- 12-Well Tip Comb
- 96-Well Nucleic Acid Output Plate

Start the purification run

1. In the instrument touchscreen, tap **Run**, then tap to select the run plan that you created for this run.



2. Ensure that the run plan selected is correct, then tap **Next**.

3. *(Optional, standalone configuration)* Import sample information.

   The import overwrites the existing **Sample ID** and **Notes** information for each sample. That is, if the run plan has 6 samples, the sample import file must include information for at least 6 samples.

   To import sample information, prepare a CSV sample import file and save it to a USB drive. See page 161.

   a. In the **Sample Assignment** screen, tap **Manage Samples**.

   b. In the **Manage Samples** screen, tap **Import**.

   c. In the **Sample Import** screen, tap **Import** to proceed.

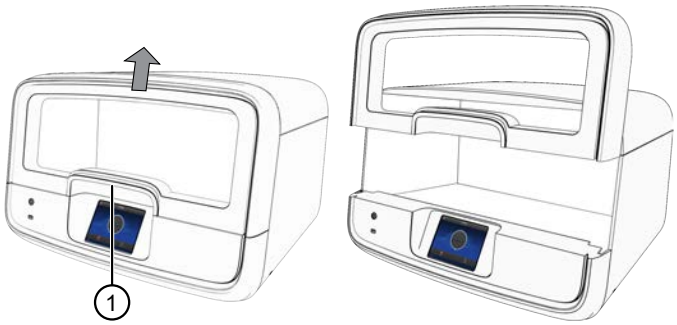
   d. Insert the USB drive that contains the sample import CSV file into the USB port on the front of the purification instrument. In the **Sample Import** screen, select the USB drive, then navigate to and select the sample import file.

   e. *(Optional)* Tap **Details** to view the CSV file that lists the sample names to be imported.

   f. Tap **Import**, then in the **Import Successful** screen, tap **OK**.
   The imported sample information is shown in the **Manage Samples** screen. If needed, select a sample then tap **Edit** to modify the **Sample ID** or **Notes**.

4. Tap **Next**.
   The instrument performs a 2-minute UV cleaning, then unlocks the door.

5. Lift the instrument door to the stop.



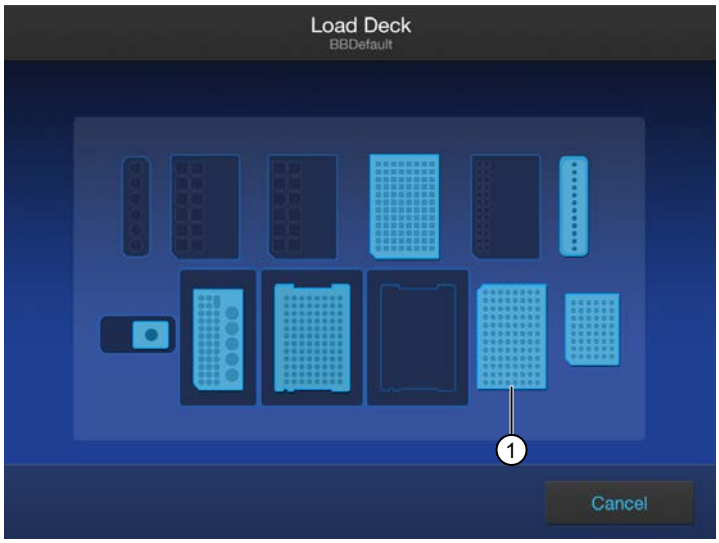
① Hold here, then lift.

Load the Genexus™ Purification Instrument

IMPORTANT!

- Do NOT load any consumables onto the instrument until after the instrument has performed the prerun UV cleaning.
- Ensure that all components are clean and dry before loading them onto the instrument.
- Ensure that the reagent and quantitation station compartments are free of condensate before loading components. If needed, use a lint-free wipe to dry the compartment.

Follow the on-screen prompts to load the instrument.

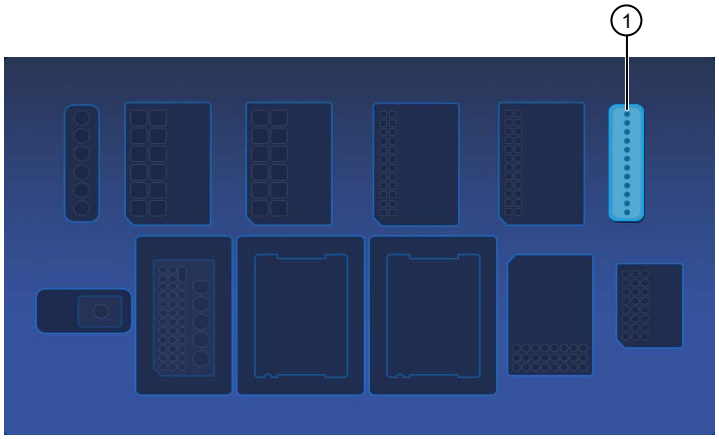


① 96-Well Nucleic Acid Output Plate, only needed when performing the purification in integrated configuration.

Load the 12-Well Tip Comb, Purification Tip Cartridge, 96-Well Nucleic Acid Output Plate, and 48-Well Nucleic Acid Archive Plate

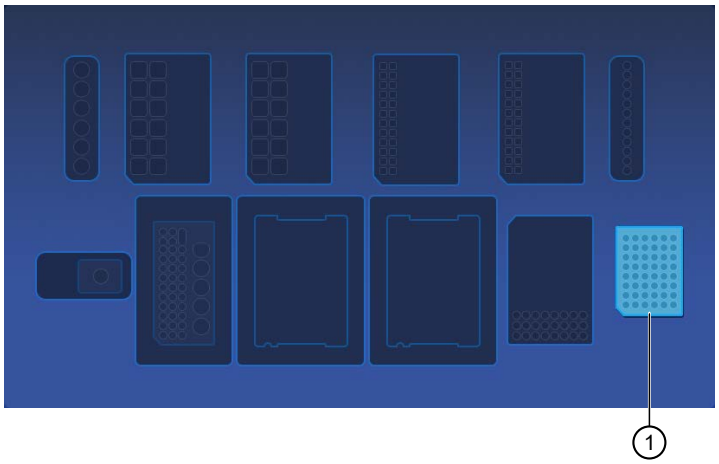
1. Unwrap, then load a new 12-Well Tip Comb.

   Ensure that the tip comb is straight and that the tabs are not bent or broken. If needed, gently bend the tip comb in the opposite direction to the curvature to straighten the tip comb before installing it.



① 12-Well Tip Comb position

2. Unwrap, then load a new 48-Well Nucleic Acid Archive Plate.

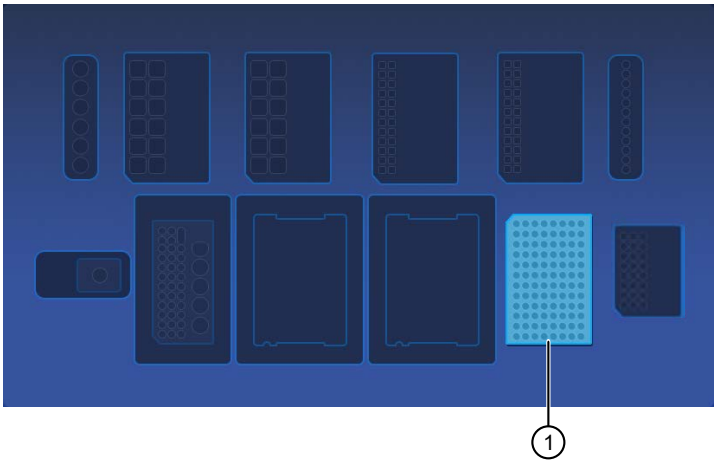


① 48-Well Nucleic Acid Archive Plate position

3. *(Integrated configuration only)* Load a new 96-Well Nucleic Acid Output Plate into the output plate position.

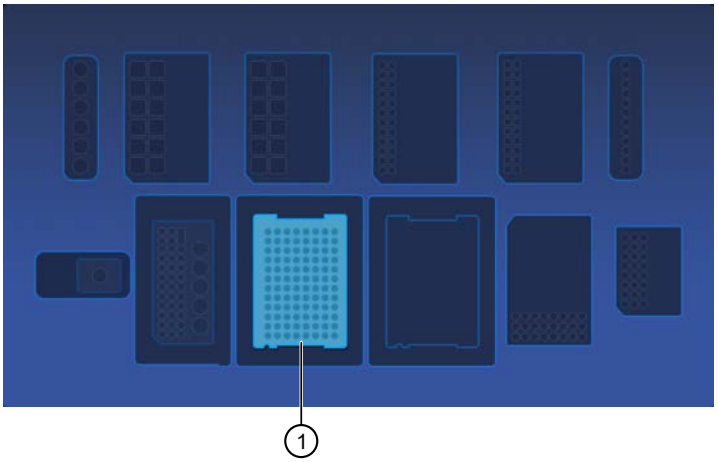
   The 96-Well Nucleic Acid Output Plate is not required when performing the purification in standalone configuration.

   After a purification run, the 96-Well Nucleic Acid Output Plate becomes the sample plate to be loaded in the Genexus™ Integrated Sequencer.



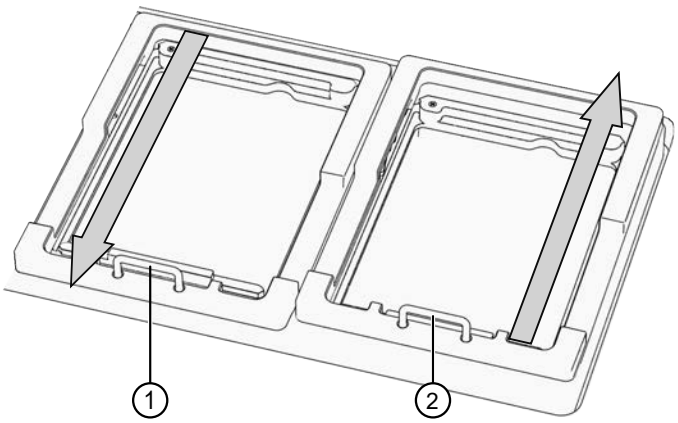
① 96-Well Nucleic Acid Output Plate position

4. Unwrap a Purification Tip Cartridge, remove the cover to expose the pipette tips, then load it in position 1.



① Purification Tip Cartridge position 1

a. Pull the locking mechanism handle forward, then place the tip box in the open position.



① Unlocked (forward) ② Locked (back)

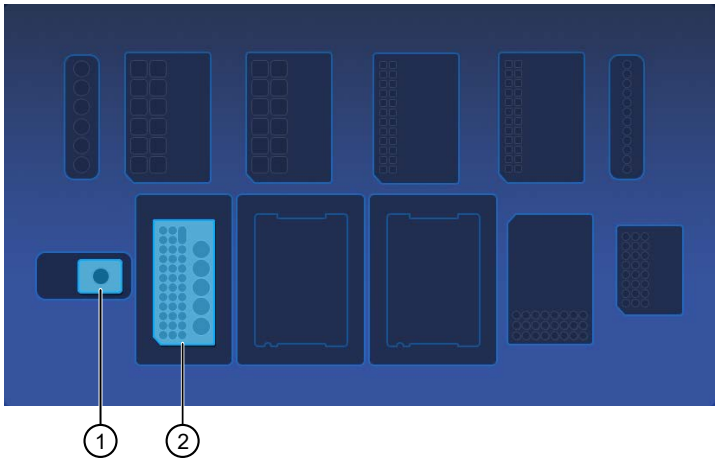
b. Push the locking mechanism handle back to lock the tip box in place.

Load the quantitation reagents and consumables

Note:

- Protect the Quantitation Plate from light to prevent photobleaching of the preloaded reagents.
- The Quantitation Plate is required even if your run plan does not include sample quantitation.
- The Quantitation Tube is not required if your run plan does not include sample quantitation.

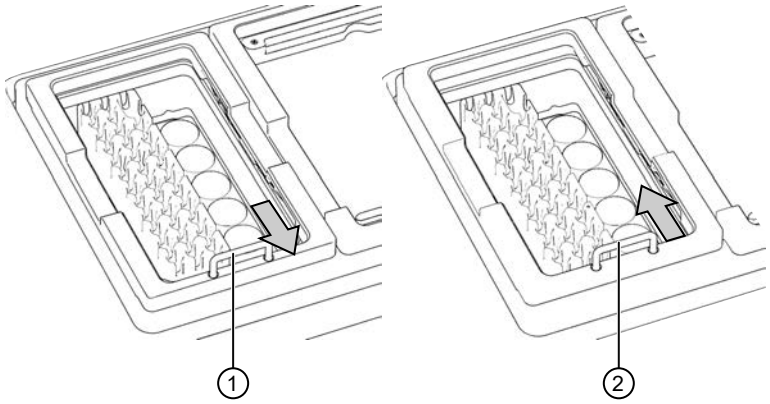
1. Centrifuge the Quantitation Plate at 1,000 × *g* for 30 seconds to collect the contents.
2. Load the Quantitation Plate in position 2.



① Quantitation Tube position
② Quantitation Plate position

   a. Pull the locking mechanism handle forward, then place the Quantitation Plate in the open position.

   b. Push the locking mechanism handle back to lock the plate in place.

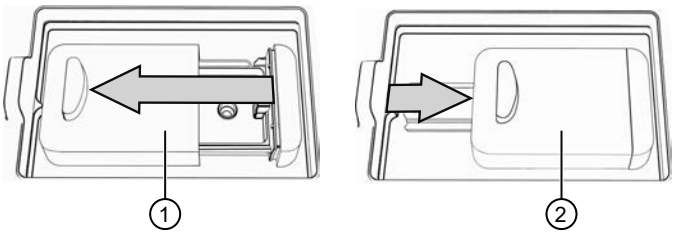


① Unlocked (forward)

② Locked (back)

3. *(If needed)* Slide and hold the quantitation module cover to the left, then insert the Quantitation Tube. **Press down firmly** to properly seat the tube, then allow the module cover to close.

WARNING! Do not force the module cover closed. Forcing the module cover closed can damage the instrument.



① Open ② Closed

Add 1X DNase digestion master mix to the Total RNA Purification Plate

The Total RNA Purification Plate contains magnetic beads in row C.

1. Vortex the DNase Buffer (blue cap) and DNase (yellow cap) supplied in the kit for ~5 seconds each, then pulse centrifuge to collect the contents.

2. In a 1.5-mL low-retention microcentrifuge tube, prepare a 1X DNase digestion master mix as indicated in the following table, where n is the number of samples:

Component	Volume per reaction[1]
DNase Buffer (blue cap)	(n + 1) × 98 µL
DNase (yellow cap)	(n + 1) × 2.0 µL
Total volume	**(n + 1) × 100 µL**

[1] Include a 5–10% overage to accommodate pipetting errors.

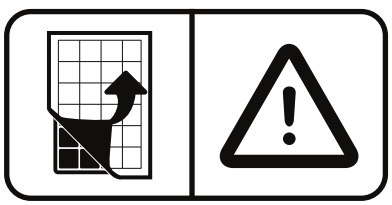
3. Vortex for ~5 seconds to mix, then briefly centrifuge to collect the contents.

4. Before use, centrifuge the plate at 1,000 x *g* for 30 seconds to collect the contents.
   Alternatively, gently tap the plate on the bench to force the reagents to the bottoms of the tubes.

IMPORTANT! Do not to create bubbles when preparing the plate.

5. Carefully remove the plate seal without disturbing the contents.

6. Pipet 100 µL 1X DNase Digestion Master Mix into each well used in Row G of the Total RNA Purification Plate.



Add samples to Total RNA Purification Plate

The Total RNA Purification Plate contains magnetic beads in row C.

1. Inspect the plate to ensure that the contents of all rows are at the bottom of the wells. If needed, gently flick or tap the plate on the bench to force the reagents to the bottoms of the tubes.

2. Add the samples to the Total RNA Purification Plate.

IMPORTANT!

- Do not change the order of pipetting.
- Add samples to consecutive wells beginning with sample 1 in well A1, through sample 12 in well A12. Do not skip wells.
- When all components are added, proceed immediately to the instrument for processing. There is no need for manual mixing beforehand.

Sample volume (X µL)[1]	Proteinase K (Y µL)[2]	100% isopropanol (Z µL)
Sample type—whole blood, fresh or frozen		
100	5	—
200	10	—
250	15	—
Sample type—fresh (recommended), or frozen bone marrow aspirates		
100	5	—
200	10	—
250	15	—
Sample type—peripheral blood leukocytes / buffy coat		
100	5	—
200	10	—
250	15	—
Sample type—PBMC, BMMC, cell lines		
275	20	—
Sample type—fresh frozen tissue		
50	5	75
100	10	175
200	20	275

[1] Sample volume after any required preprocessing.

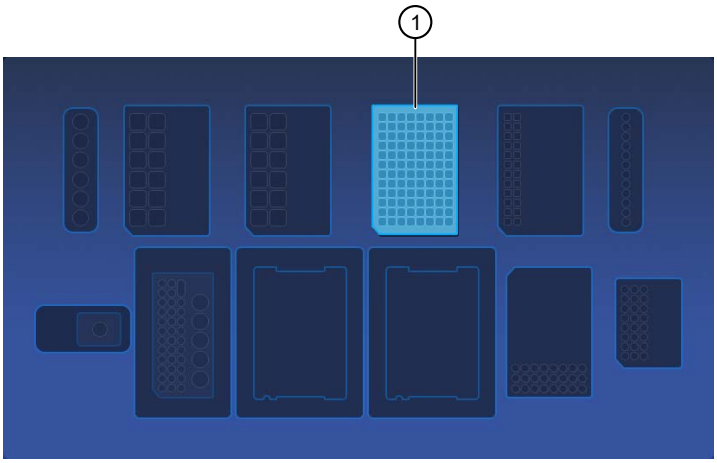
[2] Add the volume of Proteinase K equal to 10% of the preprocessed sample volume, except as indicated at maximum sample input volume.

a. Add X µL preprocessed sample to each well in Row A.

b. Add Y µL Proteinase K (red cap) to each well containing sample in Row A as indicated for the sample type.

c. Add Z µL 100% isopropanol to each well containing sample in Row A as indicated for the sample type.

3. Immediately load the 96 deep-well Total RNA Purification Plate with the samples in position 1.



① Total RNA Purification Plate position

Confirm that consumables are installed correctly

IMPORTANT! To ensure correct and safe instrument operation, confirm that all consumables are installed correctly on the deck before you start a run. The instrument vision system confirms that required reagents are in place, no reagents are expired, and foil seals are removed. The vision system does not verify all aspects of the consumable setup before beginning each run.

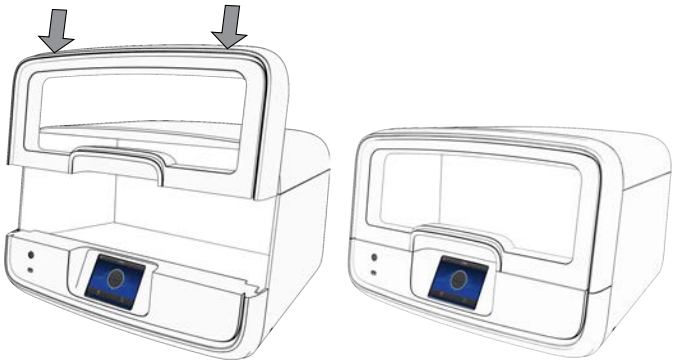
1. Confirm the following.
   - Foil seals are removed from the purification plates. Do not remove foil seal from the Quantitation Plate.
   - Each component is at the correct location and in the correct orientation. Press down on all plates and cartridges to ensure that they are firmly seated in place.
   - The Tip Comb is in place.
   - The Quantitation Plate is in the correct location, is in the correct orientation, and is locked in place.
   - *(If needed)* The Quantitation Tube is firmly seated in the quantitation module.
   - The Purification Tip Cartridge is in the correct location, in the correct orientation, and locked in place.

   If the vision system detects an error, the location indicator does not turn gray in the touchscreen.

2. If needed, tap **Help**, then accept each warning message appropriately to proceed.

Start the run

1. When all reagents and consumables are loaded in the Genexus™ Purification Instrument, tap **Next**.
2. Close the instrument door by pressing down on both top corners. Ensure that the door is locked after closing it.



The instrument vision system confirms that all reagents are in place and are not expired.

3. Tap **Start**.

   The time remaining until the purification is complete is displayed and the interior lighting turns green.

   - If you need to stop the run for any reason, tap **Cancel**, then tap **Yes** to confirm the cancellation.
   - The interior lighting turns off during quantitation, then turns blue when the run is complete.
   - If the instrument encounters a problem during the run, it aborts the run and displays the error on the instrument touchscreen. The interior lighting turns red.

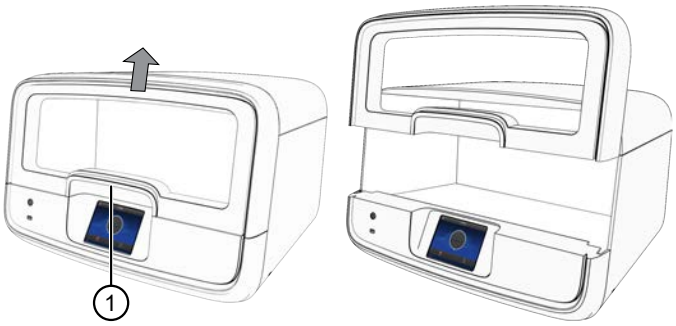
When the run is complete, the interior light turns blue, and the touchscreen displays **Run Complete**. Quantitation results are available immediately. For more information, see “View and export quantitation results” on page 149.

Unload purified RNA samples

IMPORTANT! Do not allow purified RNA to sit on the instrument. Store as directed or use in sequencing reactions within 60 minutes.

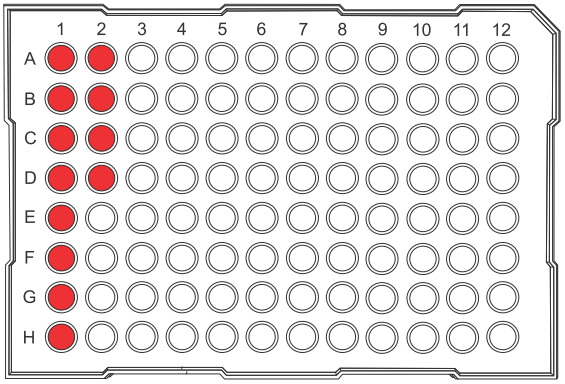
1. In the touchscreen, tap **Unload**.
   The door unlocks.

2. Lift the instrument door to access the instrument deck.



① Hold here, then lift.

3. *(**Sample to Result** run)* Remove the 96-Well Nucleic Acid Output Plate that contains the purified sample RNA that is ready for the addition of positive or nontemplate sample sequencing controls. Store on ice or at 4°C. If quantitation was performed, the sample concentration information is visible in the Genexus™ Software. Alternatively, determine sample concentrations manually if needed.

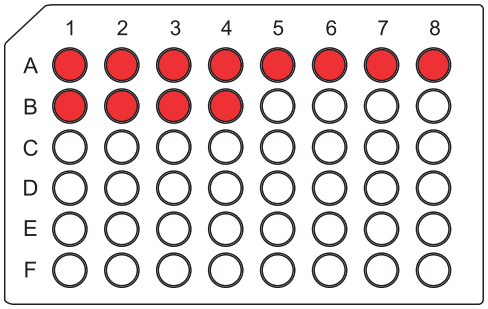


RNA

See the run set up guide for the actual sample positions. If running an assay that starts from both DNA and RNA (DNA & Fusions), the actual sample positions are optimized for convenient transfer of the RNA samples to the DNA sample input plate using a multichannel pipettor.

STOPPING POINT If not sequencing immediately, for example, while waiting for a second purification batch, seal the plate with an Adhesive PCR Plate Foil (Cat. No. AB0626), then store the plate at –20°C for up to 1 week. For long term storage (>1 week), transfer the samples to labeled low-retention tubes, then store the RNA samples at –90°C to –70°C for up to 36 months.

4. Remove the 48-Well Nucleic Acid Archive Plate that contains the purified sample RNA in wells A1–B4.



(Standalone configuration) If using the purified RNA immediately, transfer the sample to a sample input plate for sequencing. To determine the sample concentrations, see “View and export quantitation results” on page 149. See the relevant assay user guide for **Nucleic Acid to Result** guidance.

5. For short term storage, seal the plate with a 48-Well Nucleic Acid Archive Plate Seal. Store the plate at –20°C for up to 3 months. For long term storage (>3 months), transfer samples to labeled low-retention tubes, then store the RNA samples at –90°C to –70°C for up to 36 months.

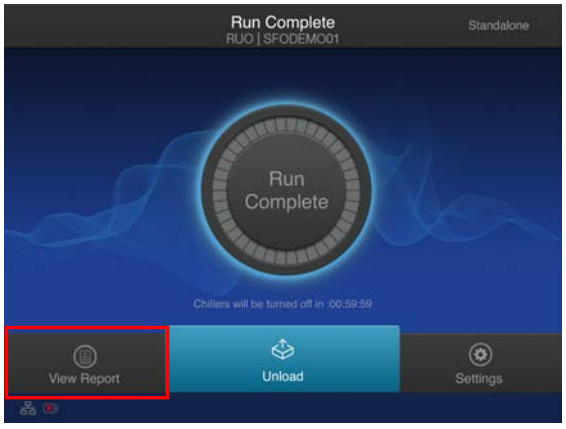
   If the archive plate is thawed during short term storage, transfer the RNA into labeled low-retention tubes. Do not reseal the archive plate with the used plate seal.

View and export quantitation results

Genexus™ Purification Instrument runs that include sample quantitation produce sample concentration results that can be accessed after the run is complete. When integrated with the Genexus™ Software, sample concentration information is automatically available in the software and used for **Sample to Result** runs.

In standalone configuration, results can be accessed from the **Run Complete** screen or the **Home** screen, then exported to a USB for transfer to the Genexus™ Software.

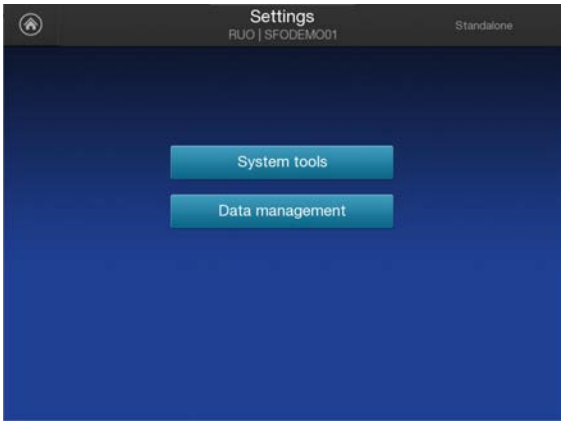
1. In the **Run Complete** screen, tap **View report**.



The **Saved Experiment Reports** screen opens. See step 4.

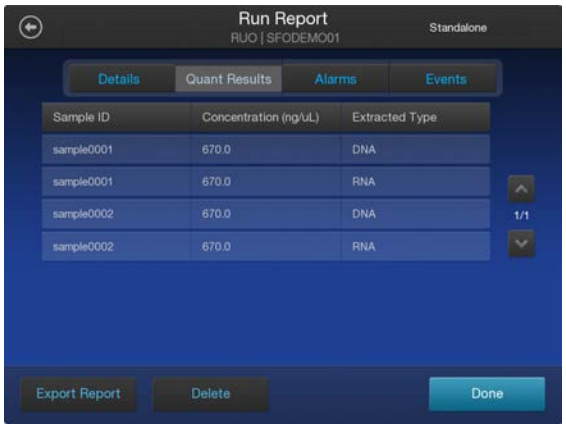
2. At any time after unloading and UV cleaning the instrument, sample concentration results can be accessed through the **Home** screen. Tap ⚙ (**Settings**).

3. In the **Settings** screen, tap **Data Management**.



4. In the **Saved Experiment Reports** screen, tap ⌄ or ⌃ to page through the list. Locate the **Experiment Name** of interest, tap in the row to select the experiment, then tap **View Report**.

5. In the **Run Report** screen, tap **Quant Results** to view the sample concentration results.



6. Insert a USB drive into the USB port on the front of the instrument, then tap **Export Report**. Navigate to the file destination, then tap **Save**.

   Sample concentration information is automatically transferred to the Genexus™ Software and used for Sample to Result runs.

Dispose of used consumables and UV clean the instrument

Unload purified RNA samples before disposal of used consumables.

IMPORTANT! Do not allow purified RNA to sit on the instrument. Store as directed or use in sequencing reactions within 60 minutes.

1. Remove and discard the deep-well sample input plates.
   a. Remove the Total RNA Purification Plate from the instrument.
   b. Dispose of the liquid waste by tipping the deep-well plate on one corner and pouring the waste into an appropriate liquid biohazardous waste container.

WARNING! Liquid waste contains guanidine thiocyanate, dispose of properly.

   c. Dispose of the deep-well plate in an appropriate waste container.
2. Unlock, then remove and dispose of the Purification Tip Cartridge in an appropriate waste container.

3. Unlock, then remove and dispose of the Quantitation Plate.
   a. Dispose of the liquid waste by tipping the deep-well plate on one corner and pouring the waste into an appropriate liquid biohazardous waste container.

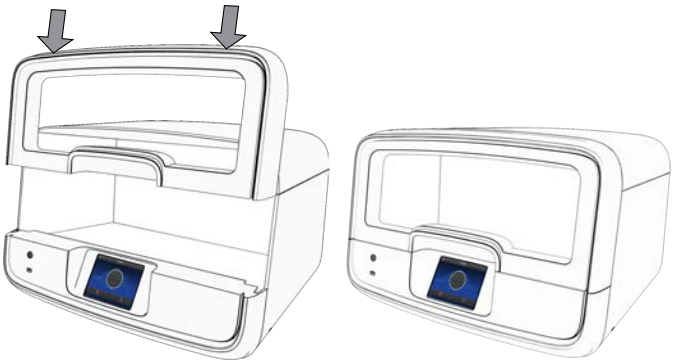
WARNING! No data are currently available that address the mutagenicity or toxicity of the Qubit™ RNA BR Reagent (Component A). This reagent is known to bind nucleic acid and is provided as a solution in DMSO. Treat the Qubit™ RNA BR Reagent with the same safety precautions as all other potential mutagens and dispose of the dye in accordance with local regulations.

   b. Dispose of the deep-well plate in an appropriate waste container.

4. Open the quantitation module cover, remove and discard the Quantitation Tube, then allow the module cover to gently close.

IMPORTANT! Do not allow the module cover to spring shut.

5. Close and lock the instrument door by pressing down on both top corners, then tap **Start UV Clean**.



The time remaining in the UV cleaning is displayed. When complete, the instrument is ready to start a new purification run.

Troubleshooting

General troubleshooting

Observation	Possible cause	Recommended action
Run Fails	Instrument detected an error or user aborted the run.	1. Record the error message displayed on the instrument touchscreen. 2. Export the Genexus™ Purification Instrument CSA file from the Run Report. 3. Remove the consumables from the deck, then clean the instrument. If possible, retain the consumables for troubleshooting. **Note:** Depending on the point during the purification run that the abort occurred, the consumables and reagents may not be suitable for reuse. 4. Restart the run beginning from "Prepare samples". If the run fails again, contact Technical Support to troubleshoot the problem.
Unexpected sample concentration (negative or greater than normal concentration values for multiple samples)	• Erroneous standard measurements were made. • Pipetting error occurred during liquid transfers. • Tip blockage occurred during liquid transfer. • Bubble in 48-Well Nucleic Acid Archive Plate sample well.	Manually quantify samples present in the 48-well archive plate (reference archive or output plate maps) according to the respective user guides. Use the Qubit™ dsDNA HS Assay Kit (Cat. No. Q32851) for FFPE DNA and cfTNA samples, and use the Qubit™ RNA BR Assay Kit (Cat. No. Q10210 or Q10211) for FFPE RNA and total RNA samples. Quantify multisample DNA samples using the Qubit™ dsDNA BR Assay Kit (Cat. No. Q32850 or Q32853).
Lower than expected DNA yield	Samples left on instrument for an extended period of time after run completion.	Unload the 96-Well Nucleic Acid Output Plate and 48-Well Nucleic Acid Archive Plate as soon as possible after the purification run is complete. The onboard plate chiller turns off after 60 minutes.

Observation	Possible cause	Recommended action
Low sample volume in some 48-Well Nucleic Acid Archive Plate wells	Pipetting error, elution buffer not centered in the well.	Reference archive plate maps and check the elution row in the 96-Well Nucleic Acid Output Plate. Recover any eluate left in the wells.
Magnetic beads in 48-Well Nucleic Acid Archive Plate	Carry over of magnetic beads.	This can lead to lower observed quantitation value but does not affect sequencing. No further action required.
		If excessive amount of beads are present, remove the beads by centrifugation or magnetic stand.

Genexus™ FFPE DNA and RNA Purification

Observation	Possible cause	Recommended action
Lower than expected yield	Protease digestion incubation temperatures were below 60°C and 90°C.	Use a calibrated thermometer to verify incubation oven temperature. Reset oven temperature, if needed.
		Ensure that incubators have reached target temperature before starting incubation.
		Increase the duration of incubation at 60°C by up to 1 hour.
	Restricted airflow limited the heat transfer to the sample tubes during incubation.	Incubate samples in a 4-way rack. Do not use a rack with a solid bottom.
	The volume of DNase or Proteinase K solution added was not correct.	Ensure that the correct volume of 1X DNA Digestion Master Mix, FFPE Protease Buffer, and Proteinase K solution is added.
	Lysate recovery from AutoLys M Tube was low.	Ensure that AutoLys M Tube caps are securely closed before incubation.
		Allow AutoLys M Tube to cool to room temperature before centrifugation.
	The start of the purification run was delayed after preparing the FFPE DNA and RNA Purification Plate 1.	Start the purification run within 5–10 minutes after addition of samples.
	The sample input amount was not correct or insufficient, or the amount of material in the sample was insufficient.	Use the recommended tissue input amount. See “Recommended input amount” on page 54.
	Sample quantitation was not correct.	Avoid prolonged exposure of the Quantitation Plate to light.
		Equilibrate the Quantitation Plate to room temperature for at least 30 minutes before starting the purification run.
		Ensure that reagents properly thaw.
		Avoid introducing bubbles into samples.
	Loss of sample occurred during preprocessing (deparaffinization).	Follow FFPE sample preparation with AutoLys M Tube protocol closely.

Observation	Possible cause	Recommended action
Unexpected sample concentration (negative or greater than normal concentration values for multiple samples) **Details:** FFPE purification run	No eluate present in the 48-well archive plate.	1. Check the FFPE DNA and RNA Purification Plate 1 row G for any remaining DNA eluate and FFPE DNA and RNA Purification Plate 2 row B for any remaining RNA eluate. Order of samples in the 96-well plate is similar to the sample order in the run plan. If eluate is present, transfer to the 48-well archive plate according to the plate map (reference archive plate maps for FFPE). 2. Manually quantify samples present in the 48-well archive plate (reference archive plate maps for FFPE DNA and RNA) according to the respective user guides. Use the Qubit™ dsDNA HS Assay Kit (Cat. No. Q32851) for FFPE DNA samples, and use the Qubit™ RNA BR Assay Kit (Cat. No. Q10210 or Q10211) for FFPE RNA samples.
Cloudy samples in some 48-Well Nucleic Acid Archive Plate and output plate wells	Deparaffinization was incomplete.	Follow FFPE sample preparation with AutoLys M Tube protocol closely. This does not affect sequencing.

Genexus™ Cell-Free Total Nucleic Acid Purification

Observation	Possible cause	Recommended action
Lower than expected yield	The sample contained low levels of cfTNA.	Increase the volume of plasma used.
	Plasma was not held on ice or at 4°C, or was subjected to repeated freeze-thaw cycles.	To maximize cfTNA recovery and downstream assay functionality, thaw plasma gently and hold on ice or at 4°C until use. Minimize freeze-thaw cycles.
	Incorrect volume of Proteinase K was added.	Ensure that the correct volume of Proteinase K is added in the correct order of addition.
	Incorrect volume of cfTNA Lysis/Binding Solution was added.	Visually inspect purification plates to ensure the correct volume of cfTNA Lysis/Binding Solution is added.
	Contamination with DNase or RNase occurred.	Use good laboratory technique. Wear personal protective equipment, change gloves regularly, use care when opening reagent vials and close after use. Regularly clean workspaces with 10% bleach solution or 70% isopropanol.

Observation	Possible cause	Recommended action
Lower than expected yield *(continued)*	Sample quantitation was incorrect.	Avoid prolonged exposure of the Quantitation Plate to light.
		Equilibrate the Quantitation Plate to room temperature for at least 30 minutes before starting the purification run.
		Ensure that reagents properly thaw.
		Avoid introducing bubbles into samples.
		Perform sample quantitation manually.
Unexpected sample concentration (negative or greater than normal concentration values for multiple samples) **Details:** cfTNA purification run	No eluate present in the 48-well archive plate.	1. Check the Cell-Free Total Nucleic Acid Purification Plate 3 row F for any remaining cfTNA eluate. Order of samples in the 96-well plate is similar to the sample order in the run plan. If eluate is present, transfer to the 48-well archive plate according to the plate map (reference archive plate maps for cfTNA). 2. Manually quantify samples present in the 48-well archive plate (reference archive plate maps for cfTNA according to the respective user guides). Use the Qubit™ dsDNA HS Assay Kit (Cat. No. Q32851) for cfTNA samples.
High level of gDNA in the eluate	Hemolytic plasma, lipemic plasma, or other compromised sample types were used.	Yields from these sample types vary greatly from donor to donor and often contain more gDNA. Recollect blood sample and centrifuge to collect cell-free plasma as early as possible. For more information, see “Prepare cell-free plasma from whole blood samples” on page 81.

Genexus™ Multisample DNA Purification

Observation	Possible cause	Recommended action
Lower than expected DNA yield	Incorrect volume of DNA Enhancer Solution or Proteinase K solution was added.	Ensure that the correct volume of DNA Enhancer Solution and Proteinase K solution is added to the given volume of sample. See Table 4.
		Add DNA Enhancer Solution and Proteinase K solution to the sample in the correct order.
	Delay in starting the purification run after preparing the Multisample DNA Purification Plate.	Start the purification run within 5–10 minutes after addition of Proteinase K solution.
	Sample quality was low.	Use fresh samples, if possible.
		Do not freeze samples.
	Sample processing was incorrect.	Process samples at 4°C. Keep on ice or at 4°C. Avoid repeated freeze-thaw cycles.
		Buffy coat—Maintain correct blood to buffy coat ratio. See, "Prepare peripheral blood leukocytes (PBL/buffy coat) samples" on page 110.
		Bone marrow—Centrifuge at 200 x *g* for 10 minutes at room temperature. Do not remove the loosely pelleted cells when removing the fatty layer and unpelleted debris. See, "Prepare bone marrow aspirate samples" on page 109.
		Bone marrow—Ensure complete removal of the fatty layer and unpelleted debris. Leave a small amount of supernatant behind to ensure that you do not disturb the cell pellet. See page 109.
		Tissue—Maintain correct tissue sample to DNA Homogenization Buffer ratio. See, "Prepare tissue samples" on page 109.
	Contamination with DNase occurred.	Use good laboratory technique. Wear personal protective equipment, change gloves regularly, use care when opening reagent vials and close after use. Regularly clean workspaces with 10% bleach solution or 70% isopropanol.
	Sample quantitation was incorrect.	Avoid prolonged exposure of the Quantitation Plate to light.
		Equilibrate the Quantitation Plate to room temperature for at least 30 minutes before starting the purification run.
		Ensure that reagents properly thaw.
		Avoid introducing bubbles into samples.
		Perform sample quantitation manually.

Observation	Possible cause	Recommended action
Unexpected sample concentration (negative or greater than normal concentration values for multiple samples) **Details:** Multisample DNA purification run	No eluate present in the 48-well archive plate.	1. Check the Multisample DNA Purification Plate row B for any remaining multisample DNA eluate. Order of samples in the 96-well plate is similar to the sample order in the run plan. If eluate is present, transfer to the 48-well archive plate according to the plate map (reference archive plate maps for Multisample DNA according to the respective user guides). 2. Manually quantify samples present in the 48-well archive plate. Quantify multisample DNA samples using the Qubit™ dsDNA BR Assay Kit (Cat. No. Q32850 or Q32853).

Genexus™ Total RNA Purification

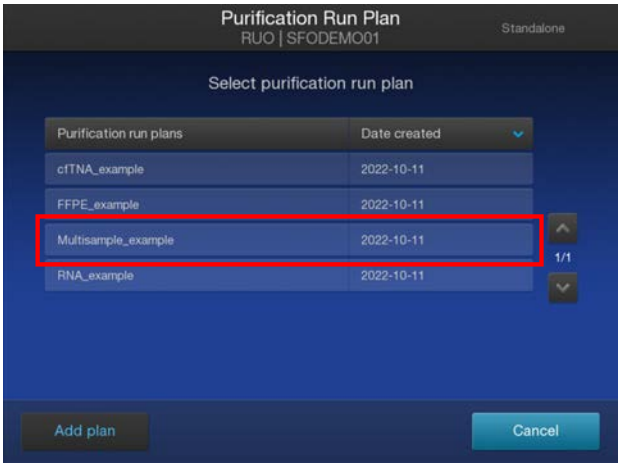
Observation	Possible cause	Recommended action
Lower than expected RNA yield	Incorrect volume of Proteinase K, PK Digestion Buffer or isopropanol was added.	Ensure that the correct volume of Proteinase K, PK Digestion Buffer, and isopropanol is added to the given volume of sample. See page 53.
		Add Proteinase K and isopropanol to the sample in the correct order of addition.
	Delay in starting the purification run after preparing the Total RNA Purification Plate.	Start the purification run within 5–10 minutes after addition of Proteinase K solution.
	Sample quality was low.	Use fresh samples, if possible.
		Do not freeze samples.
	Sample processing was incorrect.	Process samples at 4°C. Keep on ice or at 4°C. Avoid repeated freeze-thaw cycles.
		Buffy coat—Maintain correct blood to buffy coat ratio. See, “Prepare peripheral blood leukocytes (PBL/buffy coat) samples” on page 135.
		Tissue—Maintain correct tissue sample to RNA Homogenization Buffer ratio. See, “Prepare tissue samples” on page 137.
	Contamination with DNase occurred.	Use good laboratory technique. Wear personal protective equipment, change gloves regularly, use care when opening reagent vials and close after use. Regularly clean workspaces with 10% bleach solution or 70% isopropanol.

Observation	Possible cause	Recommended action
Lower than expected RNA yield *(continued)*	Sample quantitation was incorrect.	Avoid prolonged exposure of the Quantitation Plate to light.
		Equilibrate the Quantitation Plate to room temperature for at least 30 minutes before starting the purification run.
		Ensure that reagents properly thaw.
		Avoid introducing bubbles into samples.
		Perform sample quantitation manually.
Unexpected sample concentration (negative or greater than normal concentration values for multiple samples) **Details:** Total RNA purification run	No eluate present in the 48-well archive plate.	1. Check the Total RNA Purification Plate row B for any remaining total RNA eluate. Order of samples in the 96-well plate is similar to the sample order in the run plan. If eluate is present, transfer to the 48-well archive plate according to the plate map (reference archive plate maps for total RNA according to the respective user guides). 2. Manually quantify samples present in the 48-well archive plate. Use the Qubit™ RNA BR Assay Kit (Cat. No. Q10210 or Q10211) for total RNA samples.

B Supplemental information

Delete a run plan (standalone configuration)

1. Tap **Run**, then tap the plan to be deleted.



2. In the **Purification Run Plan Details** screen, tap **Edit**, then tap **Delete**.
3. Tap **Delete** to confirm deletion of the selected purification run plan.

Note: Deletion of a purification run plan is irreversible and cannot be undone.

Create a template for importing samples in standalone configuration purification run plans

To use the **Import** function to import sample information from a USB drive into a standalone configuration run plan for the Genexus™ Purification Instrument, add the sample information to a CSV

file with a specific format. Follow these steps to create an import template file with a plain text editor, or with Microsoft™ Excel™ software.

1. Use the format in the follow examples to set up two columns in a CSV file for **Sample Name** and **Notes**. Populate the sample rows with sample name and notes.

```
1   Sample Name,Notes
2   CSV Sample 1,CSV notes for sample 1
3   CSV Sample 2,CSV notes for sample 2
4   CSV Sample 3,CSV notes for sample 3
5   CSV Sample 4,CSV notes for sample 4
6   CSV Sample 5,CSV notes for sample 5
7   CSV Sample 6,CSV notes for sample 6
8   CSV Sample 7,CSV notes for sample 7
9   CSV Sample 8,CSV notes for sample 8
10  CSV Sample 9,CSV notes for sample 9
11  CSV Sample 10,CSV notes for sample 10
12  CSV Sample 11,CSV notes for sample 11
13  CSV Sample 12,CSV notes for sample 12
```

	A	B
1	Sample Name	Notes
2	CSV Sample 1	CSV notes for sample 1
3	CSV Sample 2	CSV notes for sample 2
4	CSV Sample 3	CSV notes for sample 3
5	CSV Sample 4	CSV notes for sample 4
6	CSV Sample 5	CSV notes for sample 5
7	CSV Sample 6	CSV notes for sample 6
8	CSV Sample 7	CSV notes for sample 7
9	CSV Sample 8	CSV notes for sample 8
10	CSV Sample 9	CSV notes for sample 9
11	CSV Sample 10	CSV notes for sample 10
12	CSV Sample 11	CSV notes for sample 11
13	CSV Sample 12	CSV notes for sample 12

① Example file if in a plain text editor.

② Example file in Microsoft™ Excel™ software.

The **Sample Name** field populates the **Sample ID** field in the instrument screen.

2. Save the file using a CSV file format to a USB drive.

IMPORTANT!

- Do not add extra spaces in the headings, or add other columns in either file type.
- If you transfer files between macOS™ and Windows™ computers, extra characters that can cause errors can be added to files. Check for the presence of extra characters, then delete if found.
- An alert is shown if fewer samples are in the CSV file than are selected for the run, or if two samples have the same name in the CSV file. No samples are imported until the error is corrected.

Preprocess FFPE curl samples with CitriSolv™ Clearing Agent or equivalent (xylene)

Use AutoLys M Tubes to prepare FFPE samples.

Before you begin

- Preheat heat blocks, water baths, or incubators to 50°C, 55°C and 90°C.
- Prepare Protease Digestion and DNase Digestion solutions immediately before use.

Remove paraffin from the sections

Preheat a heating block (with lid) or incubator to 50°C.

1. Label a nuclease-free 1.5-mL low-retention microcentrifuge tube for each FFPE tissue sample.
   Label each tube (cap and side) with its Sample ID using a marker that is resistant to CitriSolv™ Clearing Agent (or xylene) and ethanol.
2. Add each FFPE section curl to a labeled tube.
3. Add 1 mL of CitriSolv™ Clearing Agent, or equivalent (for example, xylene) to the section, then vortex briefly.
4. Centrifuge briefly to ensure that all the tissue is submerged in the solvent.
5. Heat the sample for 3 minutes (or until the tissue clears) at 50°C to melt the paraffin.
6. Centrifuge the sample for 2 minutes at 16,000 x *g* to collect the tissue.
   - If the sample does not form a tight pellet, centrifuge again for 2 minutes.
   - If a tight pellet still does not form, proceed with caution to the next step.
7. Remove the solvent and dispose of appropriately.
   - The tissue is usually clear and can be difficult to see.
   - If the pellet is loose, leave 50–100 µL of solvent in the tube to avoid removing any tissue pieces.

   See “Chemical safety” on page 189.

Wash section curls with ethanol

1. Add 1 mL of 100% ethanol to the tissue pellet and vortex.
   The tissue may turn opaque.
2. Centrifuge the sample at maximum speed for 2 minutes.
3. Remove and discard as much ethanol as possible without disturbing the pellet.

4. Repeat step 1 through step 3 to ensure complete solvent removal.

   IMPORTANT! Omit the second wash when working with small samples to avoid sample loss.

5. Dry the pellet using one of the following methods:

   - Use a centrifugal vacuum concentrator.

Temperature	Time
40–45°C (medium heat)	<20 minutes
37–40°C (low heat)	20–40 minutes

   - Air dry at room temperature for 15–45 minutes.

STOPPING POINT *(Optional)* The dried samples can be stored at room temperature up to 72 hours.

Prepare 1X Protease Digestion Master Mix

Prepare the 1X Protease Digestion Master Mix immediately before use.

1. Vortex the FFPE Protease Buffer and Proteinase K supplied in the kit for ~5 seconds each, then briefly centrifuge to collect the contents

2. In a 1.5-mL low-retention microcentrifuge tube, prepare a 1X Protease Digestion Master Mix as indicated, where `n` is the number of tissue samples.

Component	Volume per reaction
FFPE Protease Buffer	(n + 1) × 200 µL
Proteinase K (red cap)	(n + 1) × 10 µL
Total volume	**(n + 1) × 210 µL**

3. Vortex for ~5 seconds to mix, then briefly centrifuge to collect the contents.

Digest with protease

To minimize the amount of time between protease digestion and starting the purification run on the instrument, prepare the reagents and consumables that are required by the instrument during the 90°C incubation (step 4).

1. Pipet 210 µL 1X Protease Digestion Master Mix to each labelled tube.

2. Gently flick the tube to mix and to immerse the tissue.

   If the tissue sticks to the sides of the tube, use a pipette tip to push the tissue into the solution or centrifuge briefly to immerse the tissue in the solution.

3. Incubate at 55°C for 60 minutes, then centrifuge briefly to collect any condensation droplets.

   If you are using an incubator, use a 4-way microtube rack to allow homogeneous incubation of the samples.

   Incubation at 55°C can be extended overnight to increase DNA yields.

4. Incubate at 90°C for 60 minutes.

   Ensure that tubes are tightly capped. Tube caps can pop open during the incubation.

   Set up the processing plates during the incubation.

5. Allow samples to cool to room temperature, then centrifuge briefly to collect any condensation droplets.

STOPPING POINT If needed, samples can be stored overnight at –30°C to –10°C.

Proceed to "Add samples to FFPE DNA and RNA Purification Plate 1" on page 61.

Preprocess FFPE slide samples with CitriSolv™ Clearing Agent or equivalent (xylene)

Use AutoLys M Tubes to prepare FFPE samples.

Remove paraffin from the sections

1. Submerge the slides in CitriSolv™ Clearing Agent, or equivalent (for example, xylene), for 5 minutes.
2. Remove the slides, then drain the excess solvent by tilting the slide holder.
3. Submerge the slides in 100% ethanol for 5 minutes.
4. Remove the slides, then drain the excess ethanol by tilting the slide holder.
5. Air dry the slides for 15 minutes.

Prepare 1X Protease Digestion Master Mix

Prepare the 1X Protease Digestion Master Mix immediately before use.

1. Invert the FFPE Protease Buffer and Proteinase K tubes supplied in the kit 5X each, then briefly centrifuge.
2. In a 1.5-mL low-retention microcentrifuge tube, prepare a 1X Protease Digestion Master Mix as indicated, where `n` is the number of tissue samples.

Component	Volume per reaction
FFPE Protease Buffer	(n + 1) × 225 µL
Proteinase K (red cap)	(n + 1) × 10 µL
Total volume	**(n + 1) × 235 µL**

3. Vortex for ~5 seconds to mix, then briefly centrifuge to collect the contents.

Collect the tissue

1. Label a nuclease-free 1.5-mL low-retention microcentrifuge tube for each FFPE tissue sample.

   Label each tube (cap and side) with its Sample ID using a marker that is resistant to CitriSolv™ Clearing Agent (or xylene) and ethanol.

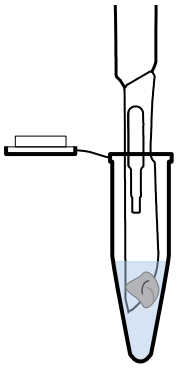
2. Pipet 210 µL 1X Protease Digestion Master Mix to each labelled tube.

3. Pipet 2–4 µL of 1X Protease Digestion Master Mix from the labeled tube evenly across the fixed tissue section on the slide to prewet the tissue section.

   Larger sections may need an additional 2–4 µL of 1X Protease Digestion Master Mix.

4. Use a sterile disposable scalpel or clean razor blade to scrape the tissue in a single direction, then collect the tissue into a cohesive mass on the tip of the scalpel blade.

5. Carefully insert the scalpel blade with the tissue mass into the 1X Protease Digestion Master Mix in the 1.5-mL low-retention microcentrifuge tube. Rinse the tissue from the blade into the buffer, then ensure that the entire mass is in solution.



6. Remove and inspect the blade to ensure that no tissue remains on it.

7. Inspect the slide to ensure that all the tissue is removed. The slide should be translucent. Discard the scalpel in a waste container for sharp objects.

8. Gently flick the tube to mix and to immerse the tissue.

   If the tissue sticks to the sides of the tube, use a pipette tip to push the tissue into the solution or centrifuge briefly to immerse the tissue in the solution.

Digest with protease

To minimize the amount of time between protease digestion and starting the purification run on the instrument, prepare the reagents and consumables that are required by the instrument during the 90°C incubation (step 2).

1. Incubate at 55°C for 60 minutes, then centrifuge briefly to collect any condensation droplets.

   If you are using an incubator, use a 4-way microtube rack to allow homogeneous incubation of the samples.

   Incubation at 55°C can be extended overnight to increase DNA yields.

2. Incubate at 90°C for 60 minutes.

   Ensure that tubes are tightly capped. Tube caps can pop open during the incubation.

Set up the processing plates during the incubation.

3. Allow samples to cool to room temperature, then centrifuge briefly to collect any condensation droplets.

STOPPING POINT If needed, samples can be stored overnight at –30°C to –10°C.

Proceed to "Add samples to FFPE DNA and RNA Purification Plate 1" on page 61.

Clean and decontaminate the Genexus™ Purification Instrument

Decontamination protocol

Perform the decontamination protocol if accidental spills or leaks of samples or reagents occur during a run.

The Genexus™ Purification Instrument includes an automated UV cleaning function that must be performed after every run. The cleaning routine is initiated from the instrument touchscreen and is designed to minimize potential contamination. After all consumables are removed from the instrument, the cleaning routine irradiates the deck with ultraviolet light for 2 minutes.

IMPORTANT! Although the Genexus™ Purification Instrument cleaning routine provides some protection against contamination, it is not a substitute for good laboratory techniques or precautions. When preparing samples for use or when preparing the instrument, ensure that you always observe sterile laboratory procedures to ensure minimal contamination.

Materials required

- Laboratory coat
- Gloves, powder-free nitrile
- Protective safety glasses
- Deionized water
- Isopropanol, 70% solution
- Wipes, lint-free

Decontaminate the Genexus™ Purification Instrument

WARNING! The samples can be potentially infectious. Dispose of all potentially contaminated consumables and wipes as biohazardous waste according to your local regulations.

The decontamination procedure must be completed before any instrument service is performed or before relocation of the instrument.

In the following scenarios, begin the decontamination procedure at the indicated step.

- Sample or reagent spill occurred while loading the instrument. The instrument door is open, begin from step 1.
- Sample or reagent spill occurred while unloading the instrument. The instrument door is open, begin from substep 2a or the next consumable that needs to be removed.
- Decontamination in preparation for instrument service (no spill). Begin from step 6.

1. In the **Home** screen, tap **Cancel** ▸ **OK**.

2. Remove and discard reagent plates and all consumables from the instrument deck.

   IMPORTANT! If needed, a UV cleaning can be performed before removing and discarding reagent plates and consumables. For more information, see step 7.

   a. Remove the purification plate, pour the liquid waste into an appropriate liquid biohazardous waste container by tipping the deep-well plate on one corner, then discard the empty plate in a solid biohazardous waste container.

   WARNING!
   - Liquid waste contains guanidine thiocyanate. Dispose of liquid waste properly.
   - The samples can be potentially infectious. Dispose of all potentially contaminated consumables and wipes as biohazardous waste.

   b. Unlock, then remove and dispose of the Purification Tip Cartridges in an appropriate biohazardous waste container.

   c. Unlock, remove, and empty the Quantitation Plate by tipping the deep-well plate on one corner and pouring the waste into an appropriate liquid biohazardous waste container. Discard the empty plate in a solid biohazardous waste container.

   WARNING! No data are currently available that address the mutagenicity or toxicity of the Qubit™ RNA BR Reagent (Component A). This reagent is known to bind nucleic acid and is provided as a solution in DMSO. Treat the Qubit™ RNA BR Reagent with the same safety precautions as all other potential mutagens, and dispose of the dye in accordance with local regulations.

   d. Open the quantitation module cover, remove and discard the Quantitation Tube, then allow the module cover to gently close.

e. Remove, then dispose of the combs, output and archive plates into an appropriate solid biohazardous waste container.

3. Use lint-free wipes to soak up as much liquid as possible, then dispose of all liquid and solid waste in the appropriate biohazardous waste containers.

4. Spray the affected area with 10% bleach solution, allow to stand for 5 minutes, then wipe surfaces with a clean wipe to soak up residual bleach solution.

5. Wipe the affected surfaces with wipes moistened with deionized water.

6. Wipe the affected surfaces with wipes moistened with 70% isopropanol. Wipe surfaces with a clean wipe, then allow to air-dry.

7. Close the instrument door, then perform a UV cleaning.
   a. Close the instrument door.
   b. In the **Home** screen, tap **Settings** ▸ **System Tools** ▸ **UV clean**.
   c. Tap **Yes**.
   d. When the UV cleaning routine is complete, tap **Open**.

   The instrument is now ready to perform a new purification run.

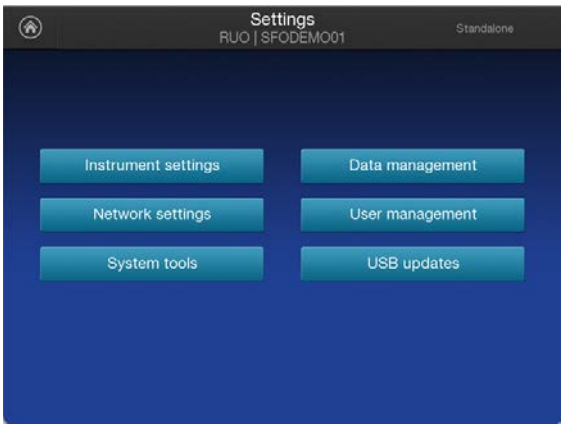
C Touchscreen reference

Touchscreen icons

Number	Icon	Description
1		User profile
2		USB – available
		USB – not available
3		Network connectivity – connected
		Network connectivity – not connected

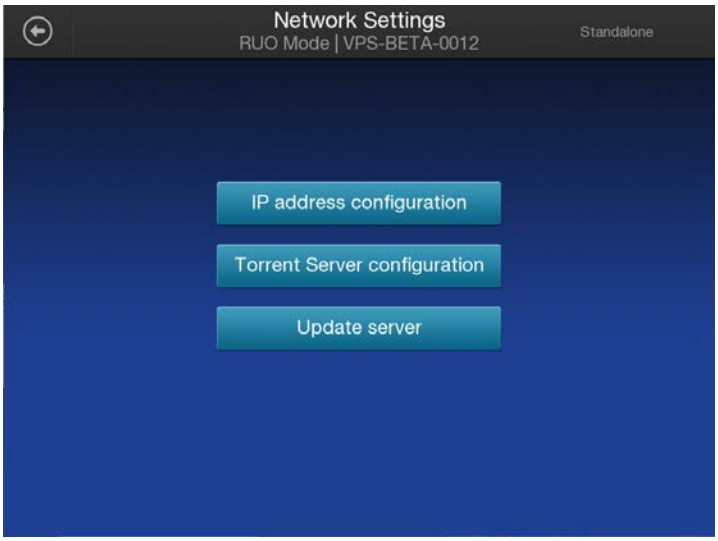
Settings

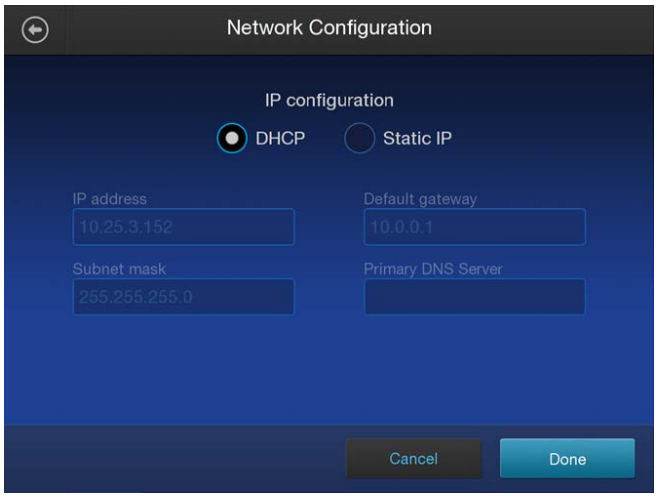
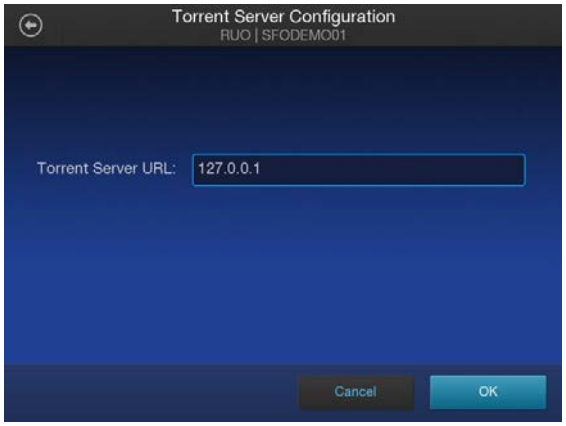
Use the **Settings** menu to view and change instrument settings, and to manage data.



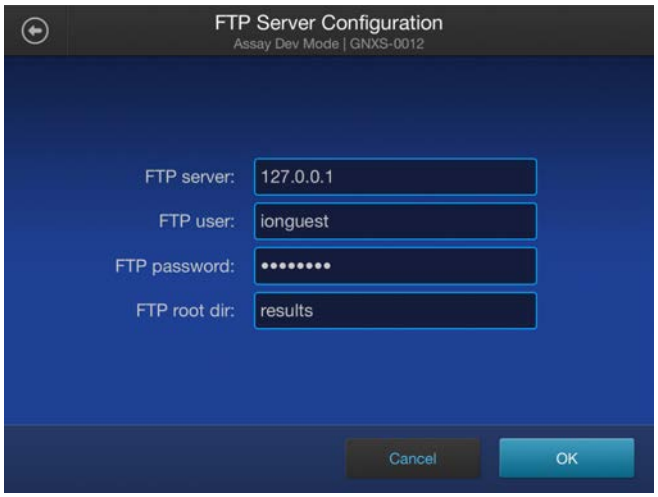
Network Settings

Use the **Network Settings** menu to configure IP address, Ion Torrent™ Server, and FTP settings.



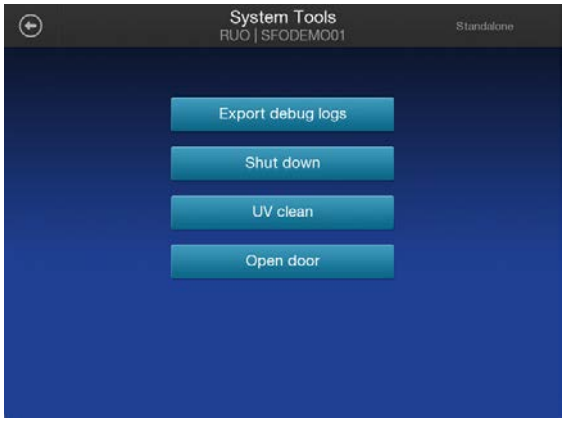
Item	Description	When and how to use
IP Address Configuration	Use this screen to set or change the IP configuration (DHCP or Static IP). 	1. Select either the **DHCP** or **Static IP** option. 2. Touch the screen in the field that you want to edit to activate the field. A virtual keyboard appears. 3. Enter the new information, then press **Done**.
Ion Torrent™ Server Configuration	Use this screen to change the Ion Torrent™ Server IP address and user information.  Enter the following IP address in the **Torrent Server URL** field for your instrument: 127.0.0.1	Use when a change to the Ion Torrent™ Server IP address or user information is needed. Do not change address unless directed to do so by a Thermo Fisher Scientific field service engineer.

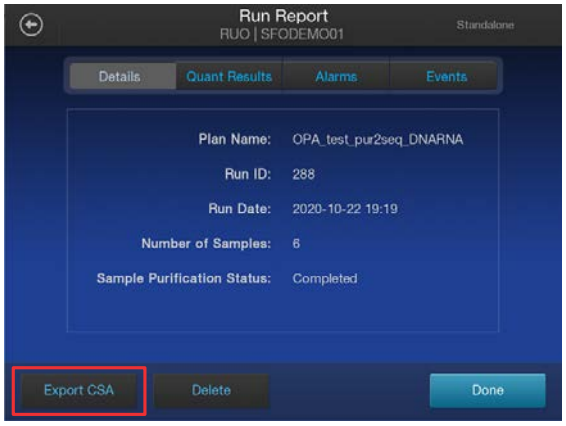
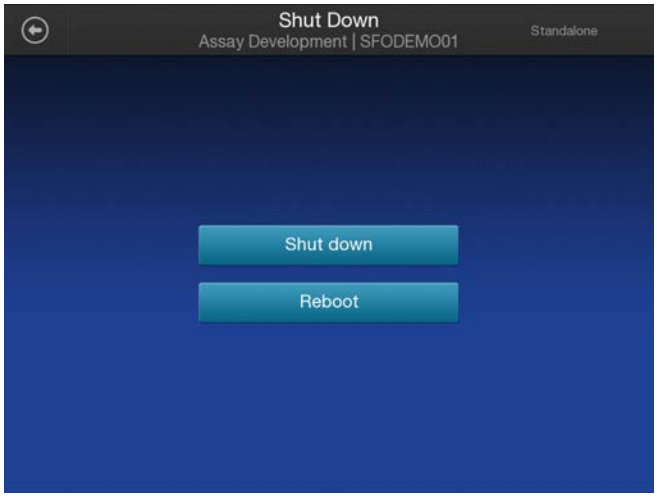
(continued)

Item	Description	When and how to use
FTP Server Configuration	Use this screen to change the FTP Server IP address and user information.  Enter the following IP address in the **FTP server** field for your instrument: 127.0.0.1	Use when a change to the FTP Server IP address or user information is needed. Do not change address unless directed to do so by a Thermo Fisher Scientific field service engineer.

System Tools

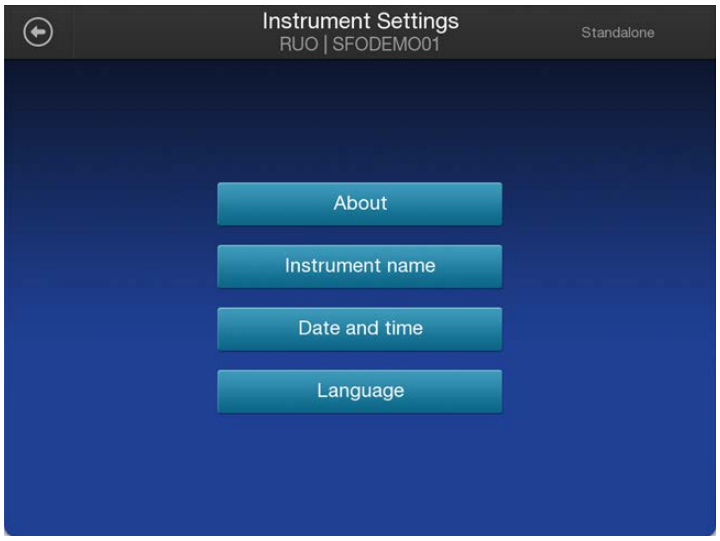
Use the **System Tools** menu to upload instrument diagnostics, manage data, and shut down or reboot the instrument.



Item	Description	When and how to use
Export debug logs	Provides instrument error configuration information. 	Use for troubleshooting if directed to do so by Technical Support. 1. Tap ⚙ **(Settings)** ▸ **Data management**, then tap in the row of the **Experiment Name** of interest. 2. In the **Run Report** screen, tap **Details** ▸ **Export CSA**. 3. Insert a USB drive into the USB port on the front of the instrument. Navigate to the file destination, then tap **Save**.
Shut down	Provides access to **Shut down** and **Reboot** commands. 	Use if directed to do so by Technical Support as part of a troubleshooting procedure, or if the instrument will not be used for more than 3 days. It is not necessary or recommended to shut down the instrument overnight or over the weekend. To power on the instrument after a shut down, see “Power on” on page 29.
UV clean	Performs a UV cleaning of the instrument deck.	If a reagent or sample spills on the instrument deck, use to clean the instrument deck. See “Clean and decontaminate the Genexus™ Purification Instrument” on page 167.
Open door	Unlocks and opens the instrument door.	If a run is aborted, use to open the instrument door to remove consumables in preparation for a subsequent run.

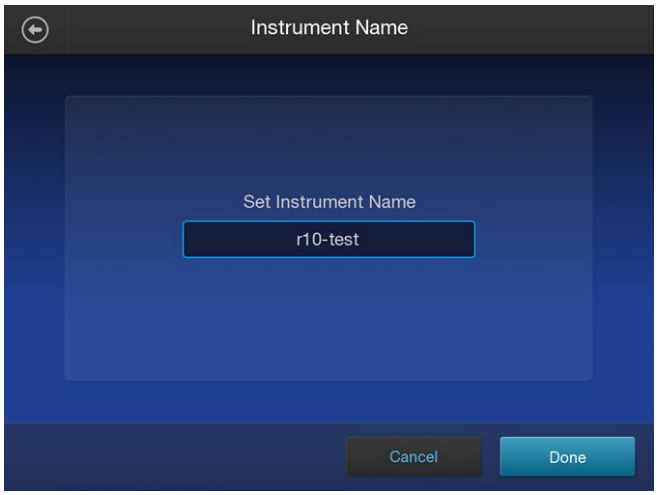
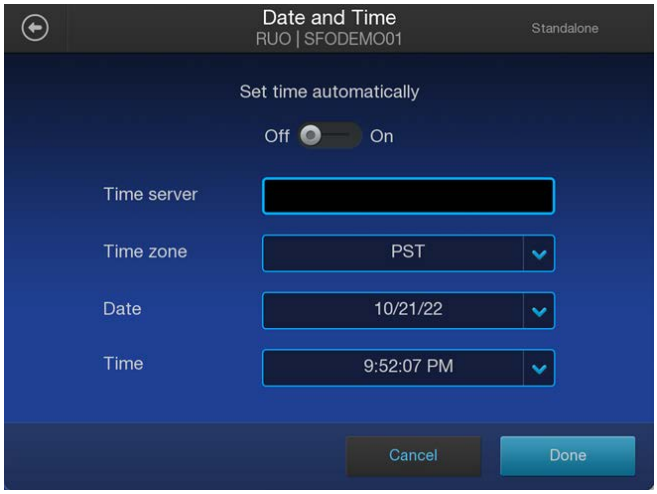
Instrument settings

Use the **Instrument Settings** menu to obtain about the instrument and to set the instrument name and calibrate the touchscreen.

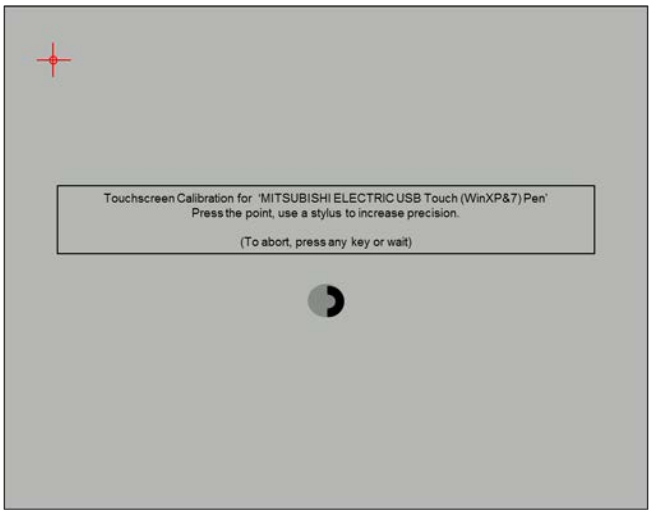


Item	Description	When and how to use
About	Provides instrument details. 	Use to view instrument reference information.

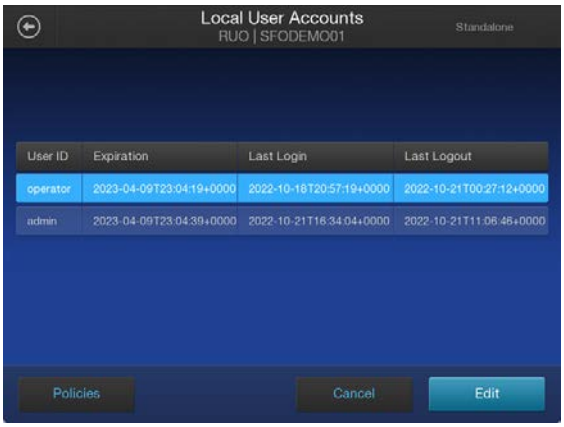
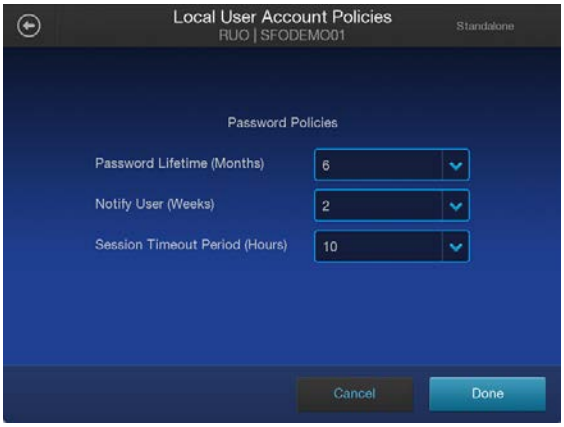
(continued)

Item	Description	When and how to use
Instrument Name		Use to change the instrument name.
Date and time		Enter the desired **Time zone**, **Date**, and **Time** to manually set the date and time. Alternatively, select **Set time automatically** to **On**, and enter and **Time server** address to reference.
Language	Lists available user interface languages. 	Tap to select a language, then tap (Back) to return to the **Instrument Settings** screen.

(continued)

Item	Description	When and how to use
Screen Calibration		Use for troubleshooting if directed to do so by Technical Support. Tap the red cross with your finger or a stylus each time it appears. In total, you tap the screen 4 times, once in each corner.

User management

Item	Description	When and how to use
User Accounts		Account Administrators use to create or edit user accounts and reset account passwords.
Policies		**Password Lifetime**—Set the number of months until a user password expires. **Notify User**—Set the number of weeks before a user account password expires that the user recieves a notification to reset their password. **Session Timeout Period**—Set the number of hours before a session times out and a user must login to their user account again.

D

Safety

WARNING! GENERAL SAFETY. Using this product in a manner not specified in the user documentation may result in personal injury or damage to the instrument or device. Ensure that anyone using this product has received instructions in general safety practices for laboratories and the safety information provided in this document.

- Before using an instrument or device, read and understand the safety information provided in the user documentation provided by the manufacturer of the instrument or device.
- Before handling chemicals, read and understand all applicable Safety Data Sheets (SDSs) and use appropriate personal protective equipment (gloves, gowns, eye protection, and so on). To obtain SDSs, visit **thermofisher.com/support**.

Symbols on this instrument

Symbols may be found on the instrument to warn against potential hazards or convey important safety information. In this document, the hazard symbol is used along with one of the following user attention words.

- **CAUTION!**—Indicates a potentially hazardous situation that, if not avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practices.
- **WARNING!**—Indicates a potentially hazardous situation that, if not avoided, could result in death or serious injury.
- **DANGER!**—Indicates an imminently hazardous situation that, if not avoided, will result in death or serious injury.

Standard safety symbols

Symbol and description
CAUTION! Risk of danger. Consult the manual for further safety information.
CAUTION! Risk of electrical shock.

(continued)

Symbol and description
 **CAUTION!** Hot surface.
 **CAUTION!** Potential biohazard.
 **CAUTION!** Ultraviolet light.

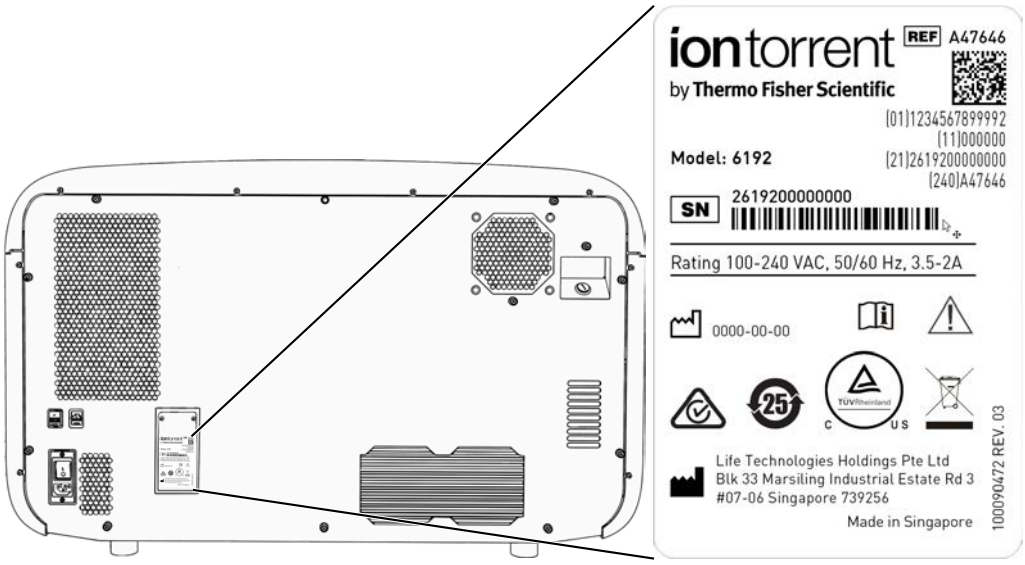
Symbole et description
 **MISE EN GARDE !** Risque de danger. Consulter le manuel pour d'autres renseignements de sécurité.
 **MISE EN GARDE !** Risque de choc électrique.
 **MISE EN GARDE !** Surface chaude.
 **MISE EN GARDE !** Danger biologique potentiel.
 **MISE EN GARDE !** Rayonnement ultraviolet.

Additional safety symbols

Symbol and description
 **CAUTION!** Moving parts.
 **CAUTION!** Piercing hazard.

Symbole et description
 **MISE EN GARDE !** Parties mobiles.
 **MISE EN GARDE !** Danger de perforation.

Location of safety labels

Label and location
 Rear panel

Control and connection symbols

Symbol	Description
	On (Power)
	Off (Power)
	Protective conductor terminal (main ground)
	Alternating current

Conformity symbols

Conformity mark	Description
	Indicates conformity with safety requirements for Canada and U.S.A.
	Indicates conformity with China RoHS requirements.
	Indicates conformity with Australian standards for electromagnetic compatibility.

(continued)

Conformity mark	Description
	Indicates conformity with the WEEE Directive 2012/19/EU. **CAUTION!** To minimize negative environmental impact from disposal of electronic waste, do not dispose of electronic waste in unsorted municipal waste. Follow local municipal waste ordinances for proper disposal provision and contact customer service for information about responsible disposal options.

Instrument safety

General

CAUTION! Do not remove instrument protective covers. If you remove the protective instrument panels or disable interlock devices, you may be exposed to serious hazards including, but not limited to, severe electrical shock, laser exposure, crushing, or chemical exposure.

Physical injury

CAUTION! Moving and Lifting Injury. The instrument is to be moved and positioned only by the personnel or vendor specified in the applicable site preparation guide. Improper lifting can cause painful and permanent back injury.

Things to consider before lifting or moving the instrument or accessories:

- Depending on the weight, moving or lifting may require 2 or more persons.
- If you decide to lift or move the instrument after it is installed, do not attempt to do so without the assistance of others, the use of appropriate moving equipment, and proper lifting techniques.
- Ensure that the path from where the object is to where it is being moved is clear of obstructions.
- Participants should coordinate lift and move intentions with each other before lifting and carrying.

CAUTION! Moving Parts—Moving parts can crush, pinch and cut. Keep hands clear of moving parts while operating the instrument. Disconnect power before servicing.

Electrical safety

WARNING! Ensure appropriate electrical supply. For safe operation of the instrument:

- Plug the system into a properly grounded receptacle with adequate current capacity.
- Ensure that the electrical supply is of suitable voltage.
- Never operate the instrument with the ground disconnected. Grounding continuity is required for safe operation of the instrument.

AVERTISSEMENT ! Veiller à utiliser une alimentation électrique appropriée. Pour garantir le fonctionnement de l'instrument en toute sécurité :

- Brancher le système sur une prise électrique correctement mise à la terre et de puissance adéquate.
- S'assurer que la tension électrique est convenable.
- Ne jamais utiliser l'instrument alors que le dispositif de mise à la terre est déconnecté. La continuité de la mise à la terre est impérative pour le fonctionnement de l'instrument en toute sécurité.

WARNING! Power Supply Line Cords. Use properly configured and approved line cords for the power supply in your facility.

AVERTISSEMENT ! Cordons d'alimentation électrique. Utiliser des cordons d'alimentation adaptés et approuvés pour raccorder l'instrument au circuit électrique du site.

WARNING! Disconnecting Power. To fully disconnect power, either detach or unplug the power cord. Position the instrument such that the power cord is accessible.

AVERTISSEMENT ! Déconnecter l'alimentation. Pour déconnecter entièrement l'alimentation, détacher ou débrancher le cordon d'alimentation. Placer l'instrument de manière à ce que le cordon d'alimentation soit accessible.

Cleaning and decontamination

CAUTION! Cleaning and Decontamination. Use only the cleaning and decontamination methods that are specified in the manufacturer user documentation. It is the responsibility of the operator (or other responsible person) to ensure that the following requirements are met:

- No decontamination or cleaning agents are used that can react with parts of the equipment or with material that is contained in the equipment. Use of such agents could cause a HAZARD condition.
- The instrument is properly decontaminated a) if hazardous material is spilled onto or into the equipment, and/or b) before the instrument is serviced at your facility or is sent for repair, maintenance, trade-in, disposal, or termination of a loan. Request decontamination forms from customer service.
- Before using any cleaning or decontamination methods (except methods that are recommended by the manufacturer), confirm with the manufacturer that the proposed method will not damage the equipment.

MISE EN GARDE ! Nettoyage et décontamination. Utiliser uniquement les méthodes de nettoyage et de décontamination indiquées dans la documentation du fabricant destinée aux utilisateurs. L'opérateur (ou toute autre personne responsable) est tenu d'assurer le respect des exigences suivantes:

- Ne pas utiliser d'agents de nettoyage ou de décontamination susceptibles de réagir avec certaines parties de l'appareil ou avec les matières qu'il contient et de constituer, de ce fait, un DANGER.
- L'instrument doit être correctement décontaminé a) si des substances dangereuses sont renversées sur ou à l'intérieur de l'équipement, et/ou b) avant de le faire réviser sur site ou de l'envoyer à des fins de réparation, de maintenance, de revente, d'élimination ou à l'expiration d'une période de prêt (des informations sur les formes de décontamination peuvent être demandées auprès du Service clientèle).
- Avant d'utiliser une méthode de nettoyage ou de décontamination (autre que celles recommandées par le fabricant), les utilisateurs doivent vérifier auprès de celui-ci qu'elle ne risque pas d'endommager l'appareil.

Instrument component and accessory disposal

To minimize negative environmental impact from disposal of electronic waste, do not dispose of electronic waste in unsorted municipal waste. Follow local municipal waste ordinances for proper disposal provision and contact customer service for information about responsible disposal options.

Safety and electromagnetic compatibility (EMC) standards

The instrument design and manufacture complies with the following standards and requirements for safety and electromagnetic compatibility.

Safety standards

Reference	Description
EU Directive 2014/35/EU	European Union “Low Voltage Directive”
IEC 61010-1 EN 61010-1 UL 61010-1 CAN/CSA C22.2 No. 61010-1	*Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements*
IEC 61010-2-010 EN 61010-2-010	*Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-010: Particular requirements for laboratory equipment for the heating of materials*
IEC 61010-2-081 EN 61010-2-081	*Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes*
IEC 61010-2-101 EN 61010-2-101	*Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment*

EMC standards

Reference	Description
EU Directive 2014/30/EU	European Union *EMC Directive*
EN 61326-1 IEC 61326-1	*Electrical Equipment for Measurement, Control and Laboratory Use – EMC Requirements – Part 1: General Requirements*
EN 61326-2-6 IEC 61326-2-6	*Electrical equipment for measurement, control and laboratory use. EMC requirements. Particular requirements. In vitro diagnostic (IVD) medical equipment*
FCC Part 18 (47 CFR)	U.S. Standard *Industrial, Scientific, and Medical Equipment*
AS/NZS CISPR 11	*Limits and Methods of Measurement of Electromagnetic Disturbance Characteristics of Industrial, Scientific, and Medical (ISM) Radiofrequency Equipment*
ICES-001, Issue 4	*Industrial, Scientific and Medical (ISM) Radio Frequency Generators*

(continued)

Reference	Description
FCC Part 15 Subpart B (47 CFR)	*U.S. Standard Radio Frequency Devices* This equipment was tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference, in which case the user is required to correct the interference at his own expense. The Genexus™ Purification System has no user serviceable parts. Contact your Thermo Fisher Scientific field service engineer for instrument service or repair with approved parts.
IEC 60601-1-2	Medical electrical equipment—Part 1-2: General requirements for basic safety and essential performance—Collateral Standard: Electromagnetic disturbances – Requirements and tests

Table 6 IEC 60601-1-2 immunity tests

Immunity test	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 8 kV contact +/- 15 kV air	+/-8 kV contact +/-15 kV air	Use flooring made of wood, concrete or ceramic tile. If floors are covered with synthetic material, maintain the relative humidity at least 30%.
Electrical fast transient/burst IEC 61000-4-4	+/- 2 kV 100 Hz repetition frequency	+/- 2 kV 100 Hz repetition frequency	Use mains power quality of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+/- 1 kV line to line	+/- 1 kV line to line	Use mains power quality of a typical commercial or hospital environment.
	+/- 2 kV line to earth	+/- 2 kV line to earth	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Maintain power frequency magnetic fields at levels characteristic of a typical location in a typical commercial or hospital environment.

Table 6 IEC 60601-1-2 immunity tests *(continued)*

Immunity test	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands between 150 kHz and 80 MHz 80% AM at 1 kHz	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands between 150 kHz and 80 MHz 80% AM at 1 kHz	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	3V/m 80 MHz to 2.5 GHz 80 MHz - 2.7 GHz 80% AM at 1 kHz	3V/m 80 MHz to 2.5 GHz 80 MHz - 2.7 GHz 80% AM at 1 kHz	
Note: • UT is the AC mains voltage before application of the test level. • At 80 MHz and 800 MHz, the higher frequency range applies. • These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			
Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. Over the frequency range of 150 kHz to 80 MHz, maintain field strengths less than 3 V/m.			

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1 Class A	The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required), this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or reorienting the equipment.
Harmonics emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Environmental design standards

Reference	Description
Directive 2012/19/EU	European Union “WEEE Directive”—Waste electrical and electronic equipment
Directive 2011/65/EU	European Union “RoHS Directive”—Restriction of hazardous substances in electrical and electronic equipment
SJ/T 11364-2014	“China RoHS” Standard—Marking for the Restricted Use of Hazardous Substances in Electronic and Electrical Products For instrument specific certificates, visit our customer resource page at **www.thermofisher.com/us/en/home/technical-resources/rohs-certificates.html**.

Chemical safety

WARNING! GENERAL CHEMICAL HANDLING. To minimize hazards, ensure laboratory personnel read and practice the general safety guidelines for chemical usage, storage, and waste provided below. Consult the relevant SDS for specific precautions and instructions:

- Read and understand the Safety Data Sheets (SDSs) provided by the chemical manufacturer before you store, handle, or work with any chemicals or hazardous materials. To obtain SDSs, see the "Documentation and Support" section in this document.
- Minimize contact with chemicals. Wear appropriate personal protective equipment when handling chemicals (for example, safety glasses, gloves, or protective clothing).
- Minimize the inhalation of chemicals. Do not leave chemical containers open. Use only with sufficient ventilation (for example, fume hood).
- Check regularly for chemical leaks or spills. If a leak or spill occurs, follow the manufacturer cleanup procedures as recommended in the SDS.
- Handle chemical wastes in a fume hood.
- Ensure use of primary and secondary waste containers. (A primary waste container holds the immediate waste. A secondary container contains spills or leaks from the primary container. Both containers must be compatible with the waste material and meet federal, state, and local requirements for container storage.)
- After emptying a waste container, seal it with the cap provided.
- Characterize (by analysis if needed) the waste generated by the particular applications, reagents, and substrates used in your laboratory.
- Ensure that the waste is stored, transferred, transported, and disposed of according to all local, state/provincial, and/or national regulations.
- **IMPORTANT!** Radioactive or biohazardous materials may require special handling, and disposal limitations may apply.

AVERTISSEMENT ! **PRÉCAUTIONS GÉNÉRALES EN CAS DE MANIPULATION DE PRODUITS CHIMIQUES.** Pour minimiser les risques, veiller à ce que le personnel du laboratoire lise attentivement et mette en œuvre les consignes de sécurité générales relatives à l'utilisation et au stockage des produits chimiques et à la gestion des déchets qui en découlent, décrites ci-dessous. Consulter également la FDS appropriée pour connaître les précautions et instructions particulières à respecter :

- Lire et comprendre les fiches de données de sécurité (FDS) fournies par le fabricant avant de stocker, de manipuler ou d'utiliser les matériaux dangereux ou les produits chimiques. Pour obtenir les FDS, se reporter à la section « Documentation et support » du présent document.
- Limiter les contacts avec les produits chimiques. Porter des équipements de protection appropriés lors de la manipulation des produits chimiques (par exemple : lunettes de sûreté, gants ou vêtements de protection).
- Limiter l'inhalation des produits chimiques. Ne pas laisser les récipients de produits chimiques ouverts. Ils ne doivent être utilisés qu'avec une ventilation adéquate (par exemple, sorbonne).
- Vérifier régulièrement l'absence de fuite ou d'écoulement des produits chimiques. En cas de fuite ou d'écoulement d'un produit, respecter les directives de nettoyage du fabricant recommandées dans la FDS.
- Manipuler les déchets chimiques dans une sorbonne.

- Veiller à utiliser des récipients à déchets primaire et secondaire. (Le récipient primaire contient les déchets immédiats, le récipient secondaire contient les fuites et les écoulements du récipient primaire. Les deux récipients doivent être compatibles avec les matériaux mis au rebut et conformes aux exigences locales, nationales et communautaires en matière de confinement des récipients.)
- Une fois le récipient à déchets vidé, il doit être refermé hermétiquement avec le couvercle fourni.
- Caractériser (par une analyse si nécessaire) les déchets générés par les applications, les réactifs et les substrats particuliers utilisés dans le laboratoire.
- Vérifier que les déchets sont convenablement stockés, transférés, transportés et éliminés en respectant toutes les réglementations locales, nationales et/ou communautaires en vigueur.
- **IMPORTANT !** Les matériaux représentant un danger biologique ou radioactif exigent parfois une manipulation spéciale, et des limitations peuvent s'appliquer à leur élimination.

WARNING! HAZARDOUS WASTE (from instruments). Waste produced by the instrument is potentially hazardous. Follow the guidelines noted in the preceding General Chemical Handling warning.

Biological hazard safety

WARNING! Potential Biohazard. Depending on the samples used on this instrument, the surface may be considered a biohazard. Use appropriate decontamination methods when working with biohazards.

WARNING! BIOHAZARD. Biological samples such as tissues, body fluids, infectious agents, and blood of humans and other animals have the potential to transmit infectious diseases. Conduct all work in properly equipped facilities with the appropriate safety equipment (for example, physical containment devices). Safety equipment can also include items for personal protection, such as gloves, coats, gowns, shoe covers, boots, respirators, face shields, safety glasses, or goggles. Individuals should be trained according to applicable regulatory and company/ institution requirements before working with potentially biohazardous materials. Follow all applicable local, state/provincial, and/or national regulations. The following references provide general guidelines when handling biological samples in laboratory environment.

- U.S. Department of Health and Human Services, *Biosafety in Microbiological and Biomedical Laboratories (BMBL)*, 6th Edition, HHS Publication No. (CDC) 300859, Revised June 2020
  www.cdc.gov/labs/pdf/CDC-BiosafetymicrobiologicalBiomedicalLaboratories-2020-P.pdf
- Laboratory biosafety manual, fourth edition. Geneva: World Health Organization; 2020 (Laboratory biosafety manual, fourth edition and associated monographs)
  www.who.int/publications/i/item/9789240011311

Documentation and support

Related documentation

Document	Publication number
Genexus™ Purification System Site Preparation Guide	MAN0018477
Genexus™ FFPE DNA and RNA Purification Kit Quick Reference	MAN0018478
Genexus™ Multisample DNA Purification Kit Quick Reference	MAN0018479
Genexus™ Total RNA Purification Kit Quick Reference	MAN0018480
Genexus™ Cell-Free Total Nucleic Acid Purification Kit Quick Reference	MAN0018481
AutoLys M TubeLifter User Guide	MAN0017676
Genexus™ Integrated Sequencer User Guide	MAN0017910
Genexus™ Integrated Sequencer Quick Reference	MAN0017912
Genexus™ Software 6.8 User Guide	MAN0026409
Oncomine™ Precision Assay GX User Guide	MAN0018508
Oncomine™ Comprehensive Assay v3 GX User Guide	MAN0018512
Oncomine™ TCR Beta-LR Assay GX User Guide	MAN0018513
Oncomine™ BRCA Assay GX User Guide	MAN0018514
Oncomine™ Myeloid Assay GX v2 User Guide	MAN0025830

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