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Instrument source and specifications for assay developers for the QuantStudio 7 Pro Dx Real-Time PCR System

Instrument model: Applied Biosystems™ QuantStudio™ 7 Pro Dx Real-Time PCR System
(Cat. No. A51188, A51190, A51192, A51225, A51227, A51229)

Manufacturer: Thermo Fisher Scientific

Intended use: The automated QuantStudio 7 Pro Dx Real-Time PCR System is an *in vitro* diagnostic device intended for performing fluorescence-based PCR to detect nucleic acid sequences in human-derived specimens. The QuantStudio 7 Pro Dx Real-Time PCR System is intended for use by trained professionals in conjunction with *in vitro* diagnostic assays.

Thermo Fisher Scientific manufactures the QuantStudio 7 Pro Dx Real-Time PCR System. Thermo Fisher Scientific and its authorized distributors are the sole suppliers of the QuantStudio 7 Pro Dx system.

Technology overview

Real-time PCR

The polymerase chain reaction (PCR) is a powerful technology that amplifies DNA or cDNA targets by 1 million-fold or more. The QuantStudio 7 Pro Dx Real-Time PCR System amplifies targets in the presence of fluorescent dyes, and the instrument captures the fluorescent signal in real time to determine how many copies of DNA are present in each cycle. The ability of the instrument to monitor the quantity of target DNA that is amplified over the course of a run enables very precise, sensitive, and accurate quantitative measurement to determine the number of starting copies in the reaction.

Real-time PCR amplifies DNA exponentially, so the number of DNA molecules in the reaction mixture doubles with each amplification cycle. The increase in the intensity of the fluorescent signal is directly proportional to the amount of PCR product generated in the exponential phase of the reaction. The number of cycles and the fluorescent signal can be used to calculate the quantity of genetic material by comparing the sample amplification data to data from a known standard.

The fluorescent reporters used for real-time PCR include dyes that bind double-stranded DNA (dsDNA), dye molecules that are attached to PCR primers, and probes that hybridize with PCR products during amplification. Fluorescence is plotted against the cycle number, and the real-time PCR instrument generates an amplification plot that shows the accumulation of product over the entire duration of the PCR run.

Real-time PCR for clinical needs

In diagnostic laboratories, molecular tests are integrated into standard practices for identifying and managing diseases, predicting the risk of developing disease or its recurrence, and informing decisions to guide lifestyle choices and behaviors. These tests have become indispensable tools that assist medical practitioners in the quest to positively impact patient outcomes. The use of molecular-based assays will only continue to grow in frequency and importance.

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Real-time PCR research applications

Real-time PCR is very flexible and can be used for the following applications:

- Detecting changes in gene expression
- Genotyping
- Copy number variation analysis
- Pathogen detection, strain typing, and viral load determination
- miRNA profiling
- Protein analysis with proximity ligation assays

Real-time PCR advantages

The advantages of real-time PCR include:

- The ability to monitor the progress of a PCR run in real time on the instrument touchscreen or with the optional desktop software and mobile app
- The ability to accurately measure the amount of amplicon in each cycle
- A wider dynamic detection range than those of other nucleic acid detection methods
- The ability to use the same tube for amplification and detection—eliminates the need for post-PCR manipulation

The QuantStudio 7 Pro Dx system has the following differentiating features and benefits:

System

1. The system includes the instrument, software, user documentation, and an optional desktop or laptop computer. The desktop computer is sometimes referred to as a tower.

Instrument

2. The interchangeable Applied Biosystems™ VeriFlex™ Blocks accommodate 96-well (0.2 mL) plates and 384-well plates.
3. The instrument can be installed without a local computer, and its 34 x 53 x 55 cm (W x D x H) dimensions maximize horizontal and vertical bench space.
4. The block can be accessed from the front of the instrument, and it can be changed via a motorized process by following the on-screen guide.
5. The melt curve for dissociation has steps in the range of $0.015°C \leq \Delta T \leq 3.66°C$.
6. The instrument has a maximum block ramp rate of 6.5°C/sec.
7. The block has a temperature range of 4–99.9°C.
8. The heated cover has a temperature range of 50–110°C.

9. The instrument includes a long-lasting, bright white light–emitting diode (LED) source with a median lifetime of at least 60,000 hours.

10. The instrument has a CMOS imager for data acquisition and collects data for each filter combination in under 2 seconds.

11. The instrument includes a heated lid assembly that heats the top half of the sample plate and provides an effective seal to minimize evaporation of reaction mixtures.

12. The 96-well VeriFlex Block consists of 6 separate Peltier elements. The maximum temperature difference that can be programmed across the block is 25°C. The maximum temperature difference allowed between adjacent blocks is 5°C.

13. The 96-well block is designed to hold 0.2 mL tubes for reaction volumes of 10–100 µL, and the 384-well block is designed for 5–20 µL reaction volumes.

14. The instrument is calibrated with Applied Biosystems™ FAM™, SYBR™ Green I, VIC™, ABY™, NED™, TAMRA™, JUN™, ROX™, MUSTANG PURPLE™, and Cy®5 dyes.

Performance

15. The instrument is designed to complete a 40-cycle real-time PCR run for an Applied Biosystems™ TaqCheck™ fast fluorogenic 5′ nuclease assay in under 35 minutes. The instrument can also run in standard ramping mode with standard chemistry.

16. The instrument includes the Applied Biosystems™ OptiFlex™ System, which combines 6 excitation (450–670 nm) and 6 emission (500–720 nm) filters that enable collection of up to 21 unique wavelength combinations in a single run for multiplexing.

17. The real-time quantitative PCR installation specifications enable the instrument to distinguish 5,000 template copies from 10,000 copies at a 99.7% confidence level.

Dx instrument software (IVD)

18. The instrument software can be accessed through the device touchscreen.

19. The instrument software allows locked IVD use for approved or cleared assays.

20. The software allows plate QC to be performed.

21. The software allows viewing of amplification curves and threshold cycle (C_t) values.

22. Sample results can be viewed on the device touchscreen.

23. The software can send results to an authorized location.

24. The software generates an IVD test report for samples in an uneditable format.

25. The software allows users to install assay definition files and run approved or cleared assays with IVD labels.

26. The instrument software and separate desktop server software provide security, auditing, and e-signature features as well as the ability to maintain centralized settings for multiple units.

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27. The software provides secure access and audit records of all user changes.
28. The software allows sample IDs and controls to be assigned to individual wells.
29. The software helps prevent accidental modification of run or analysis parameters.

Design

30. The instrument is certified by the Nationally Recognized Testing Laboratory (NRTL) and is tested to IEC safety standard 61010-1 and the IEC 60601-1-2 EMC test limit. It is also compliant with WEEE and California Proposition 65.
31. The desktop software includes security and auditing features and can maintain centralized settings for multiple units.

Vendor service and support

32. The instrument is provided with a limited warranty for a period of 12–15 months from the date of shipment (dependent on region). Optional post-warranty service contracts that include on-site repairs the next business day are available.
33. An orientation session is provided by an e-learning module or a trained technical scientist.
34. The vendor can supply all the necessary consumables to perform instrument qualification (IQ), operational qualification (OQ), and performance qualification (PQ).
35. The vendor can provide computer system validation consulting services with flexible and comprehensive audit-style documentation packages that help users reduce risk and comply with regulations and standards.
36. The vendor offers technical support via telephone as well as field application, sales, and service support to help resolve chemistry and instrumentation problems.
37. The vendor provides technical support that can be obtained using the context-sensitive help menu and Smart Help interface on the instrument touchscreen.

For development use

Software

1. The software allows users to run assays with RUO* and IUO** labels for development or clinical studies, respectively.
2. Separate accessory software allows the user to create and manage the definition file for an assay throughout the assay development life cycle.

* For Research Use Only. Not for use in diagnostic procedures.

** For Investigational Use Only. The performance characteristics of this product have not been established.

IVD