Consulting services

# Analytical validation

## Analytical validation (AV)—a pathway to quality

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

We have decades of experience designing, building, testing, supporting, and integrating our workflows into complex laboratory environments in compliance with applicable standards and regulations. We'll help you ensure compliance, supply consistency, validation, and scalability, all while offering the clarity and confidence you need for your transition to the *In Vitro* Diagnostic Regulation (IVDR) with solutions designed to support ISO 15189 accreditation and validation requirements.

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. We 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.

## 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.

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

## Features of APV

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

## 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

## Ordering information

| Description | Cat. No. |
|---|---|
| **Product** | |
| Analytical validation consulting, regional guidance | A49256 |
| Analytical validation consulting, germline panels (including pharmacogenomics) | A50650 |
| Analytical validation consulting, Ion Torrent™ CarrierSeq™ panels | A47477 |
| Analytical validation consulting, Ion Torrent™ ReproSeq™ kits | A47476 |
| Analytical validation consulting, instrument add-on (all assays and panels) | A41777 |
| Analytical performance verification | A48557 |
| Analytical performance verification, Oncomine™ Precision Assay bundle | A49552 |
| Analytical validation consulting, SARS-CoV-2 next-generation sequencing (NGS) | A48399 |
| Analytical Orthogonal Testing Service | A51247 |

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