



Next-generation sequencing (NGS)

Genexus Dx System

Automated clinical NGS testing from specimen to report in as little as 24 hours

ion torrent

Genexus Dx System

Fast, simple, flexible

The CE-IVD-marked Ion Torrent™ Genexus™ Dx System* consists of two instruments, the Ion Torrent™ Genexus™ Dx Purification System and the Ion Torrent™ Genexus™ Dx Integrated Sequencer. This clinical NGS platform automates the workflow, from patient specimen to clinical report, making in-house NGS testing more accessible.

Combining simplicity and speed, the Genexus Dx System enables clinical laboratories to deliver biomarker results in as little as 24 hours.**



Complete automated workflow

Extraction, purification, quantification, library preparation, sequencing, and analysis—all automated

Faster decision-making

Patient specimen to clinical NGS report in as little as 24 hours

Clinical certifications

CE-IVD instruments and kits compliant with IVDR guidelines

Minimal tissue requirements

Higher success rate with the smaller amounts of sample commonly available for clinical specimens

Assay and application flexibility

Run instruments in either IVD or Assay Development mode for additional flexibility

Simple informatics

Integrated reporting reduces the need for advanced bioinformatics expertise



Easy adoption in a broad spectrum of labs

Simplified workflow with walkaway automation makes clinical NGS testing more accessible



Reduce errors

Onboard vision system to help ensure proper reagent placement

Reduced need for batching

Economically run one sample or many samples; no more waiting to collect more samples

Figure 1. Benefits of the Genexus Dx System.

* Not available in all regions.

** Actual time may vary depending on sample type or specific workflow.

The content provided herein may relate to products or workflows that have not been officially released in or fully validated in all regions and is subject to change without notice.

Specimen to clinical NGS report in as little as 24 hours

Two touchpoints, 20 minutes of hands-on time

The Genexus Dx System has two user touchpoints and dual-mode software that enables both diagnostic and research applications. Now clinical labs can offer sample-to-NGS reporting in as little as 24 hours.

Easy and efficient NGS workflow with walkaway automation

The Genexus Dx System automates nucleic acid purification and quantification and also the remaining steps of the targeted NGS workflow, including cDNA synthesis and library preparation, template preparation, sequencing, data analysis, and variant reporting.

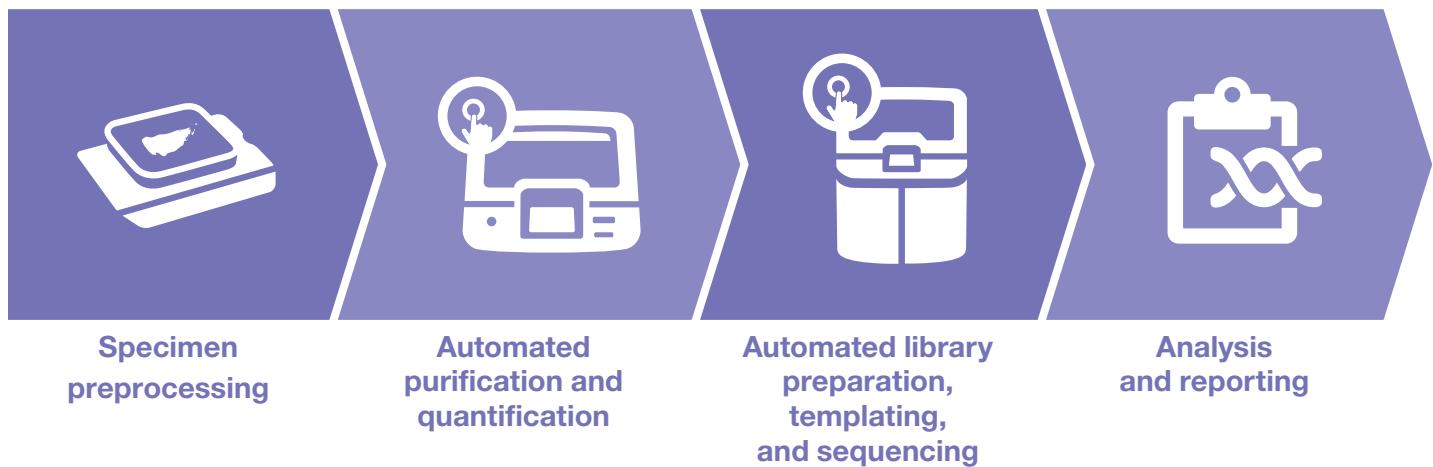


Figure 2. The Genexus Dx System workflow.

Intended use statements

The Genexus Dx Purification System is a sample preparation instrument that automates nucleic acid extraction, purification, and quantification of DNA and RNA from formalin-fixed, paraffin-embedded (FFPE) tissue lysates and cell-free total nucleic acid (cfDNA) from plasma for use in next-generation sequencing applications. The system uses Applied Biosystems™ MagMAX™ magnetic bead-based technology to perform nucleic acid extraction. Purified nucleic acid is quantified using the onboard Invitrogen™ Qubit™ Fluorometer, which uses fluorescence to measure nucleic acid.

The Genexus Dx Integrated Sequencer is an *in vitro* diagnostic (IVD) medical device intended to be used by trained personnel in a professional laboratory environment for automated, qualitative targeted sequencing of human DNA or RNA extracted from FFPE tumor tissue samples or plasma samples.

Consumables designed to simplify NGS

Ready to load, which helps save time and reduce user errors

Consumables for the Genexus Dx System are designed to reduce labor and errors due to manual processes. Ready-to-load kits, chips, and consumables simplify the NGS setup through report. A barcode system works with onboard cameras to streamline setup and reduce experimental errors.

Key features of the Genexus Dx System

Genexus Dx Purification System

- Extract, purify, and quantify DNA and RNA—on a single automated platform
- As little as 10 minutes of total hands-on time
- Flexibility of this dual-mode system allows for diagnostic procedures or research applications

Genexus Dx Integrated Sequencer

- Compatible with the low amounts of starting material commonly available from clinical specimens to reduce "quantity not sufficient" (QNS) failures
- As little as 10 minutes of total hands-on time and walkaway automation for library preparation through clinical report
- Flexibility of this dual-mode system allows for diagnostic procedures or research applications



Figure 3. Prefilled, ready-to-load reagents and consumables.
Designed to reduce labor and errors, and to simplify NGS setup.



Reduce the need for batching

Economically run one sample or many samples with multiple lanes on the reusable Ion Torrent™ Genexus™ Dx GX5™ Chip. No more waiting; run when you need results.

Figure 4. The Genexus Dx GX5 Chip.



Figure 5. Prefilled consumables for easy instrument loading.

Dual-mode software

Perform diagnostic tests and research on the same instrument

The dual-mode software allows users to run IVD assays or research assays. IVD mode provides a guided workflow from nucleic acid to report when using compatible IVD-certified assays. Assay development mode permits a variety of research applications and customized assays to be run on the Genexus Dx Integrated Sequencer for your clinical research needs.

Flexible capabilities

Run IVD assay or research assays on the same instruments with dual-mode software.

Guided IVD workflow

Genexus Dx Software provides a guided workflow when using IVD mode with compatible IVD assays.

Easy, intuitive software

Run planning is simplified to help you save time and reduce errors.

Streamlined results and reporting

Generate customizable reports for your clinical lab with support for multiple e-signatures.

A

Genexus Dx | Ion Torrent

Choose System Mode

Assay Development IVD

User Name

Password

UK English [Switch Language](#)

[Forgot Password?](#)

[Sign In](#)

[EULA | Support](#)

B

Genexus DX | Ion Torrent

Runs / Nucleic Acid to Result

Selected Assays: 1

| Assay Full Name | Analysis Version | Chip Type | Library Chemistry | Application Type |
|---|------------------|-----------------------|-------------------|---|
| Oncoline™ Dx Express Test - FFPE - EU UK v1.0.0 | 5.16 | Genexus™ Dx GX5™ Chip | AmpliSeq HD | <input checked="" type="checkbox"/> DNA and Fusions |
| Oncoline™ Dx Express Test - Plasma - EU UK v1.0.0 | 5.16 | Genexus™ Dx GX5™ Chip | AmpliSeq HD | <input type="checkbox"/> DNA and Fusions |

Genexus™ Dx GX5™ Chip

1 Lane 004ET FFPE v1.0.0 0 samples

Figure 6. Ion Torrent™ Genexus™ Dx Software interface.
(A) Easily select between Assay Development and IVD mode.
(B) Step-by-step guided run planning.



Figure 7. Features of the dual-mode Genexus Dx Software.

Engineered to enable NGS in clinical labs

Features help to support compliance with 21 CFR and Annex 11 guidelines

For clinical NGS testing, maintaining top instrument and software performance is crucial. The Genexus Dx System helps support compliance with 21 CFR guidelines, which govern electronic records and signatures in the US, and Annex 11, part of EU GMP guidelines, which emphasize system validation, data integrity, and security. Access NGS testing with reliable performance and data security to support improved patient outcomes.

Summary of key features and benefits

Internal security

- Password-protected individual accounts
- Role-based access
- Automatically logs off users when idle for long periods
- Limits number of failed log-in attempts
- Automatically records unauthorized log-in attempts

Data backup/restore

- Full backup and recovery of the system to protect against data loss
- Ability to restore data back to the system
- Backup data encryption

External security

- Data encryption during transfer
- Security patches with software upgrade

Electronic sign-offs

- Sign-offs for authorized individuals
- Signed electronic records contain name of signer, date, and time

Validations

- Installation qualification (IQ) and performance qualification (PQ) verifies and documents that upon installation, the system is able to meet all performance specifications
- Initial accuracy and performance of the instrument are established

Audit trails

- Secure, computer-generated, time-stamped actions; records the date, user, entries, and changes



A standard of support that's a cut above

Exceptional services and support for the Genexus Dx System

Thermo Fisher Scientific provides a complete suite of services and support to help ensure your instruments operate at their best.

Get started with our global customer concierge services*

Count on our dedicated global customer concierge services for an exceptional experience implementing your Genexus Dx System. From order placement through installation and training, our team is here to streamline and simplify the process.

Comprehensive warranty and service plans

Choose from a range of extended-coverage service plans to meet your budget and needs. In addition to the standard 1-year warranty,** these plans offer:

- Preventive maintenance
- Access to advanced troubleshooting features, including Smart Help and Remote Support
- Prioritized response time

AB Platinum NGS instrument service plan—premier coverage for total peace of mind

The Applied Biosystems™ AB Platinum™ NGS Plan is a premier, all-inclusive solution designed to maximize instrument performance and uptime. This comprehensive plan includes qualification services, priority technical support, and scheduled maintenance, among other benefits. It is an excellent choice for NGS laboratories seeking top-tier service and support to achieve timely and reliable results. Discover the benefits at thermofisher.com/abplatinumngs.

Qualification services

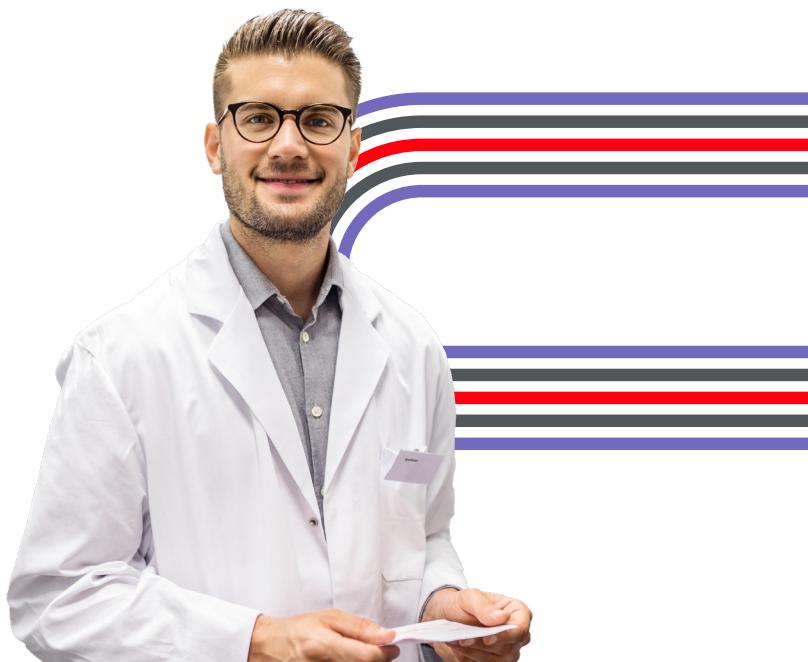
Instrument hardware qualifications for your Genexus Dx System include installation qualification, operational qualification (OQ), and performance qualification services to verify and document your instrument's ability to meet manufacturer design specifications for performance.

Our qualification specialists will work with you to support timely, cost-effective, and trusted qualification services. These services include reliable, audit-style documentation that will help ensure your instruments meet regulatory requirements.

Learn more at thermofisher.com/iqoqpg.

SmartStart Orientation enables your success

Your Genexus Dx System comes with SmartStart Orientation, led by an experienced field application scientist, to help your team quickly become proficient in using the features and instrumentation. This interactive course includes hands-on training and an introduction to data analysis.



* Concierge services are available in certain geographies.

** Refer to the User Guide for more information.

Product specifications

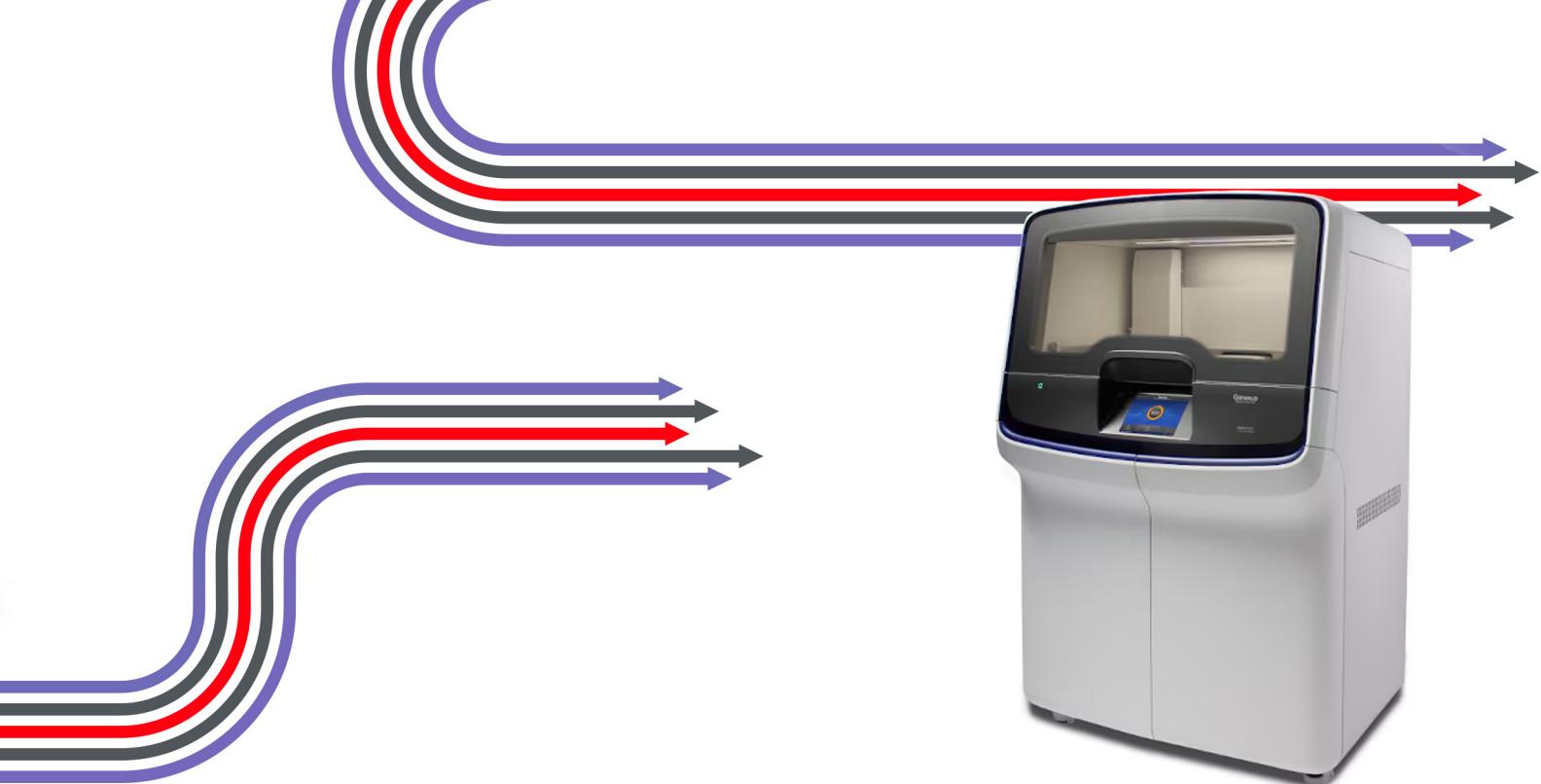


EASY



Genexus Dx Purification System

| | |
|----------------------------------|--|
| Dimensions (D x W x H) | 68.6 x 88.9 x 57.2 cm (27.0 x 35.0 x 22.5 in.) All doors closed; benchtop instrument |
| Weight | Total including crate: 95.3 kg (210 lb.) Instrument only: 76.2 (168 lb.) |
| Power | 100–240 VAC, 50/60 Hz |
| Instrument clearance | Back: 25.4 cm (10 in.); front/left/right: 7.6 cm (3 in.); top: 30.5 cm (12 in.) to allow upper door to fully open |
| Working environment | Temperature: 15–30°C Humidity: 20–70%, non-condensing relative humidity (rH) Altitude: Up to 2,500 m above sea level |
| Other connections | Network |
| Warranty | 12 months |
| Extended service warranty | Applied Biosystems™ AB Assurance™ Dx and AB Platinum NGS service contracts available |
| Software | Genexus Dx Software |
| High-quality systems | Manufactured at an FDA-registered and ISO 13485–certified facility |



Genexus Dx Integrated Sequencer

| | |
|----------------------------------|---|
| Compatible chip | Genexus Dx GX5 Chip |
| Dimensions (D x W x H) | 81.5 x 106.5 x 167.8 cm (32.1 x 41.9 x 66.1 in.) All doors closed; floor-standing instrument |
| Weight | Total including crate: 405.9 kg (895 lb.) Instrument only: 204.1 kg (450 lb.) |
| Power | 100–240 VAC, 50/60 Hz |
| Instrument clearance | Back: 30.5 cm (12 in.); left/right: 30.5 cm (12 in.); top: 50.8 cm (20 in.); front: 45.7 cm (18 in.) to allow lower doors to fully open |
| Working environment | Temperature: 15–30°C Humidity: 20–70%, non-condensing relative humidity (rH) Altitude: Up to 2,500 m above sea level |
| Other connections | Network |
| Warranty | 12 months |
| Extended service warranty | AB Assurance Dx and AB Platinum NGS service contracts available |
| Software | Genexus Dx Software |
| High-quality systems | Manufactured at an FDA-registered and ISO 13485–certified facility |



Bring automated clinical NGS to your lab

Purchasing details

Genexus Dx Purification System

| Description | Cat. No. |
|--|----------|
| Genexus Dx Purification System | A53580 |
| Genexus Dx Purification System IVD Upgrade | A53593 |

Genexus Dx Purification System—featured products

| Description | Cat. No. |
|--|----------|
| Ion Torrent™ Genexus™ Dx FFPE DNA/RNA Purification Combo Kit | A52170 |
| Ion Torrent™ Genexus™ Dx Cell-Free Total Nucleic Acid Purification Combo Kit | A52171 |

Genexus Dx Purification System—services and support

| Description | Cat. No. |
|---|----------------|
| AB Assurance Dx, 1 planned maintenance visit and operational qualification (PMOQ) | ZGD1SCGNXP-IVD |
| AB Platinum NGS warranty | ZGGWSCGNXP-IVD |
| AB Platinum NGS, 1 PMOQ | ZGG1SCGNXP-IVD |
| Priority Technical Support add-on | ZGLPSCGNXP-IVD |

Genexus Dx Purification System—required additional equipment and supplies*

| Description | Cat. No. |
|--|----------|
| Benchtop microcentrifuge | MLS |
| Vortex mixer with rubber platform | MLS |
| Thermo Scientific™ Heratherm™ Incubator (or equivalent); 2 required, 60°C and 90°C | 51028133 |
| Thermo Scientific™ Sorvall™ ST 8 Small Benchtop Centrifuge (or equivalent)** | 75007201 |
| Thermo Scientific™ M10 Microplate Swinging Bucket Rotor (or equivalent)† | 75005706 |
| Sealed Bucket; Capacity: 4 Standard or 2 Midi-Deepwell plates (Set of 2) (or equivalent) | 75005721 |

* 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.

** Centrifuge must achieve an RCF of 2,000 \times g, have a swinging bucket rotor, and accommodate deepwell plates.

† Swinging bucket rotor must carry deepwell plates in the landscape orientation.



Genexus Dx Integrated Sequencer

| Description | Cat. No. |
|---------------------------------|----------|
| Genexus Dx Integrated Sequencer | A53579 |

Genexus Dx Integrated Sequencer—featured products

| Description | Cat. No. |
|---|----------|
| Ion Torrent™ Oncomine™ Dx Express Test Panel | A54103 |
| Ion Torrent™ Genexus™ Dx Barcodes 1-32 HD | A54104 |
| Ion Torrent™ Genexus™ Dx Library Strips 1 and 2 HD | A50430 |
| Ion Torrent™ Genexus™ Dx GX5™ Chip and Genexus™ Coupler | A54106 |
| Ion Torrent™ Genexus™ Dx Templating Strips 3-GX5™ and 4 | A50431 |
| Ion Torrent™ Genexus™ Dx Sequencing Kit | A50432 |
| Ion Torrent™ Genexus™ Dx Pipette Tips | A54105 |

Genexus Dx Integrated Sequencer—services and support

| Description | Cat. No. |
|-----------------------------------|----------------|
| AB Assurance Dx, 1 PMOQ | ZGD1SCGNXI-IVD |
| AB Platinum NGS, 1 PMOQ | ZGGWSCGNXI-IVD |
| AB Platinum NGS, 2 PMOQ | ZGG2SCGNXI-IVD |
| Priority Technical Support add-on | ZGLPSCGNXI-IVD |

Genexus Dx Integrated Sequencer—required additional equipment and supplies

| Description | Cat. No. |
|--|----------|
| Benchtop microcentrifuge | MLS |
| Vortex mixer with rubber platform | MLS |
| Sorvall ST 8 Small Benchtop Centrifuge (or equivalent)** | 75007201 |
| M10 Microplate Swinging Bucket Rotor (or equivalent)† | 75005706 |
| Sealed Bucket; Capacity: 4 Standard or 2 Midi-Deepwell plates (Set of 2) (or equivalent) | 75005721 |



Financing and leasing options available

Don't let equipment financing stand between you and your results. Contact your sales representative to learn more about flexible financing, leasing, deferred payment, and trade-in programs to help you bring NGS in-house.

 Experience the future of NGS at thermofisher.com/genexusdx

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