

Thermo Fisher
SCIENTIFIC



Next-generation sequencing

Genexus Dx Integrated Sequencer

A CE-IVD next-generation sequencing platform
for clinical laboratories

ion torrent

Genexus Dx Integrated Sequencer

Fast, simple, flexible

The Ion Torrent™ Genexus™ Dx Integrated Sequencer is now CE-IVD–marked. Combining simplicity, flexibility, and speed, the Genexus Dx Integrated Sequencer offers a hands-off, automated next-generation sequencing (NGS) workflow for the clinical laboratory.



Faster decision-making—
nucleic acid to NGS report
in as little as 24 hours



**Early adoption in a broad
spectrum of labs**—
automated workflow, and
consumables designed to
minimize pipetting steps



Improved lab efficiency—
onboard vision cameras
to help ensure proper
reagent placement and
minimize errors



Seamless informatics—
integrated reporting reduces
the need for advanced
bioinformatics expertise



**Minimal tissue
requirements**—higher
success rate with smaller
amounts of sample



**Reduced need for
batching**—economically
run one sample or many
samples; no more waiting,
run when you need results

Figure 1. Benefits of the Genexus Dx Integrated Sequencer.

Nucleic acid to report in as little as 24 hours

One touch point, 10 minutes of hands-on time

The Genexus Dx Integrated Sequencer has one user touch-point and dual-mode software that enables both diagnostic and research applications. Now labs can offer nucleic acid to NGS reporting in a single day.

Easy and efficient workflow

The Genexus Dx Integrated Sequencer starts with purified nucleic acid and automates all remaining steps of the targeted NGS workflow, including cDNA synthesis and library preparation, template preparation, sequencing, data analysis, and variant reporting.

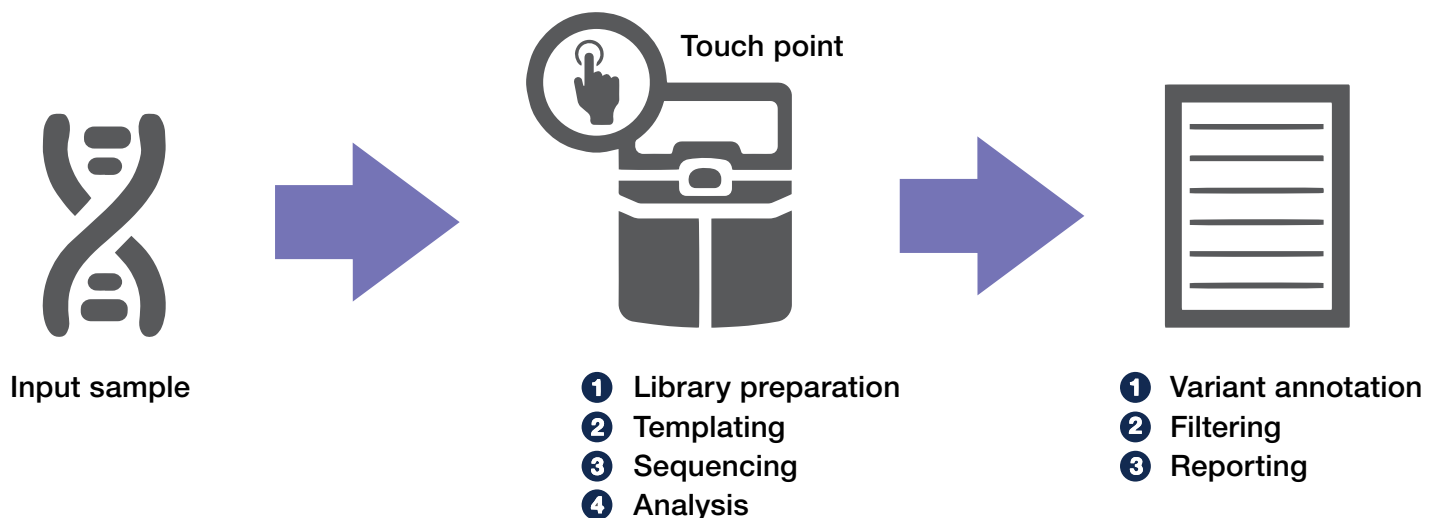


Figure 2. The workflow of the Genexus Dx Integrated Sequencer.

Intended use statement: 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 formalin-fixed, paraffin-embedded (FFPE) tumor tissue samples or plasma samples. The Ion Torrent™ Genexus™ Dx System consists of the Genexus Dx Integrated Sequencer and Ion Torrent™ Genexus™ Dx Software.

Consumables designed to minimize manual steps

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

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

Key benefits

- Up to four different assays prepared and sequenced simultaneously in a single run
- Multiplexing capability of up to 32 library preparations in a single run:
 - 32 single-pool samples
 - 16 two-pool samples
 - 8 four-pool samples
- Two-week on-instrument chip and reagent stability
- Assay and throughput flexibility facilitated by strips and multilane sequencing chip



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



Figure 4. The GX5 Chip.



Figure 5. Prefilled consumables for easy instrument loading.

Dual-mode software

Perform diagnostic tests and clinical research on the same instrument

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

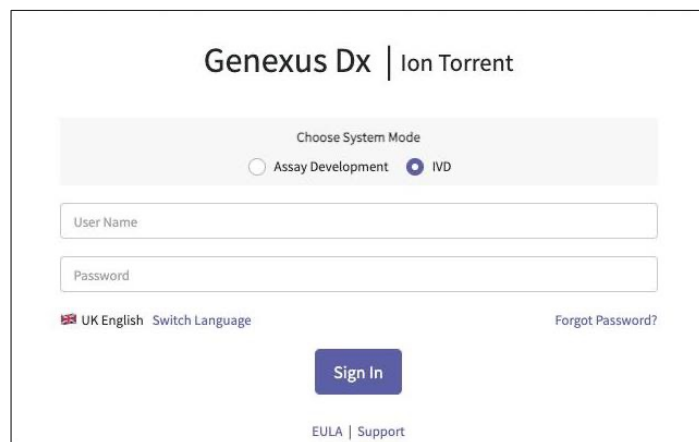


Figure 6. Log-in screen for the Genexus Dx Integrated Sequencer Software.

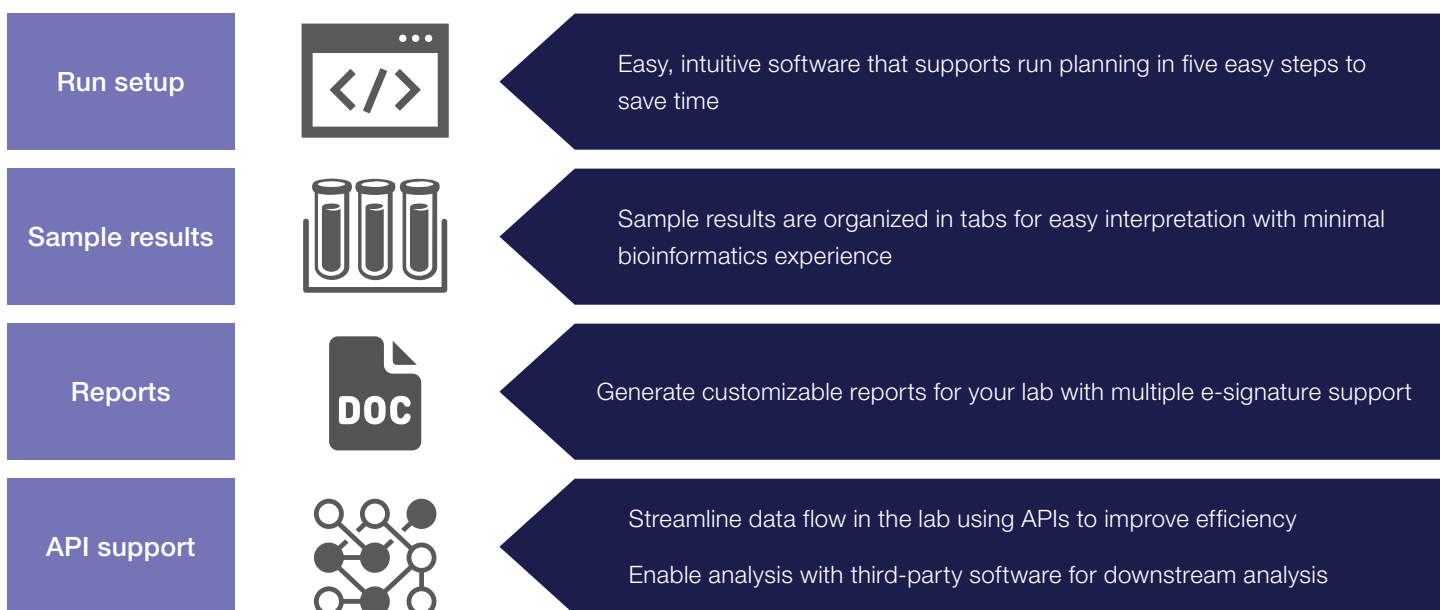


Figure 7. Features of the dual-mode Genexus Dx Software.

Features to enable 21 CFR and Annex 11 guidelines



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



Validations

- IQ/PQ validates that the software is installed correctly and operates properly



Data backup/restore

- Full backup and recovery of the system to protect against data loss
- Ability to restore data back to the system
- Back up 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, as well as meaning of signing



Audit trails

- A secure, computer-generated, time-stamped audit trail that records the date, user entries, reason for change, and actions
- Prevents users from being able to modify or delete audit trail

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.

Get started with our global customer concierge services*

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

- Preparing your laboratory space for a successful installation by providing critical documentation and checklists
- Connecting your IT department with our IT specialists to enable an easy and secure network connection so you can take advantage of cutting-edge features and advanced digital support
- Coordinating instrument installation and qualification with a highly skilled field service engineer (FSE)
- Scheduling interactive SmartStart Orientation training with an experienced field application scientist (FAS) or clinical application consultant (CAC)

* Concierge services are available in certain geographies.

Instrument specifications

The sequencing workflow in one instrument and one space

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 Dx Software
High-quality systems	Manufactured at an FDA-registered and ISO 13485-certified facility

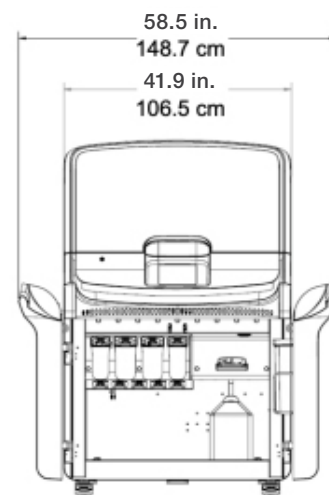


Figure 8. Genexus Dx Integrated Sequencer dimensions.

Bring clinical NGS right in your lab

Flexible purchasing options

Genexus Dx Integrated Sequencer

Description	Cat. No.
Genexus Dx Integrated Sequencer	A53579
Genexus Dx Integrated Sequencer Upgrade	A53592
Genexus Dx Integrated Sequencer Installation Kit	A52169

Genexus Dx Integrated Sequencer consumables

Description	Cat. No.
Genexus Dx Barcodes 1-32 HD	A54104
Genexus Dx Library Strips 1 and 2 HD	A50430
Genexus Dx GX5 Chip and Genexus Coupler	A54106
Genexus Dx Templating Strips 3-GX5 and 4	A50431
Genexus Dx Sequencing Kit	A50432
Genexus Dx Pipette Tips	A54105
Applied Biosystems MicroAmp EnduraPlate Optical 96-Well plates	4483348
Thermo Scientific Adhesive PCR Plate Foils	AB0626

Genexus Dx Integrated Sequencer with service plans

Description	Cat. No.
Genexus Dx Integrated Sequencer with extended warranty packages*	
Genexus Dx Integrated Sequencer System, additional 1-year AB Assurance IVD with planned maintenance**, IQ/OQ/PQ, install kit, SmartStart, bioinformatics support plan	A54576
Genexus Dx Integrated Sequencer System, additional 2-year AB Assurance IVD with planned maintenance**, IQ/OQ/PQ, install kit, SmartStart, bioinformatics support plan	A53577
Service plan*	
AB Assurance IVD for the Genexus Dx Integrated Sequencer, 1 PM, 1 OQ	ZGD1SCGNXI-IVD
AB Assurance IVD service plan add-ons*	
1 additional planned maintenance visit for the Genexus Dx Integrated Sequencer	ZPSPSCGNXI-IVD
Qualification services plan add-on for the Genexus Dx Integrated Sequencer	ZGQUSCGNXI-IVD
24-hour service response add-on for the Genexus Dx Integrated Sequencer	ZE57SCGNXI-IVD
Qualification and consulting services	
IQ/OQ/PQ service for the Genexus Dx Integrated Sequencer	A54075
OQ/PQ service for the Genexus Dx Integrated Sequencer	A54074
Bioinformatics support plan	ZGPCSCIONBFX
Analytical performance verification (APV)	A48557
Analytical validation regional guidance (AVR)	A49256
Training services	
SmartStart Orientation for the Genexus Dx Integrated Sequencer	TRN00332

* May not be available in all regions. Contact your sales representative for availability in your region.

** System is covered under factory warranty for first 12 months. No planned maintenance (PM) during factory warranty. AB Assurance IVD instrument plan is an extended warranty that covers the instrument after the initial 12-month factory warranty.

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 a 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.

 Experience the future of NGS at thermofisher.com/genexusdx

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