ThermoFisher SCIENTIFIC

The Genexus System is expected to be CE IVD–certified in 2022

The only true end-to-end integrated NGS workflow

The Oncomine™ Precision Assay on the Ion Torrent™ Genexus™ System—as fast and easy as IHC or PCR

Now, you can advance from specimen to report in a single day with a hands-off, automated, simple, next-generation sequencing (NGS) workflow. This will enable you to combine your lab's immunohistochemistry (IHC) results with timely NGS insights to deliver a complete, relevant report in as little as one day.

- Mutations, copy number variations (CNVs), and fusion variant types across 50 key genes such as *EGFR*, *ALK*, *BRAF*, *ROS1*, *RET*, *KRAS*, *PIK3CA,* and *ERBB2,* among others
- One-day workflow, with only two user touchpoints and 20 minutes of hands-on time
- Only 10 ng of DNA or RNA required, allowing for more samples to be tested
- Compatible with formalin-fixed, paraffin-embedded (FFPE) tissue as well as liquid biopsy samples

> **"We have been able to maintain a fast turnaround time with the Oncomine Precision Assay on the Genexus System, even with a small team in the laboratory."**
> – Dr. Leomar Ballester, MD, PhD, Co-Director, Molecular Diagnostics Laboratory, University of Texas Health Science Center in Houston

ion torrent

All operated by one Ion Torrent™ Genexus™ software solution

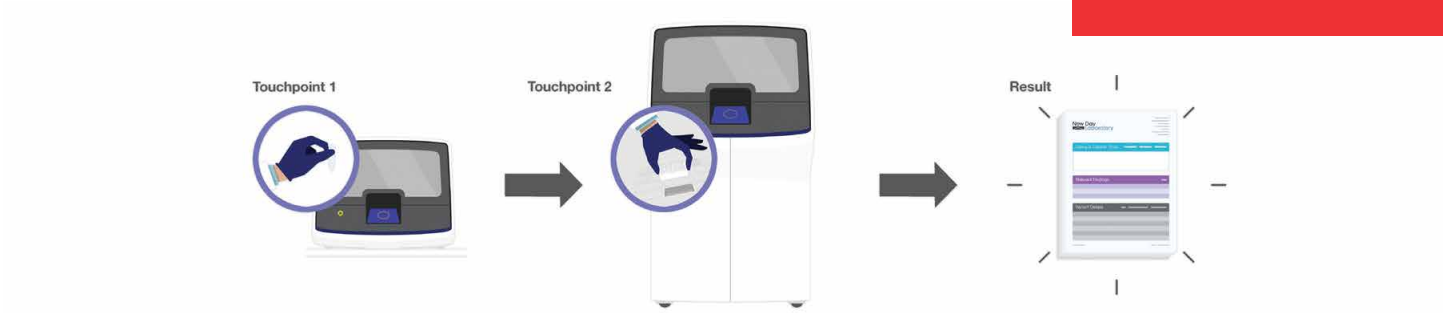


Figure 1: Touchpoint 1—(1) nucleic acid (NA) extraction, (2) NA quantification, (3) sequencing sample plate preparation, and (4) storage NA plate preparation; Touchpoint 2—(1) library preparation, (2) templating, (3) sequencing, and (4) analysis.

The Oncomine Precision Assay analyzes 78 variants, including mutations (45), CNVs (14), and fusion variants (19), across 50 key genes. Included are tumor suppressor genes such as *TP53*, cancer drivers, and resistance mutations. Content has been carefully curated to include all relevant targets and also targets of emerging importance in precision oncology clinical research.

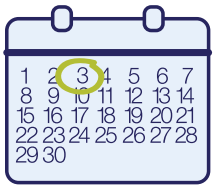
Key benefits of the Oncomine Precision Assay on the integrated Genexus System

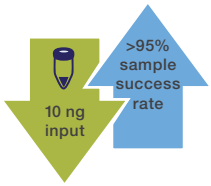
Unmatched ease of use with minimum hands-on time and no expertise required

The set-up-and-go workflow of the Genexus System makes NGS accessible even if your lab is new to the technology. It integrates and automates nucleic acid extraction quantification, library preparation, sequencing, and analysis reporting under a single software ecosystem. With less operational hands-on time (only 20 minutes with two touchpoints) compared to current technologies, the Genexus System can help improve every lab's productivity as well as reduce potential handling errors.

Single-day turnaround—get results in the same amount of time as other techniques, such as IHC

Other NGS technologies, as well as the traditional way of sending out or outsourcing samples, can take weeks to obtain results, which may delay answers. With the Genexus System, you can go from a biological specimen to a report in just one day. In addition, the system has the ability to analyze small sample batches cost-effectively—reducing your need for batching, and empowering you to deliver results faster than ever.





Minimum sample input and maximum sample success rate

Tissue is still the issue in oncology research, with a large proportion of samples having very small amounts of tissue or being of inferior quality. Some NGS technologies require large amounts of sample, leading to more than one out of four samples being unusable for sequencing. The Oncomine Precision Assay, based on Ion Torrent™ AmpliSeq™ HD technology, requires only 10 ng of DNA or RNA, resulting in more than 95% of samples producing sequencing results.

DNA hotspots					CNVs		Inter-genetic fusions		Intra-genetic fusions
AKT1	*CHEK2*	*FGFR3*	*KIT*	*NTRK3*	*ALK*	*FGFR1*	*ALK*	*NTRK1*	*AR*
AKT2	*CTNNB1*	*FGFR4*	*KRAS*	*PDGFRA*	*AR*	*FGFR2*	*BRAF*	*NTRK2*	*EGFR*
AKT3	*EGFR*	*FLT3*	*MAP2K1*	*PIK3CA*	*CD274*	*FGFR3*	*ESR1*	*NTRK3*	*MET*
ALK	*ERBB2*	*GNA11*	*MAP2K2*	*PTEN*	*CDKN2A*	*KRAS*	*FGFR1*	*NUTM1*	
AR	*ERBB3*	*GNAQ*	*MET*	*RAF1*	*EGFR*	*MET*	*FGFR2*	*RET*	
ARAF	*ERBB4*	*GNAS*	*MTOR*	*RET*	*ERBB2*	*PIK3CA*	*FGFR3*	*ROS1*	
BRAF	*ESR1*	*HRAS*	*NRAS*	*ROS1*	*ERBB3*	*PTEN*	*MET*	*RSPO2*	
CDK4	*FGFR1*	*IDH1*	*NTRK1*	*SMO*			*NRG1*	*RSPO3*	
CDKN2A	*FGFR2*	*IDH2*	*NTRK2*	*TP53*					

Figure 2. Oncomine Precision Assay gene list.

Find out more at **oncomine.com/genexus** or contact your Thermo Fisher Scientific representative.