

IQ/OQ/IPV service for the ProFlex PCR System

No one understands your Applied Biosystems™ instruments better than the people who design and develop them. When you use our qualification procedures as part of your overall system validation, it can help you save the time and effort of writing test procedures and help ensure your instrumentation meets the manufacturer's specifications.

Help ensure instrument accuracy and reduce your risk

Compliance with government and international standards requires documented verification that your instruments are installed and functioning according to the manufacturer's specifications. The process can be complex, time-consuming, and costly. The installation and operational qualification (IQ/OQ) and instrument performance verification (IPV) test procedures help ensure the following at the time that the performance verification tests are conducted:

- The instrument is installed and operating according to the documented specifications
- The service documents shipped with the instrument and the components of the system are complete
- All shipped materials were received
- Upgrades are compatible with the system configuration
- The instrument provides the expected results from a comprehensive suite of tests

The IQ/OQ/IPV service package includes a bound, printed copy of test procedures that can be used to support the IQ/OQ being performed by your own staff. The package does not include consumables required to perform the procedures. Instruments should be checked and formally tested regularly to confirm continued expected performance and to identify possible consequences of normal wear or inadequate user maintenance.

Our comprehensive IQ/OQ/IPV test procedures include the following:

- Order and system verification, confirming that the instrumentation ordered was received and fully documented
- Documentation verification, confirming that documentation is recorded
- Installation verification, confirming that the installation and configuration meet specifications
- Firmware and identification verification, documenting current versions and verifying compatibility
- Maintenance verification, confirming that SOPs for maintenance exist
- Customer training verification, confirming that customers are trained on the basic operation and use per Applied Biosystems™ specifications
- Internal certifications for test equipment and field service engineers
- A written record, documenting that instruments are installed in a suitable environment for operation
- Hardware verification, confirming that it functions according to Applied Biosystems™ specifications upon installation

Recommended times for IQ/OQ/IPV

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

- At instrument installation or reinstallation
- On a periodic basis in accordance with your SOPs
- After functionality is added to the system, such as firmware or software upgrades

The IQ/OQ/IPV service should be performed by a certified field service engineer or a qualified member of your staff.

Upon completion of the service, you should receive recorded evidence that the system meets specified performance criteria and has undergone traceable and revision-controlled test procedures.

Pre-IQ/OQ/IPV checklist

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

- Review and approve the procedures in accordance with your organizational requirements
- Ensure that the products needed for the procedure have been ordered and that user documentation is available
- Ensure that your laboratory meets the site preparation requirements detailed in the IQ/OQ/IPV procedures

Get more value out of your service plans

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

Ordering information

Product	Quantity	Cat. No.
ProFlex PCR System, 96-Well	1 system	4484075
ProFlex PCR System, 3 x 32-Well	1 system	4484073
ProFlex 96-Well Block	1 block	4483637
ProFlex 3 x 32-Well Block	1 block	4483638
ProFlex PCR System, Dual 96-Well	1 system	4484076
ProFlex PCR System, Flat Block	1 system	4484078
ProFlex Dual 96-Well Block	1 block	4484071
ProFlex Flat Block	1 block	4474074

To find out more about our compliance services, please contact your local sales representative, or email compliancesales@thermofisher.com.

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

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