

Next-generation sequencing (NGS)

# Genexus Dx System

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

# 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.

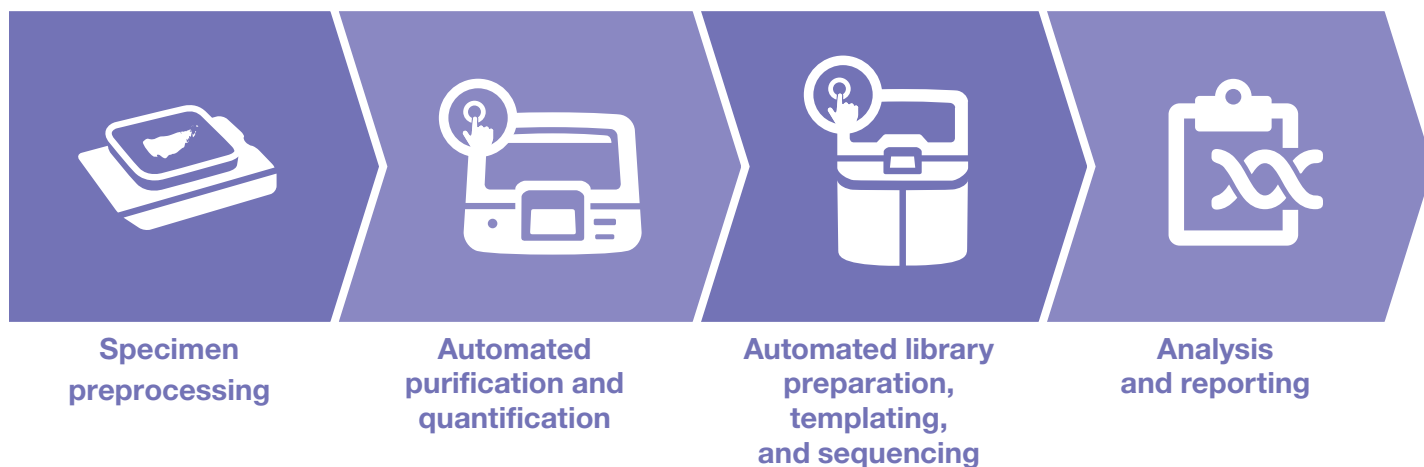
# Specimen to clinical NGS report in as little as 24 hours

## 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 (cfTNA) 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.

A close-up image of a small, square, gold-colored chip with four circular ports, held by a gloved hand.

### 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

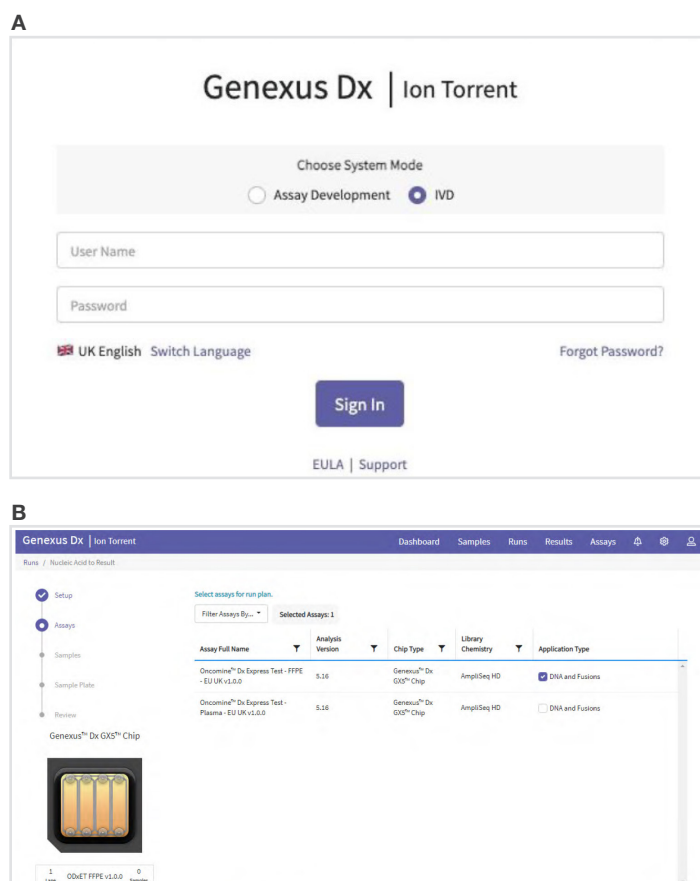
Genexus Dx Software provides a guided workflow when using IVD mode with compatible IVD assays.

### 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.



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

#### Run setup



#### Sample results



#### Reports



#### API connectivity



**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](https://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](https://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.

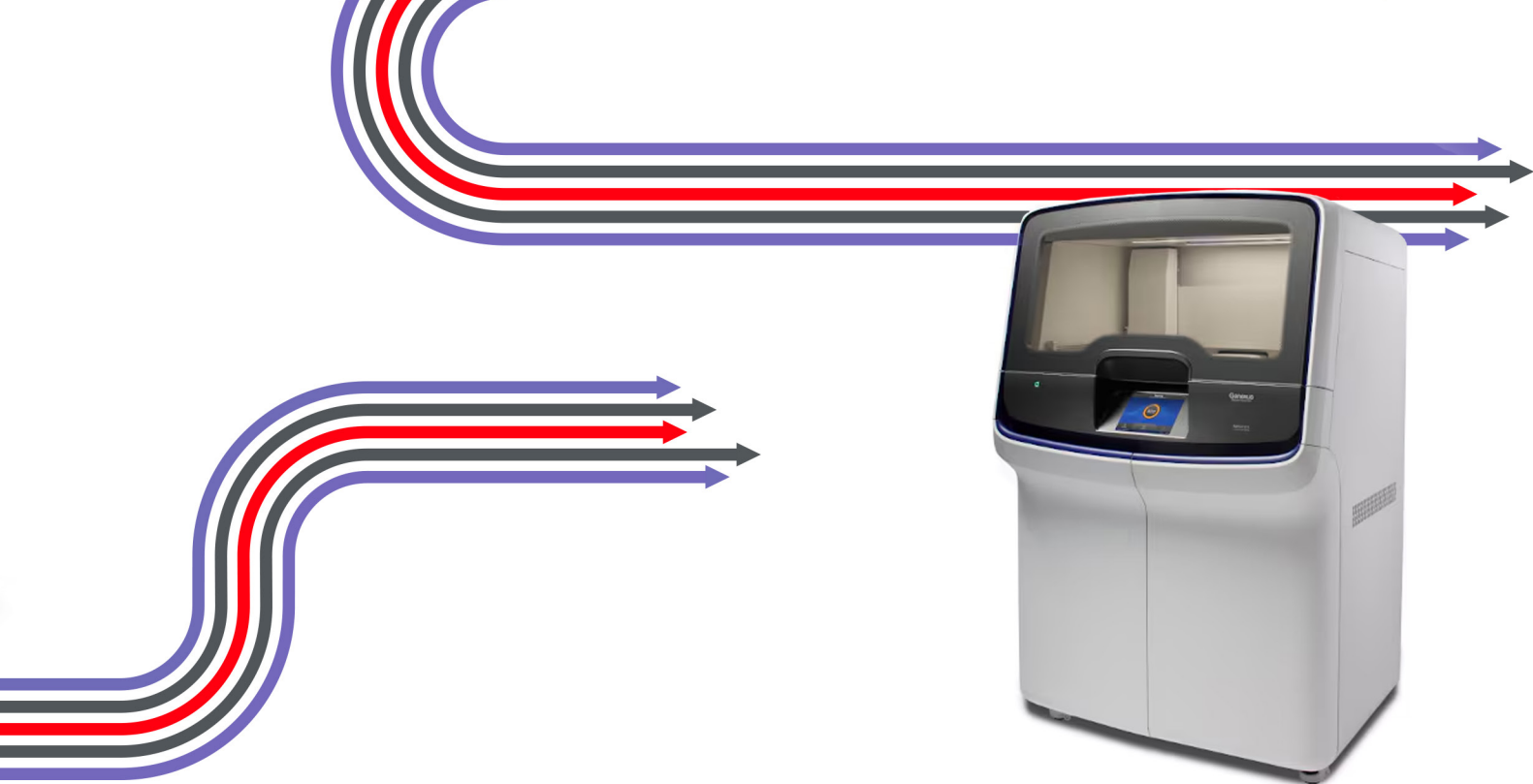
\*\* Refer to the User Guide for more information.

# Product specifications



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

<b>Compatible chip</b>	Genexus Dx GX5 Chip
<b>Dimensions (D x W x H)</b>	81.5 x 106.5 x 167.8 cm (32.1 x 41.9 x 66.1 in.) All doors closed; floor-standing instrument
<b>Weight</b>	Total including crate: 405.9 kg (895 lb.) Instrument only: 204.1 kg (450 lb.)
<b>Power</b>	100–240 VAC, 50/60 Hz
<b>Instrument clearance</b>	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
<b>Working environment</b>	Temperature: 15–30°C Humidity: 20–70%, non-condensing relative humidity (rH) Altitude: Up to 2,500 m above sea level
<b>Other connections</b>	Network
<b>Warranty</b>	12 months
<b>Extended service warranty</b>	AB Assurance Dx and AB Platinum NGS service contracts available
<b>Software</b>	Genexus Dx Software
<b>High-quality systems</b>	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](https://thermofisher.com/genexusdx)

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