

qPCR

Instrument Source and Specifications

The QuantStudio 5 Dx Real-Time PCR System (CE-IVD, IVDR)

Instrument: Applied Biosystems™ QuantStudio™ 5 Dx Real-Time PCR System (CE-IVD, IVDR) (Cat. No. A47326, A47327)

Intended use: The QuantStudio 5 Dx Real-Time PCR System is an *in vitro* diagnostic (IVD) device for fluorescence-based PCR to detect nucleic acid in human-derived specimens.

The QuantStudio 5 Dx Real-Time PCR System is intended for use by trained personnel in a professional environment to run IVD assays.

Manufacturer: Thermo Fisher Scientific

Thermo Fisher Scientific is the manufacturer of the QuantStudio 5 Dx Real-Time PCR System and is the sole supplier, by itself or through its authorized distributors.

Technology overview

Real-time PCR overview

Polymerase chain reaction (PCR) is a powerful technology that amplifies DNA or cDNA targets one million-fold or more. Real-time PCR amplifies the target 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. Monitoring the target quantity over the course of the reaction enables very precise, sensitive, and accurate measurements to determine the number of starting copies.

Real-time PCR amplifies DNA exponentially, so the number of DNA molecules doubles with each amplification cycle. The increase in fluorescence intensity is directly proportional to the amount of PCR product generated in the exponential phase of the reaction. The quantity of genetic material is determined by comparing the fluorescence intensity of the sample to that of a known standard.

Fluorescent reporters used for real-time PCR include dyes that bind to double-stranded DNA (dsDNA) and dyes that are attached to primers or probes that hybridize with PCR products during amplification. Fluorescence intensity is plotted against the cycle number to generate an amplification plot that represents the accumulation of product over the duration of the entire PCR run.

Real-time PCR for molecular diagnostics*

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

- Gene expression analysis
- Genotyping
- Copy number variation analysis
- Pathogen detection, strain typing, and viral load determination
- microRNA profiling
- Protein analysis with proximity ligation assays

Real-time PCR advantages

The advantages of real-time PCR over other methods include:

- The ability to monitor the progress of the PCR run as it occurs in real time (on the instrument touchscreen and through the software client)
- The ability to accurately measure the amount of amplicon during each cycle
- A wider dynamic range of detection than other nucleic acid detection methods
- The use of a single tube for amplification and detection, eliminating post-PCR manipulation

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The QuantStudio 5 Dx system has the following differentiating features and benefits:

System

1. The instrument has CE-IVD certification under the *In Vitro* Diagnostic Regulation (IVDR).
2. The system includes software modes for both test development and IVD workflows.
3. The system includes the instrument, software, user documentation, and a desktop or laptop computer. The desktop computer is sometimes referred to as a tower.

Instrument

4. The instrument dimensions are 27 x 50 x 40 cm (W x D x H) to maximize horizontal and vertical bench space.
5. The block is accessible from the front of the instrument to maximize bench space and is fully motorized.
6. Ramping for dissociation (melting) curve analysis can be done in steps of $0.015^{\circ}\text{C} \leq \Delta T \leq 3.66^{\circ}\text{C}$.
7. The instrument block has a maximum ramp rate of $6.5^{\circ}\text{C}/\text{sec}$.
8. The instrument block has a temperature range of $4\text{--}99.9^{\circ}\text{C}$.
9. The heated cover has a temperature range of $50\text{--}110^{\circ}\text{C}$.
10. The instrument includes a long-lasting, bright white light-emitting diode (LED) with a median lifetime of at least 60,000 hr.
11. The instrument includes a CMOS imager for data acquisition and collects data for each filter combination in <2 sec.
12. 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 the reaction mixture.
13. The 96-well Applied Biosystems™ VeriFlex™ Block has 6 separate thermal zones controlled by Peltier elements. The maximum temperature difference that can be programmed across the block is 25°C . The maximum difference in temperature allowed between adjacent thermal zones is 5°C .
14. The 0.2 mL 96-well block supports reaction volumes of 10–100 μL .
15. The instrument is factory-calibrated with Cy[®]5 dye, Invitrogen™ SYBR™ Green I and ROX™ dyes, and Applied Biosystems™ FAM™, VIC™, ABY™, NED™, TAMRA™, JUN™, and Mustang Purple™ dyes.

Performance

16. The instrument is designed to complete a 40-cycle real-time PCR run for a fluorogenic 5′ nuclease assay with fast chemistry in under 30 min. The instrument can also run in standard ramping mode with standard chemistry.
17. The instrument is designed with Applied Biosystems™ OptiFlex™ technology and has 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.
18. The instrument supports at least two reaction chemistries: fluorogenic 5′ nuclease assays with Applied Biosystems™ TaqMan™ probes and the DNA-binding chemistry of SYBR Green dye.
19. The instrument has real-time quantitative PCR installation specifications to demonstrate that it can distinguish between 5,000 and 10,000 template copies at a 99.7% confidence level.

Diagnostics (Dx) software (IVD)

20. The instrument software allows locked IVD use for cleared or approved assays.
21. The instrument software provides secure access and audit records of all user changes.
22. The instrument software enables sample IDs and controls to be assigned to individual wells.
23. The instrument software helps prevent accidental modification of run and analysis parameters.
24. The software enables users to operate the instrument in either IVD Mode or Test Development (DEV) Mode. Test Development Mode is for Research Use Only.
25. The desktop software includes security and auditing features and can maintain centralized settings for multiple units.

Design

26. The instrument is NRTL TUV SUD–certified to meet UL and CAN/CSA safety standards, EMC-certified to meet IEC Standard 60601-1-2, and compliant with WEEE and with California Proposition 65.

* *In vitro* diagnostic (IVD) usage will depend on the assay developer's cleared or approved application.

Vendor service and support

27. The instrument comes with a limited warranty for a period of 12–15 months from the date of shipment depending on region. Optional post-warranty service contracts that include on-site repairs the next business day are available.
28. An orientation session with a trained technical specialist is included with purchase.
29. The vendor can provide the service and supply all the necessary consumables to perform instrument qualification (IQ), operational qualification (OQ), and instrument performance verification (IPV).
30. The vendor offers telephone technical support and field application, sales, and service support to help resolve chemistry and instrumentation problems. Access to 24/7 technical support is available in some regions.



Learn more at thermofisher.com/quantstudio5dx

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