Consulting services

Analytical validation for real-time PCR

Helping ensure the success of your research workflow verification through the AV process

An analytical validation (AV) is the use of an analytical technique, process, and procedure to develop and produce results in documentation form as tangible evidence, which helps assure all parts within the scope of a workflow are suitable for their intended use. Our AV consulting services follow an industry-accepted process and adhere to stringent guidelines such as those set by CAP, CLIA, CLSI, NYSDoH, or ISO 15189. So, whether you're a start-up lab, you're a lab looking to accelerate your time-to-revenue stream, or you simply need assistance with experiment setup and control material sourcing, our professional services are the right choice to help shorten your validation time, control your validation cost, and facilitate compliance with regulatory requirements.

These are the most common performance parameters evaluated during an AV:

Accuracy	Precision	Analytical sensitivity	Analytical specificity	Reportable range	Reference range or normal values
The closeness of the agreement between the result of a measurement and a true value of the measurand.	The closeness of agreement between independent test results obtained under stipulated conditions.	The ability of an assay to detect a given analyte, or the lower limit of detection (LOD).	The ability of a test method to determine only the target analytes to be detected or measured.	The span of test result values over which the laboratory can establish or verify the accuracy of the instrument or test system measurement response (linear range).	The range of test values expected for a designated population of persons.

Consultation and support

- Highly experienced project management by AV specialist
- Dedicated on-site field application specialist (FAS)
- Workflow training, guidance, and optimization*
  - Workflow training is highly recommended for new assay AV
- Technical review with guidance around data analysis
- Optional: additional format bridging, additional instrument**

Resources and materials

- Validation plan and template to help meet quality requirements
- Protocol templates
- Design and delivery of custom controls for each engagement
- Data analysis consultation
- Final report template
- Summary documentation templates

* Training led by FAS at additional cost.

** Contact an AV specialist or professional services business development manager for details.

Let our AV consulting services help navigate common pain points of laboratory-managed validation

AV development and project management

- Managing daily responsibilities while developing an AV
- Managing project plan timelines within scope vs. using standardized timeline expectations

Control materials

- Identifying appropriate controls
- Designing synthetic controls
- Procuring controls
- Preparing and testing controls

Data analysis

- Large number of runs—high volume of data
- Familiarity with running and analyzing data
- Assessing data and establishing criteria

Documentation

- Meeting requirements for standard operating procedures (SOPs) and report templates
- Assay manuals do not always provide the complete process

Help accelerate setup time and reduce costs of implementing your research workflows

AV consulting services provide technical project management of your lab's AV to help verify that the assay is tested for required parameters. We work with you to optimize and manage your validation workflow while providing data analysis support and template documentation as part of your end-to-end instrument and reagent investment. On average, we can help you manage the validation process up to 75% faster than on your own. By supplying control samples and support for data analysis and reporting, we can help you reduce costs up to 50% for your completed AV.

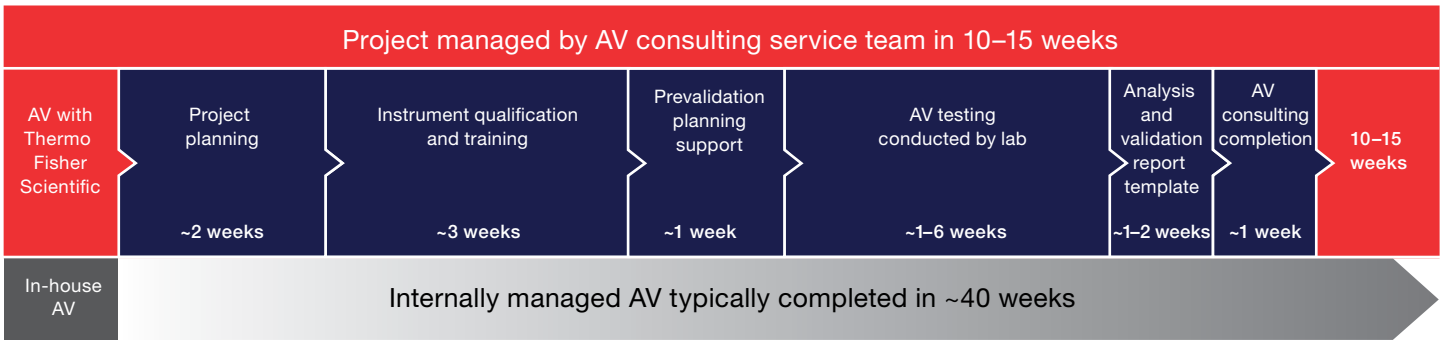

Figure 1. AV workflow completed up to 75% faster with AV consulting services. Our AV consulting services help labs manage the validation process up to 75% faster than the average in-house AV. The services provide project management from a validation specialist, a dedicated on-site application scientist (where available), workflow training, workflow review and optimization, technical review, and assistance with confirmatory sequencing. Deliverables include validation plan templates, protocol templates, controls and samples, data analysis workflow, and a report template.

Ordering information

Description	Cat. No.
AV consulting services for qPCR	
AV consulting service for predesigned OpenArray plates and TaqMan Array Cards	A41781
AV consulting service for predesigned 384-well plate	A41300
AV consulting service for predesigned 96-well plate	A43331
AV consulting service for custom qPCR-based panel or assay*	A34091
AV consulting service for additional qPCR instrument	A41778
AV consulting service for qPCR-based bridging study	A34089
Training	
2-hour remote clinical qPCR training	TRN00407
1-day clinical qPCR training	TRN00406
1-day clinical OpenArray plates training	TRN56211
3-day pharmacogenomics or cystic fibrosis workflow training	A26745
3-day pathogen detection training	TRN00302
2-day TaqMan Array Card or plate pathogen detection training	TRN00401
2-day qPCR TaqMan Array Card pathogen detection training	TRN56216
3-day AV respiratory and pathogen training	A51986
3-day AV urinary tract microbiota and pathogen training	A51985
3-day AV pharmacogenomics 120-array and pharmacogenomics training	A51987
Advanced QuantStudio OpenArray product training	4476591

* Custom panels and workflow components not developed by the Applied Biosystems™ brand can limit our capability to deliver custom training.

Don't see the service you're looking for? Contact professionalservices@thermofisher.com

Find out more at **thermofisher.com/av**