

Illumina instrument qualification services

Qualify Illumina sequencing systems with professional services to ensure optimal instrument performance

- Maximize productivity and improve turnaround time by reducing service calls and instrument down time
- Maintain regulatory compliance with audit-quality reports documenting data quality and performance
- Add instrument qualifications to any service event or a la carte with flexible quality service plans



Why qualify Illumina instruments?

Quality system implementation is vital to maintaining effective and efficient lab operations. Proactive planning and integration of a quality process not only mitigate the risk of noncompliance but can save time and reduce costs. It is important for laboratories to maintain compliance by adopting well-documented qualification protocols for their next-generation sequencing (NGS) instruments.

At Illumina, we understand the changing regulatory landscape and strive to provide solutions to help our customers comply with standards and regulations. Illumina qualification services make sure that each Illumina instrument is tested, validated, and operating according to specifications. Additionally, our qualification services help accomplish regulatory compliance by providing the necessary documentation to satisfy internal or external reviews. For laboratories operating in a purely research environment, Illumina instrument qualification services can provide peace of mind, reduce reactive service calls, and minimize instrument down time (Figure 1).

Illumina qualification services

Illumina qualification reports can be used to satisfy the specific performance and reporting needs of both clinical and research laboratories. Our Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification services (Table 1) have been developed after conducting rigorous experiments for each Illumina instrument. These procedures involved testing and validation of each critical component, setting cut-off metrics, and verifying these metrics to confirm operation and performance in accordance with Illumina specifications. Certified engineers perform IQ, OQ, and PQ services onsite and deliver a signed, audit-ready report for review (Figure 2).

Illumina instrument qualification services reduce service calls and instrument down time and deliver audit-quality reports to provide ongoing assurance of exceptional data quality and instrument performance.



Figure 1: Benefits of Illumina instrument qualification services.

Installation Qualification service

During IQ, a trained engineer confirms that the latest supported firmware and software versions were installed, verifies instrument setup and accessory logistics, checks that physical and environmental safety conditions are met, and provides a signed, audit-ready, digital document.

Operational Qualification service

OQ service evaluates the individual system components, including motion, optics, fluidics, and thermal qualifications, to make sure they are operating correctly and within Illumina specifications. The OQ protocol was developed and validated in Illumina labs and is updated after each instrument hardware and software release, so labs receive the most up-to-date service.

Performance Qualification service

The PQ service helps make sure that the instruments are performing according to validated Illumina performance specifications. PQ includes a PhiX control data run, including projected yield total. Results of the control run are evaluated for data quality and compared against expected results. Additionally, the overall system performance is evaluated with an actual run. Like the OQ protocol, the PQ protocol is updated after each instrument hardware and software release, so labs receive the most up-to-date service.

Flexible service plans

Illumina qualification services are available in two flexible options for convenience. Services can be added-on to existing service events or purchased a la carte as needed.

Table 1: Illumina instrument qualification services

Qualification service	Service description	Recommended qualification interval	Event-specific service
IQ service	Provides documented verification that the instrument is installed according to Illumina specifications and safety regulations	During initial installation After relocation and reinstallation	Before first-time use After general changes to lab environment (eg, remodeling, construction, electrical disruptions)
OQ service	Follows a comprehensive, well-defined protocol to make sure that the system components, including motion, optics, fluidics, and thermal qualifications, are functioning according to Illumina preset and validated operational specifications	During initial installation After reactive service, software upgrade, or preventive maintenance Periodically, according to lab standard operation procedure	With IQ to test for baseline level of instrument performance Before starting a major study or experiment
PQ service	Follows a comprehensive, well-defined protocol, including a PhiX control run, to make sure that the instrument is functioning according to Illumina preset and validated performance specifications	After any qualified major repair	After maintenance, replacement, or upgrade of selected modules



Figure 2: Experienced Illumina field service staff perform qualification services, enabling labs to maximize productivity, reduce turnaround time, and maintain regulatory compliance.

Learn more

[Illumina Installation Qualification](#)

[Illumina Operational Qualification](#)

[Illumina Performance Qualification](#)

Ordering information

Explore [service ordering options](#) or [contact us](#) for help with selecting the right service for your needs.

Summary

Illumina provides comprehensive qualification solutions to certify that instruments are installed and operating according to specifications. Illumina IQ, OQ, and PQ services verify that instruments meet peak performance standards and provide audit-ready reports to help laboratories maintain regulatory compliance and produce high-quality results. With more than 500 certified field service engineers and application scientists, Illumina has the expertise to deliver complete instrument qualification services, helping labs protect their investment, maximize performance, and minimize interruptions.



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