

IQ/OQ/IPV service for genetic analyzers

Applied Biosystems 310, 3100, 3100-Avant, 3130, 3130xl, 3500, 3500xL, 3730, and 3730xl Genetic Analyzers

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

In regulated industries, compliance with government, international, and laboratory 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 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 for specific applications, such as human identification.

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 help ensure 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 impact due to normal wear or inadequate user maintenance.

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 systems that require routine planned maintenance (PM), we advise you to complete the PM immediately before an IQ/OQ/IPV to ensure system 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 standard operating procedures (SOPs)

IQ/OQ/IPV tests

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

For Applied Biosystems™ ABI PRISM™

310 Genetic Analyzer

- Optical verification
- 4- or 5-dye matrix standard test
- System performance verification using Applied Biosystems™ sequencing standards
 - DNA sequencing test to ensure accuracy specification at 580 bases
 - Fragment analysis test to ensure standard deviation and average peak height
- Verification that the GeneMapper™ Allelic Ladder meets peak height and separation expectations

For Applied Biosystems™ 3130, 3130xl, 3100, 3100-Avant, 3500, 3500xL, 3730, and 3730xl Genetic Analyzers

- System verification
- Software identification
- Maintenance verification
- Power-on verification
- Subsystem function verification
 - Laser output certification
 - Laser beam overlap, intensity, signal intensity variation
 - CCD performance verification, normalization
- Performance qualification (system operation verification)
 - Identify the capillary array, polymer, anode buffer, and cathode buffer
 - Run spatial calibration
 - Run spectral calibration
 - Verify contiguous read length (CRL)

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 annual instrument calibration activities
- On a periodic basis in accordance with your SOPs
- After service or replacement of the following critical components:
 - Optics assembly
 - Camera assembly
 - Lens assembly
 - Filter assembly
 - Oven assembly
 - Pump assembly (replacement and/or calibration)
 - Autosampler assembly (replacement and/or alignment)
- After major relocations
- After functionality is added to the system, such as hardware or software upgrades

The IQ/OQ/IPV service is performed by a 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 field service engineer are also included.

To learn more about our instrument 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**

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