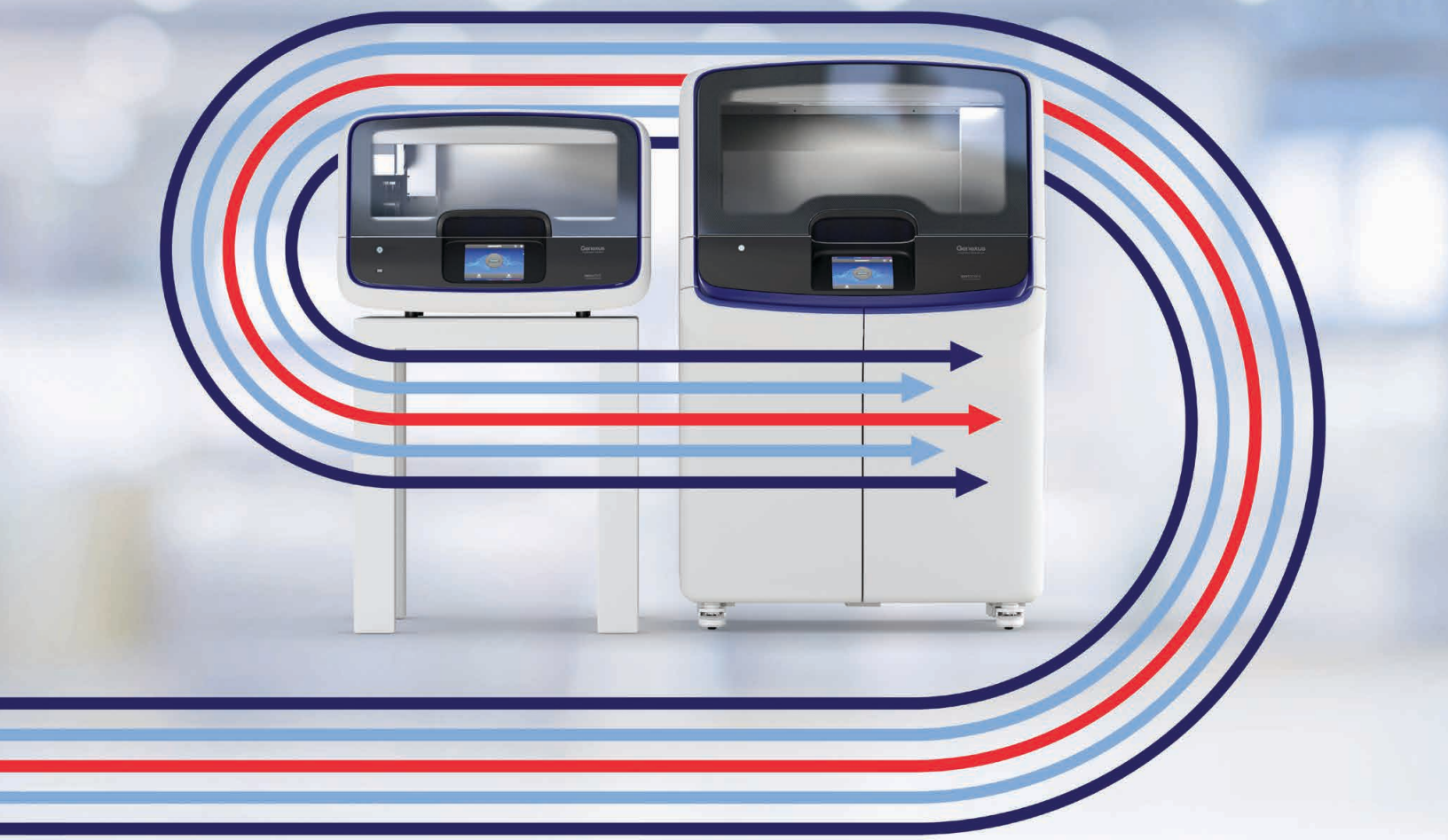
ThermoFisher SCIENTIFIC



Next-generation sequencing (NGS)

# The Genexus System

## Automated specimen-to-report NGS test results in as little as 24 hours

ion torrent

# NGS test results in as little as 24 hours

## Walkaway automation with only two manual steps and 20 minutes of hands-on time

NGS doesn't have to be complicated. The Ion Torrent™ Genexus™ System automates your lab's NGS workflow, from biological specimen to final report. Increase the efficiency of your NGS testing with a system that automates sample and library preparation, sequencing, analysis, and reporting.

The Ion Torrent™ Genexus™ Purification System and Ion Torrent™ Genexus™ Integrated Sequencer with Ion Torrent™ Genexus™ Software work together easily, tracking sample information and results automatically through the process.

**Labor efficient—**
As little as 20 minutes of hands-on time.

**1 vendor**
**1 system**
for your software, instrument, and reagent needs.

**Reliable record-keeping**
enables 21 CFR Part 11 compliance.

**Preserve samples**
Reduce quantity-not-sufficient failure.

**Simple**
Easy to learn and easy to use.

**Flexible**
Run 1 sample or many samples.

**Meet standards**
Manufactured in facilities registered with the FDA and that have ISO 13485 certification.

**Many research applications**
- Oncology
- Reproductive health
- Inherited disease
- Infectious disease

**1**
simple software guides you from sample prep to report.

**Reduce errors**
Sample tracking and barcoded consumables.

**Figure 1. Benefits of the Genexus System.**

# Simple workflow

## Load and go—from nucleic acid extraction to report

**Overcome technical barriers in the NGS workflow with the Genexus System. The automated instrument and software platform reduces manual steps while providing quality data and reports.**

The Genexus Purification System automates sample prep.
Benefits include:

- **Fast**—Extract and quantify nucleic acids within two to five hours
- **Flexible**—Run anywhere from one to 12 samples
- **Unified**—Fully integrated with the Genexus sequencer or can be used alone
- Ready to run—Pre-filled consumables help save time and reduce errors

The Genexus Integrated Sequencer automates NGS with a flexible workflow.
Benefits include:

- **Time**—Perform library prep, templating, and sequencing with walkaway automation
- **Economical**—Reusable chip with two-week stability reduces batching
- **Decrease errors**—Tracks reagent positions and detects errors with automatic scanning of barcodes
- **Quick results**—Minimum run time of 14 hours from sample to results

Software and analytics tools make NGS accessible to all types of users.
Benefits include:

- **Customizable**—Generate reports in customized formats
- **Useful**—Report known biomarkers and novel variants
- **Protected**—Data filtering, backup, and restoration
- **Seamless**—Perform analyses with a single software ecosystem

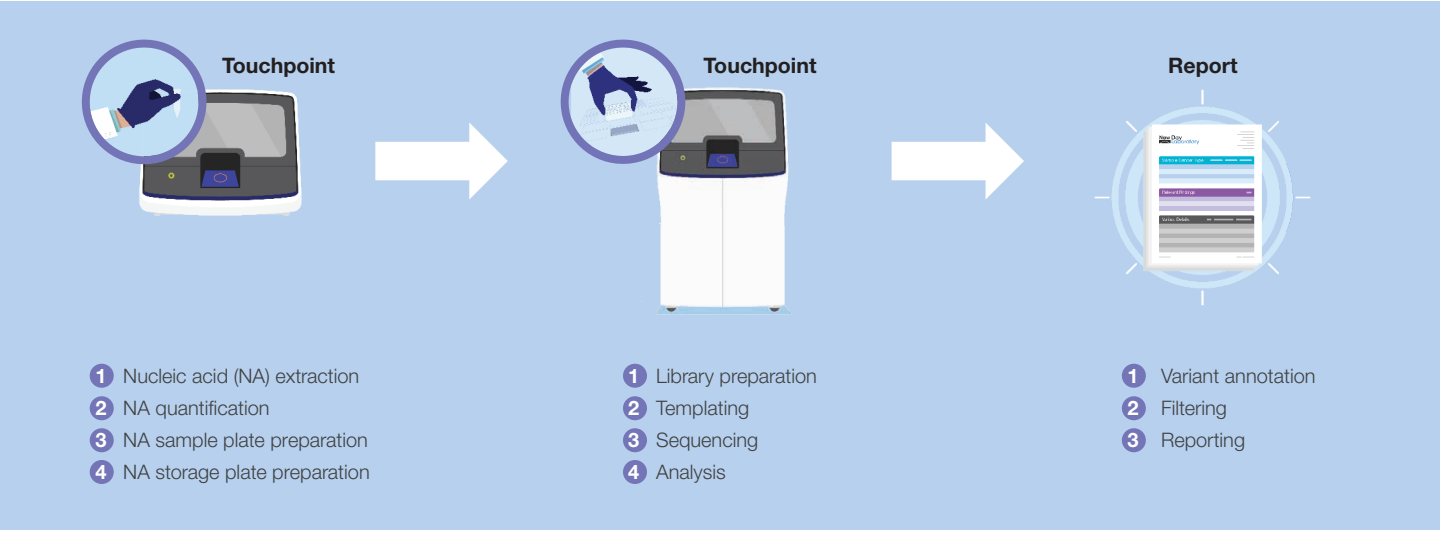



**Figure 2. The Genexus System.** The Genexus System is two instruments connected by one software ecosystem.

"Very user-friendly and easy to set up. It frees up our technologists to work on other things."

—David Seidman, PhD, MB (ASCP)CM
Sentara Healthcare, USA, July 2021

# Consumables to reduce manual steps

## Ready to load—helps save time and reduce user errors

Consumables for the Genexus System are designed to reduce labor and errors. Ready-to-load kits, chips, and packs with the Genexus System simplify the NGS setup and process. A barcode system works with onboard cameras to prevent setup and experimental errors.

### Key benefits

- **Fast setup**—Pre-filled, barcoded plates help reduce hands-on time
- **Established technology**—Proven Ion Torrent™ and Ion AmpliSeq™ products enable consistent results throughout the workflow
- **Reduced labor**—Fully automated nucleic acid extraction; accessible to novice users
- **Decrease quantity-not-sufficient (QNS) failures**—Ability to run smaller tissue volumes
- Extract nucleic acids from sources including:
  - Lysate from FFPE tissue
  - Lysate from fresh-frozen tissue
  - Lysate from bone marrow
  - Plasma
  - Whole blood
  - Peripheral blood leukocytes (PBLs)


**Figure 3. Ready-to-go reagents.**

**Reduced need for batching. Economically run one sample or many samples with a reusable Ion Torrent™ GX5™ Chip. No more waiting; run when you need results.**

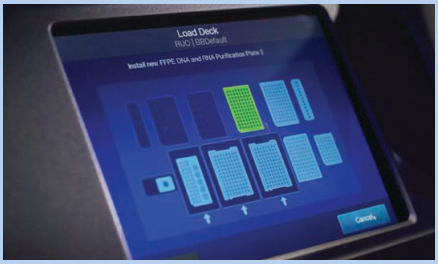
**Figure 4. The GX5 Chip.**

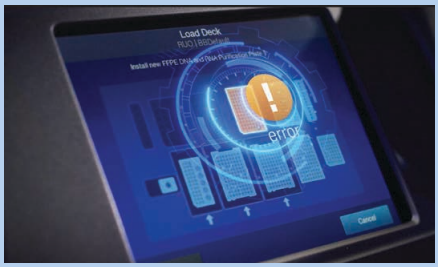
**Figure 5. Loading reagents into the Genexus System.**

# Intuitive software

## One ecosystem

The Genexus System is controlled by a single integrated software solution. A simplified user interface helps reduce the learning curve and the chance for user errors. State data meaningfully with custom or prepackaged reports. Automatic system backup and data encryption helps keep data secure.




### On-instrument benefits:

- Software walks you through step by step
- Onboard camera helps ensure correct setup
- Single setup process for sequencing and purification

**Figure 6. Software guides the run setup, tracks samples,and prevents errors in experiments.**

### Data analysis

- Universal data file for use with integrated reporting or third-party analysis
- Find meaning in generated data by identifying markers based on relevant evidence
- Even novice users with limited bioinformatics experience can generate analyses
- User-defined reporting parameters
- Algorithm is curated monthly with relevant markers

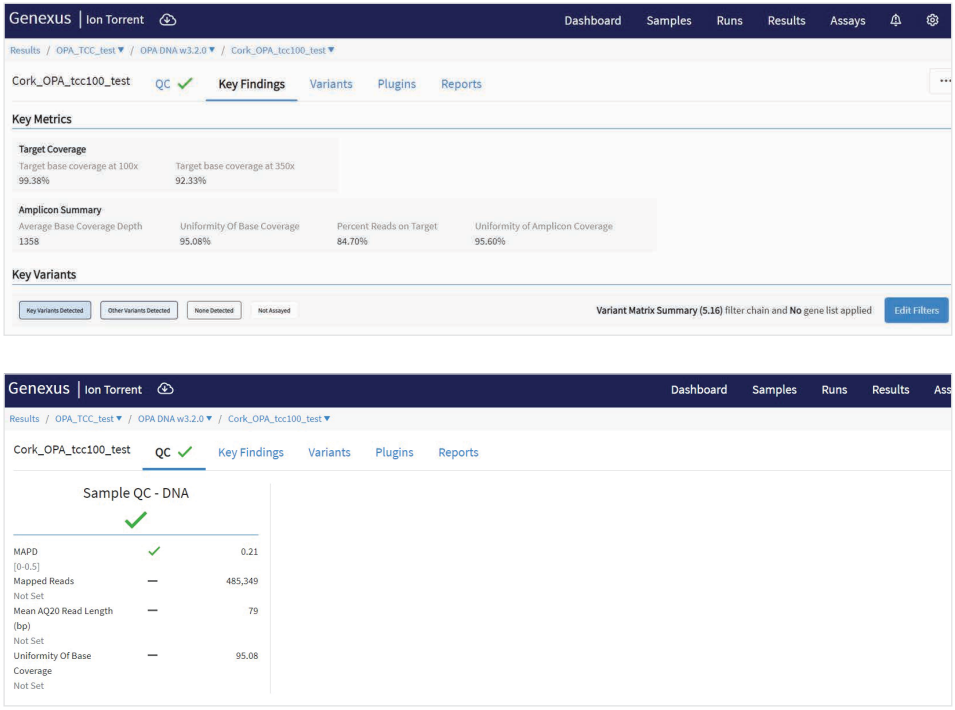



**Figure 7. Process QC and results within the software ecosystem.**

# Simplified NGS data reporting

## Customizable reports, deeper insights

Generate reports in-house and get them in the hands of the people who need them to make decisions.

### Reporting system benefits

- **Customizable**—Relevant evidence in a concise and customized report
- **Easier analysis**—Extensions to manage and interpret data
- **Novice-friendly**—Analysis tools designed for those with small and large amounts of bioinformatics training

Reporting workflows are easy with the Ion Torrent™ Oncomine™ Reporter. It is a genomic analysis software that examines NGS data and annotates sample-specific variants in a few simple steps for a report.

- No costly third-party vendor needed
- Curated from public sources and updated monthly
- Generate customizable reports
- Seamless integration with Genexus data files
- No additional data processing

Find out more at [oncomine.com/oncomine-reporter](oncomine.com/oncomine-reporter).

example Labs

Example Labs
123 Street
City, State USA 00000
Tel +1 000-000-0000
email@examplelabs.com
www.examplelabs.com

Case ID: 00-123457890 Date: 30 Jul 2020 1 of 5

**Sample Cancer Type**: Non-Small Cell Lung Cancer

**Relevant Non-Small Cell Lung Cancer Findings**

| Gene | Finding | Gene | Finding |
|---|---|---|---|
| ALK | Not detected | NRAS | Not detected |
| BRAF | Not detected | NTRK1 | Not detected |
| EGFR | Not detected | NTRK2 | Not detected |
| EFBB2 | Not detected | NTRK3 | Not detected |
| KRAS | Not detected | RET | ***KIF5B-RET fusion*** |

**Figure 8. Example report generated from the Genexus System data analysis software.** Reports are customized by the end user.

"The sensitivity of the Genexus System was exceptional for some of our targeted regions, and we gained significant efficiency with our turnaround time, hands-on time, and reagent costs."

—Craig Mackinnon, MD, PhD, Director, Genomic Diagnostics and Bioinformatics, and Professor, Department of Pathology, University of Alabama at Birmingham

# Versatile assays

## Expand menu without extra training

Ion AmpliSeq™ assays are sensitive and easy to implement. Many assays come with bioinformatics and reporting mechanisms.

Oncomine™ Solutions, when used with the Genexus System, provide a complete NGS testing workflow from sample to report. The time to complete the workflow is comparable to other methods including IHC and yet provides full genomic profiling for decision-making. Ion Torrent™ Oncomine™ assays are available on the Genexus System to assess key biomarkers found in multiple cancers. Visit **oncomine.com** to learn more.

Oncomine assays can be used for a range of research applications:

- Genomic profiling from FFPE tissue
- Liquid biopsies
- Hematological malignancy pathology
- Immuno-oncology

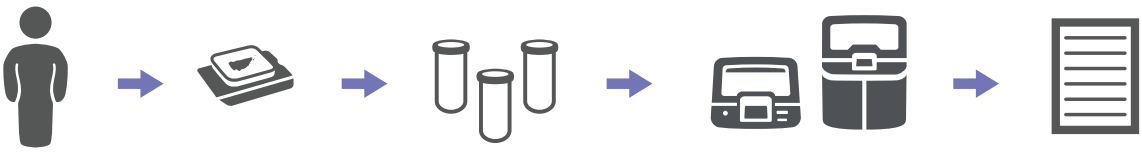


**Figure 9. Assay-to-report workflow.**


**Figure 10. Ready-to-use NGS assays.**

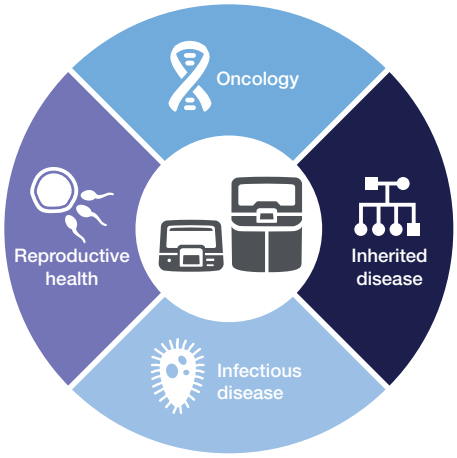



**Figure 11. Application areas for Genexus systems.**

Ion Torrent™ NGS technology is based on ultrahigh-multiplex PCR, the same technology that has enabled public health agencies to closely monitor viral infections. This includes assays to complete viral genome sequencing and variant detection. Find out more at **thermofisher.com/coronavirus-genexus**.

# Design assays that fit your needs

## Guidance to modify or build your own

The Ion AmpliSeq™ Designer helps you obtain custom assays with minimal time and effort. This web-based tool leads you through steps and choices to build custom primer panels. Benefits include:

- **Range of size**—Target sizes ranging from 1 kb to 5 Mb
- **Scalability**—12 to 6,144 primer pairs per pool—targeting a single gene or thousands of genes
- **Flexible**—Design panels with catalog of over 5,000 pre-tested genes for many disease areas

Ion AmpliSeq™ On-Demand Panels are predesigned, wet lab–tested, and customizable targeted NGS panels that target >5,000 genes within the inherited disease space. Target genes in more than a dozen reference genomes or upload your own. Learn more about Ion AmpliSeq panels at thermofisher.com/ampliseq.

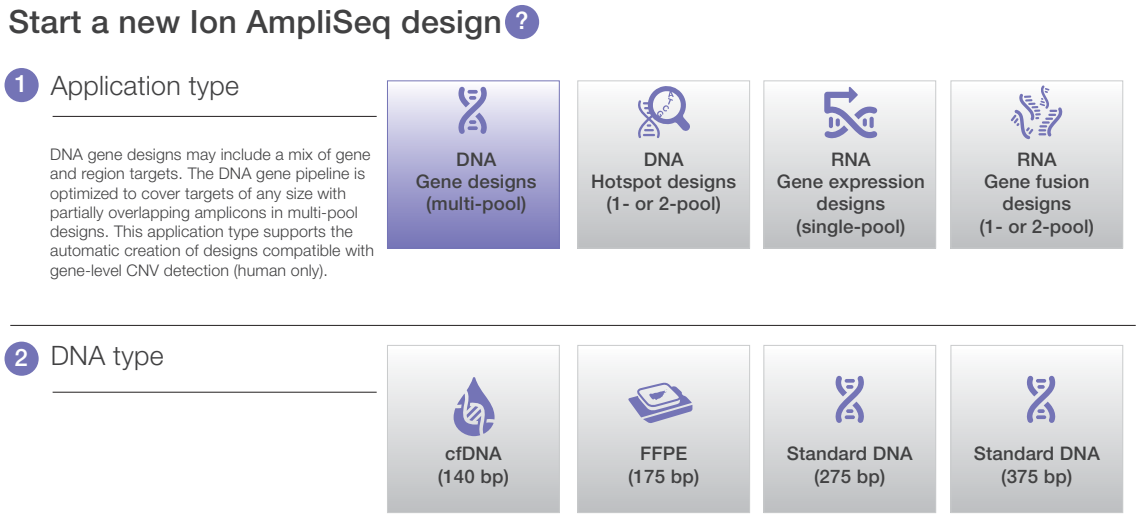



**Figure 12. Ion AmpliSeq Designer is a free and easy-to-use web-based tool to design primer sets for sequencing.**

**Incorporate NGS into your research workflow. Choose from an optimized catalog of over 5,000 tested genes relevant in clinical research of inherited diseases like hereditary cancers, primary immunodeficiency, hearing loss, muscular dystrophy, Noonan syndrome, and others. Find out more at thermofisher.com/inherited-genexus.**

# Analytical validation consulting services for NGS assays

## Experienced project management

To help address your NGS testing needs, we've developed analytical validation (AV) consulting services* that help shorten your analytical validation time and control your cost.

Perform the analytical validation process up to 75% faster than the average in-house AV. The service provides:

- Project management from a dedicated on-site application scientist, workflow training, workflow optimization, technical review, and assistance with confirmatory sequencing
- Deliverables include analytical validation plan templates, protocol templates, controls and samples, a data analysis workflow, and a report template

**Installation qualification (IQ), operational qualification (OQ), and performance qualification (PQ) or instrument performance verification (IPV) services verify and document your instrument's ability to meet manufacturer design specifications for performance. Find out more at thermofisher.com/iqoqpq.**

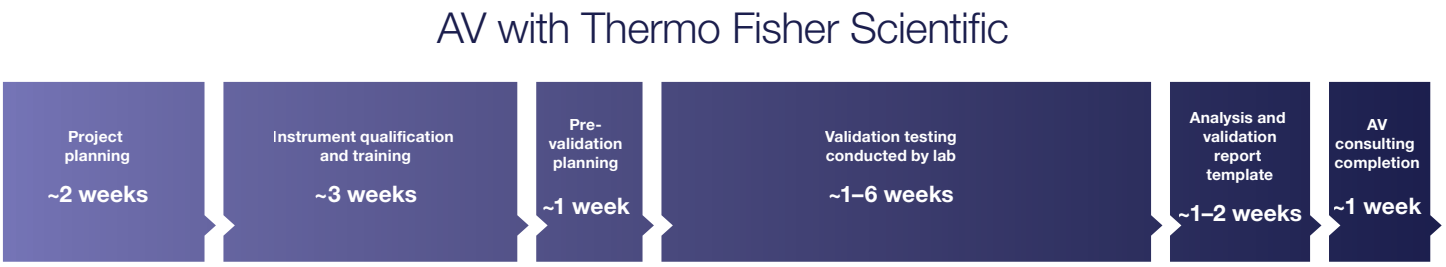



**Figure 13. AV service workflow.**

* Consulting services offered for the guidance in enabling the analytical validation in support of research efforts only.

# Comprehensive service and support

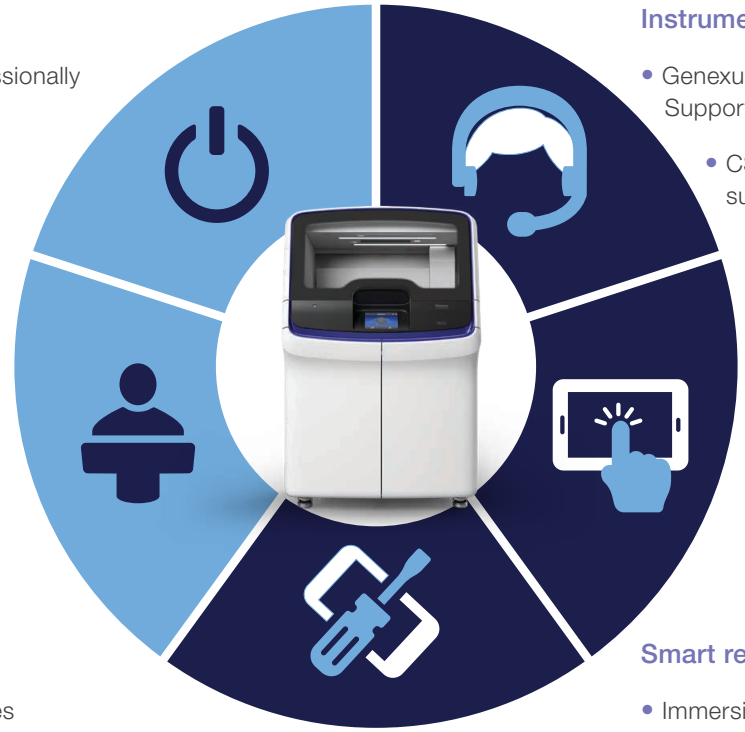
## Remote and in-person, we'll keep you going

Equipment shouldn't slow you down. In addition to hands-on training at your lab, we offer on-site service plans, self-paced online courses, remote support options, and consulting services to help you get the most from your instrument investment.

Get more information on service plans, qualification services, and training specific to your region, at **thermofisher.com/instrumentservices**.

### Installation

- Conducted on-site by a professionally trained Field Service Engineer



### Instrument-driven support

- Genexus Software enables Customer Support Archives (CSA)
  - CSA generates technical support request
    - Easy sharing of log and run files
    - Instrument connectivity required

### Training

- SmartStart Orientation includes hands-on training and an introduction to data analysis

### Field service

- Exceptional support from experienced field service specialists
- 12-month warranty
- Applied Biosystems™ AB Assurance™ service contract available
- Additional service package offerings to include Priority Technical Support, 24-hour response, and on-site service plans available

### Smart remote support

- Immersive collaboration tool for faster troubleshooting and resolution
- Augmented-reality technology with real-time video and audio collaboration
- Advanced remote desktop support tool
- Instrument connectivity not required

**Figure 14. Diagram of services.**

# Instrument specifications

## Fits into your lab space

### Genexus Purification System

| | | | | | | |
|---|---|---|---|---|---|---|
| **Instrument type** | Benchtop sample preparation system | | | | | |
| **Instrument capability** | Automated nucleic acid extraction, purification, and quantitation | | | | | |
| | Specimen types | | | | | |
| | FFPE lysate* | Whole blood | Multi-sample DNA | Fresh-frozen tissue | PBLs or bone marrow | Plasma |
| **Input quantities** | 200 µL (DNA or RNA) | 50–150 µL (total RNA) | 50–200 µL | 1–10 mg | 50–200 µL (DNA) | 1–8 mL (cfTNA) |
| **Samples/run** | 12 | 12 | 12 | 12 | 12 | 6 |
| **Elution volumes** | 20–115 µL | | | | | |
| **Dimensions (D x W x H)** | 58.4 x 91.4 x 67.3 cm (23 x 36 x 26.5 in.) | | | | | |
| **Weight** | 68 kg (150 lb) | | | | | |
| **Power** | 100–240 VAC, 50/60 Hz, 5–12 A | | | | | |

### Genexus Integrated Sequencer

| | |
|---|---|
| **Compatible chip** | GX5 Chip |
| **Dimensions (D x W x H)** | 32.1 x 41.9 x 66.1 in. (81.5 x 106.5 x 167.8 cm) All doors closed; floor-standing instrument |
| **Weight** | Total including crate: 895 lb (405.9 kg); Instrument only: 450 lb (204.1 kg) |
| **Power** | 100–240 VAC, 50/60 Hz |
| **Instrument clearance** | Back: 6 in. (15.2 cm); left/right: 10 in. (25.4 cm) on each side to allow lower doors to fully open; top: 15.5 in. (39.4 cm) to allow upper door to fully open |
| **Working environment** | Temperature: 15–30°C<br>Humidity: 10–80% relative humidity (rH)<br>Altitude: Up to 2,500 m above sea level |
| **Other connections** | Network |

### Warranties

| | |
|---|---|
| **Warranty** | 12 months** |
| **Extended service warranty** | AB Assurance service contract available |
| **Software** | Genexus Software |
| **High-quality systems** | Manufactured at an FDA-registered and ISO 13485–certified facility |

* FFPE sample volumes vary due to the number of slides or thickness and amount of nucleic acid.

** Contact us at thermofisher.com/support for more information.

# Bring simplified NGS right to your lab

## Flexible purchasing options

### Genexus System instruments

| Description | Instrument only Cat. No. | Instrument with service* Cat. No. |
|---|---|---|
| Genexus Integrated Sequencer | A45727 | A46409, A46410 |
| Genexus Purification System | A48148 | A53276, A52581 |

* Extended warranty packages include the instrument, SmartStart Orientation, and a 3-year AB Assurance Plan with 1 planned maintenance (PM) visit per year and with/without qualification services. Packages are not available in all countries. Contact your local sales representative for more information.

### Genexus Integrated Sequencer consumables and accessories

| Description | Size | Cat. No. |
|---|---|---|
| GX5 Chip and Genexus Coupler | 2 GX5 Chips (8 lanes) | A40269 |
| Genexus GX5 Starter Pack-AS | AS library prep for 32 reactions, and 8 lanes of sequencing | A40279 |
| Genexus GX5 Starter Pack-HD | AS-HD library prep for 32 reactions, and 8 lanes of sequencing | A40280 |

### Genexus Purification System consumables and accessories

| Description | Reactions/run | Size | Cat. No. |
|---|---|---|---|
| Genexus FFPE DNA/RNA Purification Kit | 12 | 48 reactions | A45539 |
| Genexus Multisample DNA Purification Kit | 12 | 48 reactions | A45540 |
| Genexus Total RNA Purification Kit | 12 | 48 reactions | A45541 |
| Genexus Cell-Free Total Nucleic Acid Purification Kit | 6 | 24 reactions | A45542 |

**Financing and leasing options available****

Don't let equipment financing stand between you and your results. Find out more about flexible financing, leasing, deferred payment, and trade-in programs to help you bring NGS in-house at thermofisher.com/financengs.

** Regional variations apply.

Experience the future of NGS at **thermofisher.com/genexus**

ion torrent