

The Genexus System

An end-to-end NGS platform to automate your workflow

NGS results in less than a day

Two touchpoints, 20 minutes 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 Genexus Purification System and Genexus Integrated Sequencer with Genexus Software work together seamlessly, tracking sample information and results automatically through the process.



vendor system

for your software, instrument, and reagent needs.

Reliable record keeping

enables 21 CFR Part 11 compliance.

Preserve samples

Minimize 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
- Inherited disease
- Infectious disease
- Reproductive health



simple software guides you from sample prep to report.



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. Automated instrument and software minimizes manual steps while providing quality data and reports.

The Ion Torrent™ Genexus™ Purification System automates sample prep. Benefits include:

- Fast—Extract and QC nucleic acids within two to five hours.
- Flexible—Run anywhere from 1 to 12 samples.
- Unified—Fully integrated with the Genexus sequencer or used alone.
- Ready to run—Pre-filled consumables help save time and reduce errors.

The Ion Torrent™ Genexus™ Sequencer automates NGS with a flexible workflow. Benefits include:

- Time—Automate library prep, templating, and sequencing. No intervention.
- **Economical**—Reusable chip with twoweek stability reduces batching.
- Minimize error—Tracks reagent positions and detects errors with automatic scanning of barcodes.
- Quick results—Minimum run time of 14 hours sample-to-results.

Software and analytics tools makes NGS accessible to all types of users.

Benefits include:

- Customizable—Generate reports in customized formats.
- Useful—Report markers from guidelines, therapy, clinical trials, and novel variants.
- Protected—Data filtering, backup and restoration.
- **Seamless**—Perform analyses with a single software ecosystem.

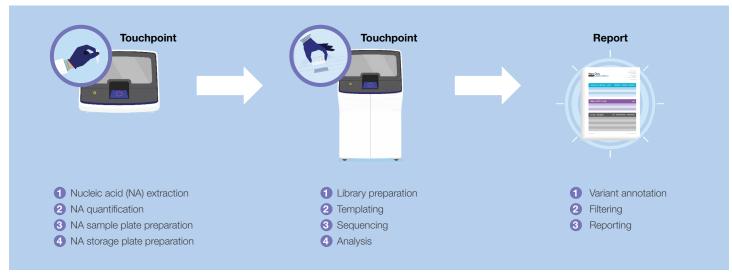


Figure 2. The Genexus System. The Genexus system is two instruments connected by one software.

"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 minimize 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 simplifies NGS setup and process. A barcode system works with on-board 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.
- Minimize 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 4. The Ion Torrent Chip.





Figure 3. Ready-to-go reagents.



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 chance for user errors. State data meaningfully with custom or prepackaged reports. Automatic system back up and data encryption helps keep data secure.



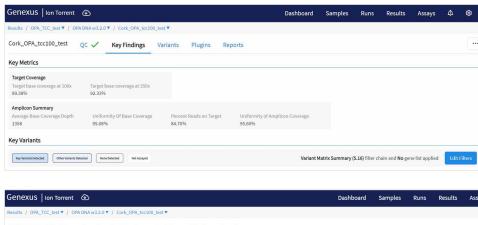
On-instrument benefits:

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

Figure 6. Software guides, tracks, 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 analysis.
- User-defined reporting parameters.
- Algorithm is curated monthly with relevant markers.



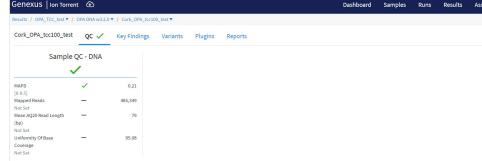


Figure 7. Process QC and results within the software ecosystem.

"Experienced labs can also benefit from the Genexus System because it allows them to automate many steps that are error-prone."

-Philip Jermann, University Hospital, Basel, Switzerland

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. Get genomic profiles.

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.
- Updated monthly.
- Generate customizable reports.
- · Seamless integration with Genexus data files.
- No additional data processing.

Find out more at oncomine.com/oncomine-reporter



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 superior 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 for laboratory use. Assays come with primer pools.

Many assays come with bioinformatics and reporting mechanisms.

Ion Torrent™ 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 clinical decision-making. Ion Torrent™ Oncomine™ assays are available on the Genexus System to assay key biomarkers found in multiple cancers. Visit oncomine.com

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

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

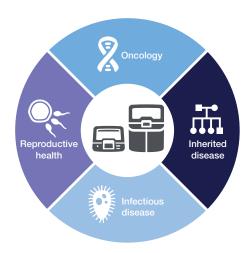


Figure 11. Application areas for Genexus systems.

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 pre-tested gene targets for customized panels 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

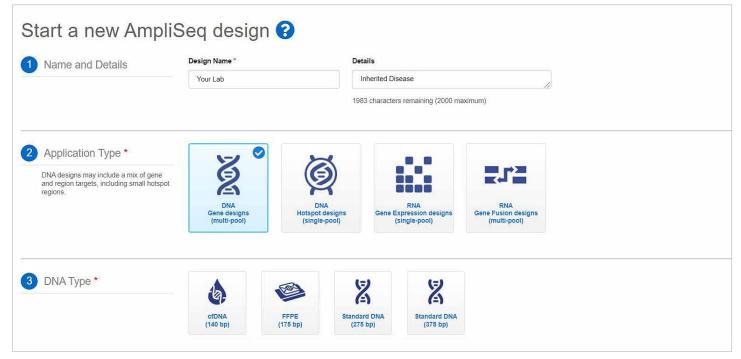


Figure 12. Web-based tool to design prime sets for sequencing.

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 validation cost.

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

- Project management from a CSS, a dedicated on-site application scientist, workflow training, workflow optimization, technical review, and assistance with confirmatory sequencing.
- Deliverables include 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

AV with Thermo Fisher Scientific



Figure 13. AV service workflow.

Superior 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 product.

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

Installation Instrument-driven support · Conducted on-site by a professionally Genexus Software enables Customer trained Field Service Engineer Support Archives (CSA) CSA generates technical support request Easy sharing of log and run files Instrument connectivity required **Training** Smart remote support SmartStart[™] Orientation includes • Immersive collaboration tool for faster hands-on training and an introduction to troubleshooting and resolution

data analysis

Field service

- Superior support from experienced field service specialists
- 12-month warranty
- AB Assurance Service Contract available
- Additional service package offerings to include Priority Technical Support, 24-hour response, and on-site service plans available

- 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 volumes	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	58.4 x 91.4 x 67.3 cm (23 x 36 x 26.5 in)					
$(D \times W \times H)$						
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 Humidity: 10–80% relative humidity (rH) 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

 $^{^{\}star}$ FFPE-sample volumes vary due to the number of slides or thickness and amount of nucleic acid. For example, 5 μ m-thick slides per sample: core needle biopsy 9; fine needle aspirates 7; surgical resections 2.



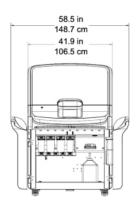
- (2) 88.9 cm (35 in.)
- (3) 98.6 cm (27 in.)

 3 98.6 cm (27 in.)

 3 9.5 cm (12 in.) clearance above the instrument with door closed

 25.4 cm (10 in.) clearance behind the instrument

 27.6 cm (3 in.) clearance in front and on each side of the instrument



Bring simplified NGS, right in 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 Integrated Sequencer 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	A45542
Genexus Cell-Free Total Nucleic Acid Purification Kit	6	24 reactions	A45541

^{**} Some consumables may not yet be available. Visit thermofisher.com/genexus for a complete list and availability.

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

Minimize large upfront capital investment costs with our subscription services program by Thermo Fisher Scientific, helping you better manage risk and complexity by bundling together equipment, service, and

consumables into one OPEX payment so you can avoid the hassle of CAPEX approval. This can also preserve your existing credit lines and give you first access to upgrades and future innovation. Find out more at

thermofisher.com/ngssubscriptions





^{*} Regional variations apply