

IQ/OQ/IPV service for Applied Biosystems real-time PCR systems

No one understands your Applied Biosystems™ instruments better than the people who design, develop, and support them. When you use our qualification service, trained and certified engineers from Thermo Fisher Scientific will help you through your Installation and Operational Qualification (IQ/OQ) and Instrument Performance Verification (IPV) as part of your overall initial and ongoing system validation needs.

Help verify instrument accuracy and reduce your risk and workload

Global standards (e.g., ISO 17025 and ISO 15189) and country-specific regulations (e.g., US FDA 21 CFR Part 11) require documented verification that your instruments are installed and routinely functioning according to their operational specifications. Performing these tests on your own can be complex, time-consuming, costly, and challenging to complete.

Our IQ/OQ/IPV service verifies and records the instrument's ability to meet specified performance criteria after installation, repetitive use, or major service events. The IQ/OQ/IPV service involves comprehensive testing of the complete system using established conditions and known sample characteristics.

Our ability to schedule the IQ/OQ/IPV service at designated intervals according to your requirements reduces your risk of using out-of-compliance systems and lessens your asset-tracking efforts.

A key benefit of this service is to verify the ongoing accuracy and precision of your instrument and to uncover potential problems before you spend valuable time running performance checks following repairs. It is important to have your instruments checked and formally tested regularly, to confirm they are working according to manufacturer's specifications and to identify possible impacts due to normal wear or inadequate user maintenance.

IQ/OQ/IPV tests

Our engineers have extensive experience and knowledge of our instruments and systems. The comprehensive IQ/OQ/IPV service includes the following tests:

- Instrument optical alignment
- Instrument average cycle time and standard deviation
- Sample block temperature accuracy
- Sample block temperature uniformity
- Heated cover temperature accuracy
- Optional robotic performance
- Background signal performance
- Pure dye calibration performance
- Verifying the instrument is capable of discriminating between two sample populations with a 2-fold difference in copy number, using the Applied Biosystems™ TaqMan® RNase P plate

Recommended times for IQ/OQ/IPV

To help ensure optimal performance of your systems and to support instrument compliance, we recommend that you have IQ/OQ/IPV service performed at the following times:

- At instrument installation
- During semi-annual instrument calibration activities
- On a periodic basis in accordance with your standard operating procedures (SOPs)
- After repair or replacement of critical components
- After major repair or relocation
- After functionality is added to the system, such as hardware or software upgrades

The IQ/OQ/IPV service is performed by a certified Thermo Fisher Scientific field service engineer and includes recorded evidence that the system meets specified performance criteria using certified service tools, traceable and revision-controlled test procedures, and certified chemical test kits. Travel and labor of the field service engineer are also included.

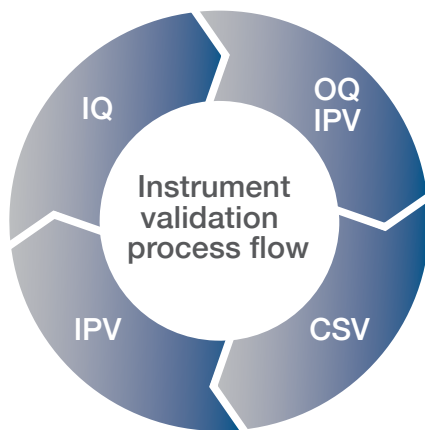
Pre-IQ/OQ/IPV recommendations

To help maximize the effectiveness of your IQ/OQ/IPV service, we recommend you do the following prior to the service:

- For instruments that require a routine planned maintenance (PM) procedure, it is advisable to complete the PM immediately before a periodic IQ/OQ/IPV to ensure instrument maintenance is up to date
- Review and approve the procedures in accordance with your organizational requirements
- Check that the Applied Biosystems™ software that will be used to calculate results for the IQ/OQ/IPV test procedures is qualified or validated according to your documented SOPs

Get more value out of your service plans

We offer single-event services for IQ/OQ/IPV. After an IQ/OQ/IPV, choose our AB Complete service plan, which includes qualification after every maintenance and major repair event.



IQ/OQ/IPV is an integral part of the total instrument validation process.

Ordering information

| Product | Cat. No. | |
|--|----------------|-----------------|
| | IQ/OQ material | OQ/IPV material |
| 7300 Real-Time PCR System | 4357197 | 4365569 |
| 7500 Real-Time PCR System | 4357196 | 4365570 |
| 7500 Fast Real-Time PCR System | 4365572 | 4365571 |
| 7900HT Fast Real-Time PCR System, Standard 96-Well | 4363054 | 4346879 |
| 7900HT Fast Real-Time PCR System, Fast 96-Well | 4363050 | 4363053 |
| 7900HT Fast Real-Time PCR System, 384-Well | 4363052 | 4346880 |
| 7900HT Fast Real-Time PCR System, Low Density Array | 4363051 | 4346878 |
| StepOne Real-Time PCR System | 4413678 | 4415178 |
| StepOnePlus Real-Time PCR System | 4415138 | 4415318 |
| ViiA 7 Real-Time PCR System, 96-Well | 4462130 | 4462132 |
| ViiA 7 Real-Time PCR System, 384-Well | 4457830 | 4457832 |
| ViiA 7 Real-Time PCR System, TaqMan Array Card | 4460884 | 4460885 |
| QuantStudio 12K Flex Real-Time PCR System, 96-Well | 4471076 | 4472010 |
| QuantStudio 12K Flex Real-Time PCR System, Fast 96-Well | 4471327 | 4471982 |
| QuantStudio 12K Flex Real-Time PCR System, 384-Well | 4471980 | 4472011 |
| QuantStudio 12K Flex Real-Time PCR System, TaqMan Array Card | 4471981 | 4472012 |
| QuantStudio 12K Flex Real-Time PCR System, OpenArray | 4472009 | 4471983 |
| QuantStudio 7 Flex Real-Time PCR System, 96-Well | 4487357 | – |
| QuantStudio 7 Flex Real-Time PCR System, Fast 96-Well | 4487015 | – |
| QuantStudio 7 Flex Real-Time PCR System, 384-Well | 4487008 | – |
| QuantStudio 7 Flex Real-Time PCR System, TaqMan Array Card | 4487002 | – |
| QuantStudio 6 Flex Real-Time PCR System, 96-Well | 4487005 | – |
| QuantStudio 6 Flex Real-Time PCR System, Fast 96-Well | 4487010 | – |
| QuantStudio 6 Flex Real-Time PCR System, 384-Well | 4487006 | – |
| QuantStudio 5 Real-Time PCR System, 96-Well | A28482 | A28487 |
| QuantStudio 3 Real-Time PCR System, 96-Well | A28480 | A28485 |

To learn more about our compliance services, please contact your local Thermo Fisher Scientific sales representative or email us at compliancesales@thermofisher.com

Find out more at [thermofisher.com/complianceservices](https://www.thermofisher.com/complianceservices)

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