

Analytical validation consulting services

Helping ensure speed and success through your validation process

We have decades of experience designing, building, testing, and supporting validated systems. No one has a longer history of integrating our workflows and software into complex laboratory environments. Whatever level of service you require, our compliance and qualification services are the right choice to help shorten your validation time, control your validation cost, and reduce your compliance risk.

Managed by a field applications scientist (FAS) and a compliance service specialist (CSS), compliance and validation services help ensure that the instrumentation workflow, from DNA and RNA extraction to data analysis, operates according to manufacturer specifications.

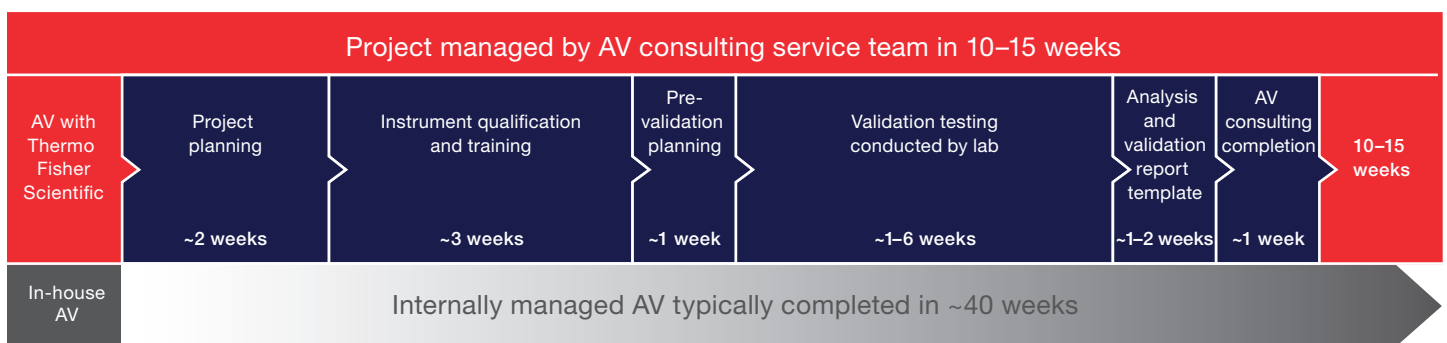
Our AV consulting service helps accelerate launch time and reduce costs

Analytical validation (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 develop 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 complete the validation process 62–75% faster than on your own; and by supplying control samples, data analysis, and reporting, we can help you reduce costs up to 50% for your completed AV.

Instruments supported:

- Applied Biosystems™ QuantStudio™ 12K Flex and Real-Time PCR System with OpenArray™ block
- Applied Biosystems™ QuantStudio™ 6 and 7 Flex Real-Time PCR Systems
- Ion Torrent™ GeneStudio™ S5 System
- Ion Personal Genome Machine™ (PGM™) System

Table 1. Analytical validation workflow completed 62–75% faster with AV consulting service.



Our analytical validation consulting service helps labs complete their validation process 62–75% faster than the average in-house AV. The service provides project management from a CSS, a dedicated on-site FAS, workflow training, workflow 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.

AV consulting services included:

- Project management from a CSS
- Dedicated on-site support from a FAS
- Confirmatory sequencing or detection review for qPCR assays
- Optional confirmatory testing review available for NGS panels
- Workflow optimization
- Technical review
- Workflow training

What you receive with this service:

- Validation plan template
- Protocol templates
- Controls
- Data analysis review
- Final report template
- Orthogonal testing review

Ordering information

Product	Cat. No.
AV consulting services for qPCR panels	
AV Consulting Service, vaginal microbiota, OpenArray format	A28966
AV Consulting Service, cystic fibrosis, OpenArray format	A28279
AV Consulting Service, pharmacogenomics, OpenArray format	AVQS12K
AV Consulting Service, pharmacogenomics, 384-well format	A27145
AV Consulting Service, custom assay	A34091
AV assistance pack	A34090
Bridging study, 384-well to OpenArray format	A34089
Workflow training, genotyping assays	A26745
Workflow training, microbial assays	A30162
AV consulting services for NGS panels, North America	
AV Consulting Service, oncology,	A34088
AV Consulting Service, oncology, consultation only	A39199
Confirmatory Testing, NGS platform	A39200
Confirmatory Testing, Sanger sequencing platform	A39201
Confirmatory Testing, qPCR platform	A39202
Confirmatory Testing Reagent Kit	A39203
AV consulting services for NGS panels, non-US	
AV Consulting Service, oncology—controls only	A39558

Ordering information

Product	Cat. No.
Vaginal microbiota: instrument with OpenArray block and AV consulting package	A35371
QuantStudio 12K Flex Real-Time PCR System with OpenArray block	
IQ/OQ/IPV qualification service	
AV Consulting Service, vaginal microbiota, OpenArray format	
Vaginal microbiota OpenArray panel workflow training	
Cystic fibrosis: instrument with OpenArray block and AV consulting package	A35369
QuantStudio 12K Flex Real-Time PCR System with OpenArray block	
IQ/OQ/IPV qualification service	
AV Consulting Service, cystic fibrosis, OpenArray format	
Cystic fibrosis OpenArray block workflow training	
Pharmacogenomics: instrument with OpenArray block and AV consulting package	A35370
QuantStudio 12K Flex Real-Time PCR System with OpenArray block	
IQ/OQ/IPV qualification service	
AV Consulting Service, pharmacogenomics, OpenArray format	
Pharmacogenomics OpenArray panel workflow training	
Pharmacogenomics: instrument with 384-well block and AV consulting package	A35372
QuantStudio 12K Flex Real-Time PCR System with 384-well block	
IQ/OQ/IPV qualification service	
AV Consulting Service, pharmacogenomics, 384-well format	
Pharmacogenomics 384-well panel workflow training	

Find out more at thermofisher.com/complianceservices

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