



Diagnostics

Documented verification for your instrument and assay

Accreditation Support Service

Get back quickly to molecular diagnostics,
knowing your instrument is verified and audit-ready

In a diagnostic lab, you need to ensure that your instruments are verified and fulfill the regulatory guidelines and requirements. Your staff has to stay on top of the differences between IVDD and IVDR requirements. You need proper verification documentation to assure your instrument is always audit-ready and get back to delivering results to patients on time.

ISO 15189 accreditation commits your lab to a high-performance quality management system. The QIAGEN® Quality Policy is ISO 9001 and ISO 13485 certified. We can provide you with the Accreditation Support Service, so you are confident your instruments and assays are properly verified according to the highest standards.

Your staff will gain knowledge of the accreditation process and its requirements. Our service specialists bring their vast experience and expertise acquired by supporting the performance of medical laboratories. A dedicated service specialist will tailor the service to your specific needs. Together, we will develop optimal methodologies for high productivity and reliable results.



Tools and services offered:

Accreditation Support Service:

Tools, documents and support files needed for ISO 15189 accreditation (including but not limited to training documents, method verification protocol, risk management and performance evaluation support document).

- Support for using our tools during the accreditation process to guarantee correct execution
- Computer processing support of transfers/manipulations/data management
- Comprehensive report of the results obtained during the use of our tools and services
- On-site support from a QIAGEN service specialist for routine implementation
- QIAGEN follow-up visit

Benefits of the Accreditation Support Service:



Quality Management System implemented according to ISO 15189



Optimized operation for quality and performance



Easy access to documentation for the subsequent verification set-up



Up-to-date verification method know-how



Reduced audit preparation time



Quick return to your daily routine

Ordering information

Service Product	Description	Cat. no.
NeuMoDx®, Verification Method Support	On-site service to help customers verify their method on the NeuMoDx instrument for obtaining ISO 15189 standard accreditation.	9245449
QIAstat-Dx®, Verification Method Support	On-site service to help customers verify their method on the QIAstat-Dx instrument for obtaining ISO 15189 standard accreditation.	9245471



For more information about QIAGEN Service Solutions, visit www.qiagen.com/instrument-services

Register on My QIAGEN at login.qiagen.com/login

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