

Re-Qualification-OQ/IPV Services for AB SCIEX Hybrid Triple Quadrupole/Linear Ion Trap Mass Spectrometers

No one understands your AB SCIEX instruments better than the people who design, develop, and support them. When you use AB SCIEX Qualification Services, our 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

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

AB SCIEX OPERATIONAL QUALIFICATION/INSTRUMENT PERFORMANCE VERIFICATION (OQ/IPV) SERVICE

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

We help confirm that the instrument hardware, firmware, and software revisions meet AB SCIEX tested and approved compatibility requirements.

A key benefit to the Re-Qualification-OQ/IPV service is to ensure the accuracy and precision of the instrument. 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.

OQ/IPV RECOMMENDATIONS

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

- Review and approve the procedures in accordance with your organizational requirements
- Verify that the site requirements as outlined in the system site preparation guide are met or continue to be met
- Check that the AB SCIEX software that will be used to calculate results for the OQ/IPV test procedures is qualified according to your documented standard of operation
- 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

SUPPORTED AB SCIEX QTRAP® MASS SPECTROMETERS

We offer Re-Qualification-OQ/IPV services for the following QTRAP® mass spectrometers:

- AB SCIEX TripleTOF™ 5600 System
- AB SCIEX QTRAP® 5500 System
- 4000 QTRAP® LC/MS/MS System
- 3200 QTRAP® LC/MS/MS System
- QTRAP® LC/MS/MS System

OQ/IPV TESTS

AB SCIEX engineers have unmatched experience and knowledge of our instruments and systems. To ensure linearity, sensitivity and accurate performance, our comprehensive

Re-Qualification-OQ/IPV service tests include the following:

- Quadrupole-mode operation for sensitivity, resolution, and extended mass range resolution in both positive and negative ion modes. Note that the masses tested for each instrument are based on the mass range specification for the instrument.
- Tandem MS mode (MS/MS) for sensitivity
- Linear Ion Trap functionality testing for sensitivity and resolution at all scan speeds in negative and positive polarities
 - 250 amu/sec scan speed
 - 1000 amu/sec scan speed
 - 4000 amu/sec scan speed
- MS/MS/MS Trap functionality in positive mode
- Ion source purchased with the system (plus optional specified sources)

RECOMMENDED TIMES FOR OQ/IPV

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

- At instrument installation
- On a periodic basis in accordance with your standard operating procedures (SOPs)
- After a major repair such as replacement of a quadrupole or other hardware/electrical component critical to the performance of the system, or performance of any service procedure that the AB SCIEX certified field service engineer deems is critical to the performance of the system

- After relocating an instrument to another laboratory
- After functionality is added to the system, such as a hardware or software upgrade
- After any software change that affects system security, data integrity, or administrative controls
- 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 research)

The OQ/IPV service is performed by an AB SCIEX 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 AB SCIEX field service engineer is also included.

CONTACT US

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

For more information on AB SCIEX Compliance Services, contact your local AB SCIEX Sales representative or email: complianceservices@absciex.com

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