

Torrent Suite Assay Development Software for the Ion PGM Dx System

Secure, powerful, and streamlined next-generation sequencing for clinical research

The Ion PGM™ Dx System with Software Pack v5.0 or higher empowers your clinical laboratory with a combined-functions next-generation sequencing (NGS) platform, offering both the secure Torrent Suite™ Dx Software for *In Vitro* Diagnostic (IVD) use* and the Torrent Suite™ Assay Development Software** for greater system utility to help advance clinical research.



Key benefits for clinical research environments

- Combined-functions software offers multiple applications on a single NGS system, helping you better manage capital equipment budgets and limited laboratory space
- Audit trail functionality enables electronic record keeping of all actions made to samples as they are processed in the workflow
- Electronic signature capability offers assurance that data entry and sign-off are performed by authorized personnel only
- Reagent and chip tracking capabilities help minimize manual record keeping of consumable lot numbers, usage start, and expiration dates
- Automatic QC pass/fail reporting helps save time by enabling you to quickly assess the quality of sequencing before moving forward with further sample processing steps
- Compatibility with many LIMS solutions helps you integrate the Ion PGM Dx System into your lab with ease

NGS is an indispensable tool, enabling the simultaneous interrogation of hundreds of genes and biomarkers to accurately and affordably generate genetic information. The Ion PGM Dx System delivers the speed and simplicity of the Ion Torrent™ platform, combined with key workflow advantages designed specifically for regulated laboratory environments and *in vitro* diagnostic applications.

Easy-to-use, streamlined software

Torrent Suite Assay Development Software achieves its unique flexibility and ease of use by integrating functionalities from two key Ion Torrent™ software products: Torrent Suite™ Software and Ion Reporter™ Software. By combining operating system features, as well as primary and secondary data analysis, Torrent Suite Assay Development Software has capabilities to run assays and analyze the resulting data (Figure 1). With Torrent Suite Assay Development Software, there is no need for clinical researchers to switch back and forth between two separate software products on separate servers—with the Ion PGM Dx System, all the software functionalities needed

for clinical research are now integrated into one package (Figure 2).

More applications and preloaded run templates to advance precision genomics research

Torrent Suite Assay Development Software enables clinical researchers to run a broad range of preset run parameters to further their development and optimization efforts in numerous research application areas, such as germline and somatic DNA assays, RNA fusions, and more (Figure 3). With Torrent Suite Assay Development Software, users may analyze DNA or RNA from a wide range of sample types, including blood or other tissues; formalin-fixed, paraffin-embedded (FFPE) samples; bacterial cultures; and swabs. A number of commonly used run templates come preloaded in the Torrent Suite Assay Development Software (Figure 4). Users who need ultimate flexibility to design and optimize their own run templates can utilize the customization functionality of the “Generic Sequencing Application” file.

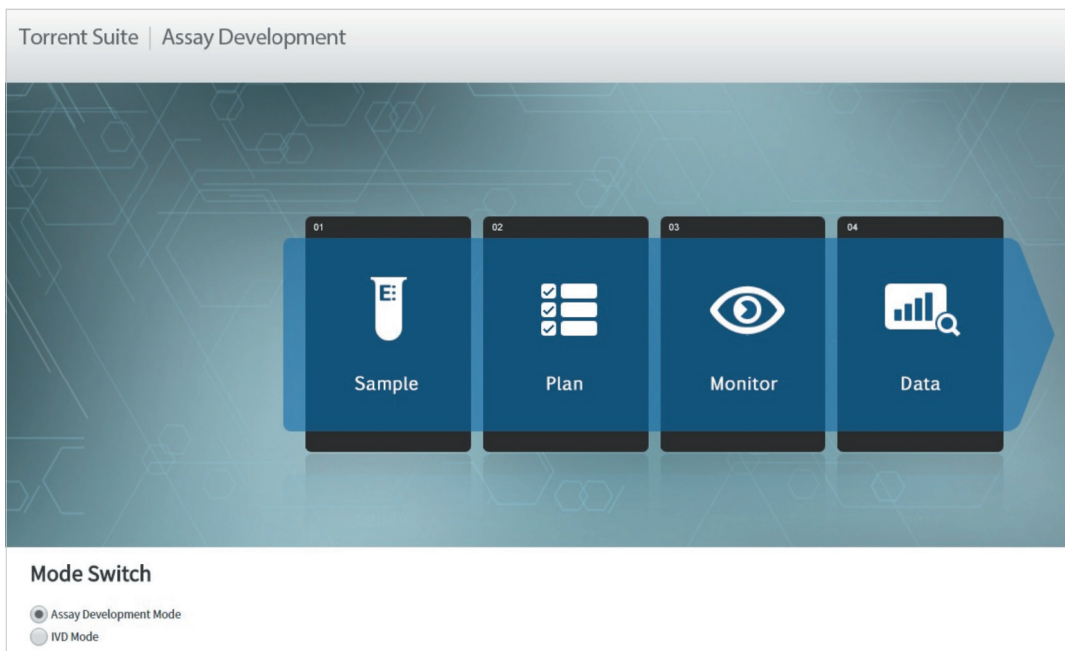


Figure 1. Assay Development Software front page with user login and mode switch functionality.

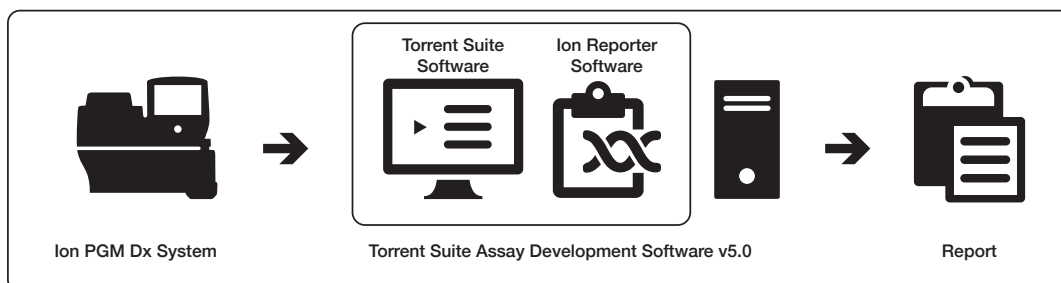


Figure 2. Streamlined workflow from sample sequencing to data analysis and reporting.

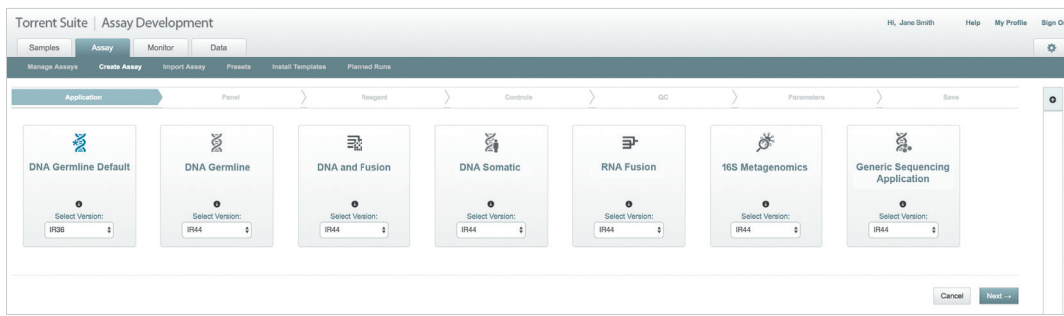


Figure 3. A variety of assay application templates.

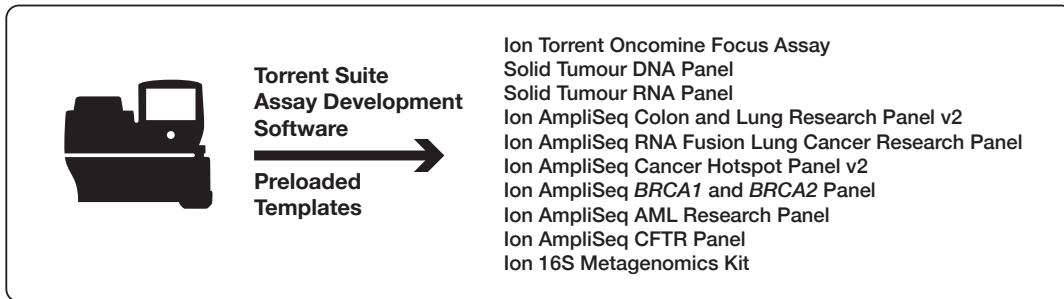


Figure 4. Preloaded templates available in Torrent Suite Assay Development Software.

A report for every sample

Torrent Suite Assay Development Software tracks each sample analyzed, automatically generating a report for every run. The report template is customizable, allowing clinical researchers to tailor report outputs to display exactly the information needed (Figure 5). Reports may contain details such as the sample ID, as well as its condition, type, source, collection time, and descriptions of tests performed on the sample. In addition, reports may show results of analyses, such as the presence or absence of variants, gene fusions, and CNVs.

Torrent Suite Assay Development Software is specially designed to streamline instrument setup and operation with subsequent data analysis. As such, it incorporates features that support a future transition to IVD mode, helping clinical researchers to organize important details from start to finish. Reports integrate electronic signature and audit trail features to assist clinical researchers with regulatory compliance or laboratory ISO accreditation requirements, and an automatic QC pass/fail feature helps maintain high performance standards. Torrent Suite Assay Development Software is also compatible with many laboratory information management systems (LIMS) to offer researchers streamlining solutions for data generation and analysis.

ThermoFisher Scientific		Sequencing Lab Report				
180 Oyster Point Boulevard South San Francisco, CA 94080 Tel: +1 650 576 1900 Fax: 1 650 576 1949 customerservice@thermofisher.com https://www.thermofisher.com		Date: 2016-01-20				
Sample ID: Sample1 Collection Date: 2016-01-20						
Sample Details						
* Sample ID: Sample1	* Gender: Unknown	%Necrosis:				
* Sample Condition: Moderate	* Receive Time: 2016-01-20 16:35	%Cellularity:				
* Sample Type: FFPE	Reference Interval:					
* Collection Date: 2016-01-20	Sample Source: Tissue					
Test Description						
Oncomine Focus Assay detects and annotates low frequency somatic variants (SNPs, InDels, CNVs) from targeted DNA libraries, as well as gene fusions from targeted RNA libraries, from the Oncomine Focus Assay v1 (using Ion AmpliSeq technology).						
Analytical Test Results Summary						
Variant Present						
COSM778, COSM19940, COSM1304, COSM24842, COSM13786, COSM24802, COSM564, COSM736, COSM6239, COSM52975, COSM21338, COSM4867, COSM14060, COSM5677, COSM11865, COSM775, COSM38056, COSM28053, COSM6224, COSM6223, COSM691, COSM29803, COSM39804, COSM554, COSM12500, COSM700, COSM35912, COSM546, COSM11590, COSM22415, COSM28746, OM3157, COSM4959, COSM977, COSM5662, COSM739, COSM29633, COSM754, COSM13146, COSM6213, COSM21683, COSM5661, COSM737, COSM11326, COSM715, COSM5667, COSM716, COSM1420864, COSM31765, COSM584, COSM36904, COSM36906, COSM36903, COSM483, COSM216037, COSM1251412, COSM21687, COSM965, COSM21690, COSM769, COSM33733, COSM521, COSM721, COSM763, COSM1048, COSM471, COSM760, COSM1296, COSM21651, COSM476, COSM52969						
Gene Fusion Present						
RET, ROS1						
CNV Present						
None						
Analytical Test Result Detail						
Variant						
Gene Symbol	Hotspot ID	Test Result	Locus	Type	Genotype	Ref
NRAS	COSM584	Pos	chr1:11526529	snv/mnv	TGTCG	TC
NRAS	COSM564	Pos	chr1:11528747	snv/mnv	CC/TC	CC
ALK	COSM28036	Pos	chr2:29436644	snv/mnv	C/T	C
ALK	COSM28055	Pos	chr2:2944695	snv/mnv	G/T	G
IDH1	COSM28746	Pos	chr2:20911312	snv/mnv	CG/TC	CG
CTNNB1	COSM5677	Pos	chr3:4126101	snv/mnv	C/G	C
CTNNB1	COSM5662	Pos	chr3:4126113	snv/mnv	C/T	C
CTNNB1	COSM5664	Pos	chr3:4126124	snv/mnv	A/G	A
CTNNB1	COSM5667	Pos	chr3:4126137	snv/mnv	CTCTAG/TCTGAG	CTCTAG
PK3CA	COSM754	Pos	chr3:17891553	snv/mnv	T/A	T
PK3CA	COSM757	Pos	chr3:17891780	snv/mnv	T/C	T
PK3CA	COSM759	Pos	chr3:17896074	snv/mnv	C/G	C
PK3CA	COSM760	Pos	chr3:17896082	snv/mnv	GA/AA	GA
PK3CA	COSM763	Pos	chr3:17896091	snv/mnv	G/A	A
PK3CA	COSM1420864	Pos	chr3:17896098	snv/mnv	A/G	A
PK3CA	COSM778	Pos	chr3:17898860	snv/mnv	A/C	A
PK3CA	COSM769	Pos	chr3:17897827	snv/mnv	G/T	G
Laboratory Director: Lab Directort CLIA/CAP Number: CLP12345						
Report generated by Life Technologies Torrent Suite Assay Development Software v5.0 Disclaimer: For Research Use Only. Not for use in diagnostic procedures. Not approved/Cleared by FDA.						
			iontorrent by Thermo Fisher Scientific			

Figure 5. Customizable sample report output.

Key report fields compatible with many LIMS systems:

- Sample ID
- Analysis type
- Sample type, source, and condition
- Collection time
- Audit trail
- QC pass or fail report
- Electronic signature

Consolidated power for the future of clinical research

Moving forward, NGS may enable clinical researchers in the development of new applications supporting the progression of precision genomics. The Ion PGM Dx System with combined functions offers the powerful efficiency of NGS analysis to molecular diagnostic and clinical research laboratories, and aims to provide a practical approach to better manage capital equipment budgets and limited laboratory space.

Ordering information

Product	Cat. No.
Ion PGM Dx System	A25511

System includes:

- Ion PGM Dx Sequencer
- Ion OneTouch Dx Instrument
- Ion OneTouch ES Dx Instrument
- Ion PGM Dx Chip Minifuge
- Ion Torrent Server with Ion PGM Dx Software Pack v5.0
- Wireless Handheld 2D Barcode Scanner
- Ion PGM Dx System consumables
- Ion PGM Dx System Installation and Training Kit
- 1-Year Manufacturing Warranty (Parts & Labor)

To learn more, go to thermofisher.com/pgm-dx



* The Ion PGM Dx System is for *In Vitro* Diagnostic Use. Available in the US and other selected countries globally. Please inquire with your Thermo Fisher Scientific representative for local availability.

** Torrent Suite Assay Development Software is For Research Use Only. Not for use in diagnostic procedures.

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