

Instrument Installation and Operational Services

Installation Qualification (IQ) and Operational Qualification (OQ) services are performed by our Field Service Engineers and are critical to ensuring that your instrument is properly installed, and operating according to specifications. Luminex offers standard IQ/OQ for new instruments, and Yearly OQ to confirm system reliability of any xMAP® instrument in your laboratory.

Each service includes a final protocol document which can be used to fulfill a broad range of regulatory and quality requirements.

Why are these services needed?

- You will benefit from the expertise of engineers that know your instrument inside and out.
- IQ/OQ protocols are the evidence you need to prove that your instrument is properly installed, and operating according to specifications.
- Yearly OQ provides additional assurance that the system will produce precise and reliable assay results, even after being repaired or moved to a different location in the lab.

IQ/OQ

The IQ service confirms that the instrument, operating software, and other accessories have been supplied as ordered and that the system has been installed per Luminex guidelines.

During the IQ, we will:

- Verify that the installation site meets the environmental requirements for the instrument (bench space, power, temperature, etc.)
- Review the hazards and safety precautions pertinent to the use of the Luminex system
- Provide installation checklists for the software, and hardware (including tubing, cables, and accessories)
- Document preventative maintenance (PM) requirements for inclusion in the PM schedule

Once the system is installed, the OQ service will be conducted to demonstrate that the system is functioning according to its operational specifications.

The OQ will:

- Test all components of the Luminex system for proper functionality
- Challenge instrument specifications using calibration and performance verification operations



Yearly OQ

The Yearly OQ service verifies lab environmental fitness for optimal system performance and is highly recommended to confirm system reliability on an annual basis or after a renovation event or instrument repair. Yearly OQ offers additional services which are not a part of routine PM.

Yearly OQ includes:

- All standard OQ verifications, plus some additional IQ parameters
- Identifying environmental factors that may affect system performance such as—electrical changes in the lab or other parts of the facility, HVAC maintenance, facility room renovations, or changes to bench top and capital equipment configurations within the lab
- Checks to ensure that maintenance has been adequately performed by lab personnel

When combined with routine PM, Yearly OQ can help to ensure that your system will produce precise and reliable assay results.

Ordering Information

| System | Initial IQ/OQ Part Number | Yearly OQ Part Number |
|-------------------|---------------------------|-----------------------|
| MAGPIX® | VP-MAGPIX-XPON4.2 | VP-MAGPIX-XPON-IQOQ |
| Luminex® 100/200™ | VP-XPONENT3.1 | VP-LX-XPON-IQOQ |
| FLEXMAP 3D® | VP-FM3D-XPON4.2 | VP-FM3D-XPON-IQOQ |

All IQ/OQ and Yearly OQ services are performed solely by experienced Luminex Field Service Engineers. Please contact your Luminex representative for information on how to order this service.

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complexity simplified.

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