OQ/IPV Service for Applied Biosystems Real-Time PCR Systems

7300, 7500, 7500 Fast, 7900HT Fast, StepOne™ and StepOnePlus™ 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, Applied Biosystems trained and certified engineers will help you through your Operational Qualification/Instrument Performance Verification (OQ/IPV) as part of your overall system validation.

Help Ensure Instrument Accuracy and Reduce Your Risk and Workload

In regulated industries, compliance with government, international and clinical standards requires documented verification that your instruments are installed and routinely functioning according to their operational specifications. The process can be complex, time-consuming, costly, and challenging to ensure complete.

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

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

A key benefit to this service is to ensure the ongoing accuracy and precision of the 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 continued high-quality performance and identify possible impact due to normal wear or inadequate user maintenance.

Pre-OQ/IPV Recommendations

To help maximize the effectiveness of your 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 OQ/IPV to ensure instrument maintenance is up to date
- Review and approve the procedures in accordance with your organizational requirements
- In GLP and GMP laboratories, check that the Applied Biosystems software that will be used to calculate results for the OQ/IPV test procedures is qualified or validated according to your documented standard of operation*

OQ/IPV Tests

Applied Biosystems engineers have unmatched experience and knowledge of our instruments and systems.

Our comprehensive OQ/IPV service tests the following:

- Optical verification and pure-dye calibration
- On-board Thermal Cycler verification tests including:
  - Temperature accuracy for heated cover and thermal cycler block
  - Verification of thermal cycler block temperature uniformity
- Complete system verification and statistical analysis using Raze P plate to verify Applied Bios stems specifications are routinely met—defined as the ability to distinguish two-fold discrimination between 5,000 and 10,000 genome equivalents with a 99.7% confidence level

Recommended Times for OQ/IPV

To help ensure optimal performance of your systems and to support compliance, we recommend that you have an 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 SOPs
- After service or replacement of the following system components
  - Optics Assembly replacement or alignment
  - Camera Assembly replacement or alignment
  - Lens Assembly replacement
  - Filter Assembly replacement
  - Laser replacement (for 7900HT Fast Real-Time PCR System)
- After relocating major relocations
- After functionality is added to system, such as a hardware or software upgrade
- Before a previously-installed system will be used in a regulated test environment for the first time (e.g. an instrument used for basic research transitions for use in clinical trials testing)

The OQ/IPV service is performed by an Applied Biosystems certified 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 Applied Biosystems field service engineer is also included.

Contact Us

To help you manage your compliance risk and your annual budget, we offer our Applied Biosystems OQ/IPV services as part of our comprehensive AB Complete Service Plan. Our OQ/IPV services are also available on an à la carte basis to allow in you to supplement in-house abilities based on your laboratory needs and budget.

To learn more about our Compliance Services, please visit info.applied biosystems.com/services, contact your local Service Sales representative, or email at complianceservices@appliedbiosystems.com.

ORDERING INFORMATION

IQOQ Material

Description	Part Number
7300 Real-Time PCR System	4357197
7500 Real-Time PCR System	4357196
7500 Fast Real-Time PCR System	4365572
7900HT Fast Real-Time PCR System, Standard 96-well block	4363054
7900HT Fast Real-Time PCR System, Fast 96-well block	4363050
7900HT Fast Real-Time PCR System, 384-well block	4363052
7900HT Fast Real-Time PCR System, Low Density Array	4363051
StepOne™ Real-Time PCR System	4413678
StepOnePlus™ Real-Time PCR System	4415138

OQ/IPV Material

Description	Part Number
7300 Real-Time PCR System	4365569
7500 Real-Time PCR System	4365570
7500 Fast Real-Time PCR System	4365571
7900HT Fast Real-Time PCR System, Standard 96-well block	4346879
7900HT Fast Real-Time PCR System, Fast 96-well block	4363053
7900HT Fast Real-Time PCR System, 384-well block	4346880
7900HT Fast Real-Time PCR System, Low Density Array	4346878
StepOne™ Real-Time PCR System	4415178
StepOnePlus™ Real-Time PCR System	4415318

*For 7300, 7500, and 7500 Fast Real-Time PCR Systems, you must be using SDS v1.4/1.5 FDA 21 CFR Part 11 or AccuSEQ software in order to be able to demonstrate the ability to use electronic records or signatures. StepOne™ and StepOnePlus™ Real-Time PCR Systems do not currently utilize a software version that can be used or validated to support electronic records and signatures.

Printed in the USA. 01/2010 Publication 138PB10-03

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