OQ/IPV Service for Genetic Analyzers

ABI PRISM® 310, 3100, 3100-*Avant*, and Applied Biosystems 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 Compliance Services, 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 for specific applications, such as Human Identification.

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 systems that require routine Planned Maintenance (PM), we advise you to complete the PM immediately before an OQ/IPV to ensure system maintenance is up to date
- Review and approve the procedures in accordance with your organizational requirements
- In GLP, GMP, and GCP 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 may test the following:

For 310 Genetic Analyzers

- 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 allelle standard deviation and average peak height[1]
- Verify the HID GeneMapper® Allelic Ladder meets peak height and separation expectations

For 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 Verification
  - — 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 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 annual instrument Calibration activities
- On a periodic basis in accordance with your SOPs
- After service or replacement of the following critical components:
  - — Optics assembly replacement and/or alignment
  - — Camera assembly replacement and/or alignment
  - — Lens assembly replacement
  - — Filter assembly replacement
  - — Oven assembly replacement
  - — Pump assembly replacement and/or calibration
  - — Autosampler assembly replacement and/or alignment
- After 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.appliedbiosystems.com/services, contact your local Service Sales representative, or email at complianceservices@appliedbiosystems.com.

[1]For HID, IPV GeneMapper® Allelic Ladder Standard is used.

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Headquarters
850 Lincoln Centre Drive | Foster City, CA 94404 USA
Phone 650.638.5800 | Toll Free 800.327.3002
www.appliedbiosystems.com

International Sales
For our office locations please call the division headquarters or refer to our Web site at
www.appliedbiosystems.com/about/offices.cfm