Services and support

Overcome the complexities of your IVDR transition. We're with you through the rough terrain.

The *In Vitro* Diagnostic Regulation (IVDR) transition will bring positive changes to European Union (EU) regulation of medical devices and in-house developed tests. But it also presents potential obstacles. Fortunately, Thermo Fisher Scientific can help you conquer these roadblocks quickly. We'll help you ensure compliance, supply consistency, validation, and scalability, all while offering the clarity and confidence you need for your IVDR transition.

We are committed to supporting all our customers during this transition phase. If you have any questions or would like to learn more about IVDR, read our blog, **Getting Ready for the IVDR**.

Analytical validation consulting services—assistance to meet demanding quality requirements

Molecular testing laboratories face several challenges when introducing new assays. One critical, time-consuming, and costly challenge is planning and executing the analytical validation (AV) process—a requirement of process validation.

Fortunately, Thermo Fisher has decades of experience in designing, building, testing, and supporting validated systems, in compliance with applicable standards and regulations. No other company has a longer history of integrating workflows and software into complex laboratory environments.

Whatever level of service you require, we are the right choice to help shorten your validation time, control your validation cost, and facilitate your compliance with regulatory requirements. Managed by a validation specialist and with the support of a clinical application consultant, our validation services help accelerate the onboarding of new assays and assist in adhering to quality standards.

Looking to verify your assay's performance, unsure about the AV process, or need an assay bridging solution?

Consider starting with a verification evaluation. Our analytical performance verification (APV) solution service helps save you time and reduce costs by determining whether your workflow is ready to move to a complete AV. It can also provide verification of wet lab changes to your assay workflow.

Guided by a technical project manager and experienced validation specialist, the APV service enables you to evaluate your workflow on a controlled scale, and it helps you improve your chances for success.

Features of APV

- Comprehensive prevalidation or bridging study
- Custom control kit*
- Workflow guidance
- Data analysis
- Consultation with AV specialist
- APV summary template

Analytical validation regional service

Our AV consulting services are flexible and adapt to regional validation requirements. The analytical validation regional (AVR) service is designed to follow regional requirements, guided by a technical project manager and experienced validation specialist. This takes you through an AV process tailored to fit your global region.

The IVDR presents new regulatory challenges but puts greater emphasis on quality. Our AV consulting services provide the guidance, materials,* and support to help you complete the AV faster. This process enables you to meet ISO 15189 quality guidelines.

Get a complete list of the assays and panels we support, or contact an AV consulting services specialist at thermofisher.com/av.

Features of AVR

- Designed to support international accreditation and validation requirements for custom in-house developed workflows
  - ISO 15189, CLSI, or national guidelines
- Dedicated project management guidance*
- Workflow training, guidance, and optimization
- Template documentation
- Samples and controls*
- Data analysis
- Validation summary template

* For additional details, contact your product specialist, AV specialist, or email professionalservices@thermofisher.com. Offerings depend on consulting service purchased.

Keep your instruments compliant with instrument hardware qualification services

Our manufacturer-trained and certified field service engineers will conduct and document comprehensive tests, including software and hardware compatibility matrixing, component verification, and site requirements. This helps verify performance, providing reliable, audit-style documentation to meet your regulatory requirements.

Installation qualification (IQ), operational qualification (OQ), and performance qualification (PQ), also known as instrument performance verification (IPV), services verify and document your instrument's ability to meet manufacturer design specifications for performance.

- **IQ**—provides documented evidence and verification that the instrument has been delivered and installed according to the manufacturer's specifications
- **OQ**—provides documented verification that the instrument subsystems are operating as designed; verifies that the functionality of an instrument meets the manufacturer's operational specifications
- **PQ or IPV**—provides documented verification that the instrument system can perform effectively and reproducibly within performance specifications; helps ensure confidence in results by verifying that the accuracy and precision of an instrument is maintained

Learn more or contact an instrument qualifications specialist at **thermofisher.com/iqoqpq**.

Share, store, and back up your lab's data with DataSafe storage solutions

The DataSafe™ Solution provides on-premises storage with enterprise-class redundancy, adding layers of protection to your data should a disaster or hard drive failure occur. The DataSafe Solution includes end-to-end features, such as IT consultation, data strategy planning, system design, hardware, integration, and ongoing support.

The DataSafe Solution offers flexibility, protection, and rapid retrieval of genomics and life science data.

Find out more about the **DataSafe Solution**.

Turnkey

- Fully rely on our next-generation sequencing (NGS) and IT professionals for a personalized solution built for your lab
- Includes design, integration, software, hardware, and support

Scalable

- Private storage space for all your instrument data
- Compatible with NGS, mass spectrometry, and imaging data
- Scales as you grow; add instruments and storage as needed

Protected

- Be 100% in control of your data with a physical, on-site device
- Secure access to sample data via encryption and optional write once read many (WORM) technology
- Automatically back up and mirror your data

Fast

- Transfer up to 100x faster than off-site or cloud storage
- Make your instrument run like new by cleaning up primary storage

Maximize your instrument uptime with superior services and support

AB Assurance Dx Service Plan

The AB Assurance Dx Service Plan is exclusively for CE-IVD instruments and designed to maintain instrument performance to help ensure availability of critical instrument systems in your workflow. This plan will help keep your laboratory operations running smoothly with planned maintenance, proactive instrument monitoring (where available), and, should your instruments require service, a timely response. Service and instrument hardware qualification documentation are provided as supporting proof of instrument performance and maintenance history for customer Quality Management Systems (QMS).

Explore the **AB Assurance Dx Service Plan**.

AB Platinum Service Plan

Raise your testing confidence even higher with our premium service plan* that promises the total lab support you need to deliver reliable patient results. This service plan is ideal for clinical labs, and its enhanced features include rapid-response, on-site support, Priority Technical Support, comprehensive repair coverage, planned maintenance, digital remote support, qualification services, training by a field application scientist (FAS), and a 98% uptime guarantee.**

Plan to stay up and running at **thermofisher.com/abplatinum**.

* Available for selected Thermo Scientific™ KingFisher™ and Applied Biosystems™ instruments. Application support offered for customers using our EUA, IVD, or CE-IVD approved workflows; limited application support for non-IVD workflows.
Terms and conditions apply. For complete details, go to **thermofisher.com/uptime.

Learn more at **thermofisher.com/instrumentservices**

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