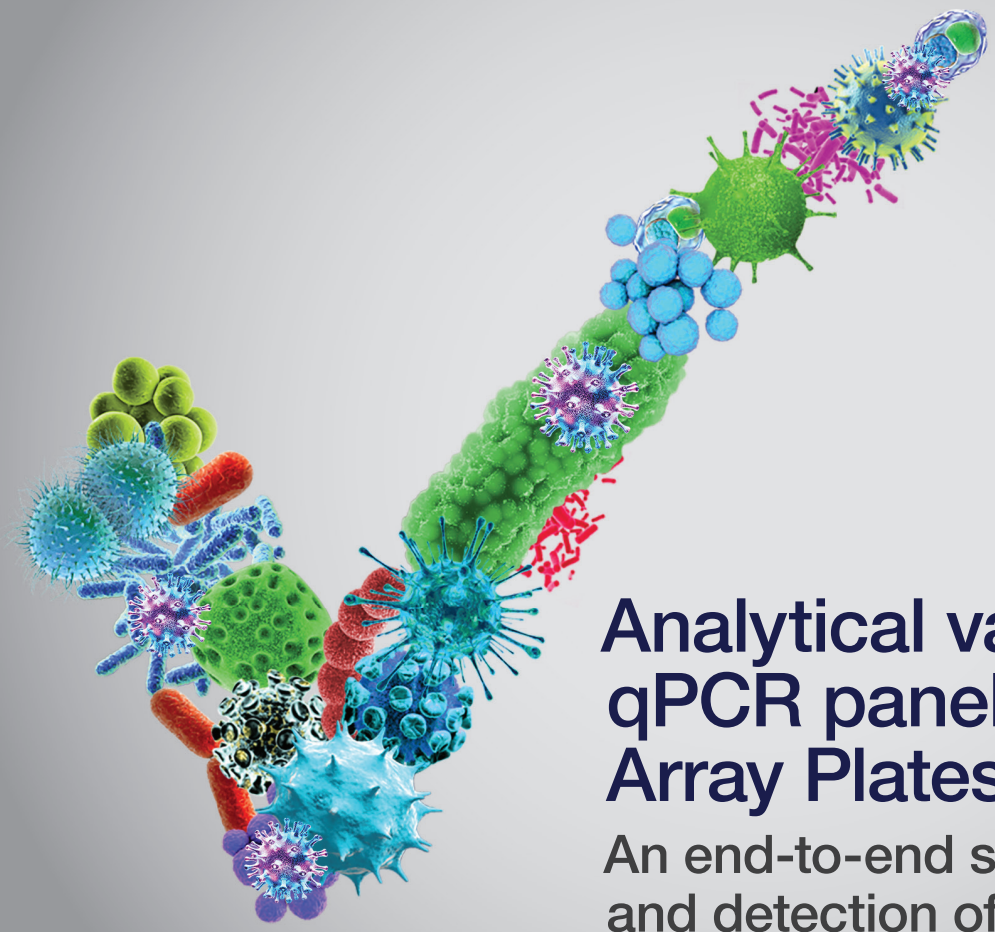


Analytical validation for qPCR panels on TaqMan Array Plates

An end-to-end solution for validation and detection of infectious diseases

Our analytical validation consulting services provide clinical testing labs with fast and cost-effective validation of real-time PCR (qPCR) assays and panels on Applied Biosystems™ TaqMan™ Array Plates that follow industry quality standards and regulatory guidelines.

A typical validation can take anywhere from 6–12 months for DIY customers; however, we can help labs complete their validation process with TaqMan Array Plates an average of up to 75% faster than they could on their own.

What is an analytical validation (AV)?

Analytical validation, also known as method or process validation, is:

- An industry-accepted process
- A test of a procedure or workflow by analytical methods
- Documentation of results with tangible evidence
- Proof the workflow or procedure is suitable for the intended use

How frequently should it be performed?

AV testing in a laboratory environment is recommended:

- Upon adding a new test to a laboratory menu
- After a major change in the workflow*
- Upon adding new tissues or targets to the test*
- Upon adding instruments or updating instruments in the workflow*

* We recommend performing risk analysis as part of your established change control process.

Common pain points with 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

Managing your spending with Thermo Fisher Scientific AV consulting services for qPCR assays

Lower fixed-assay implementation costs (potential savings: ~$50–$80K)

- Estimated cost of complete set of controls: ~$18K
- Estimated cost to prepare controls, validation design, management and data analysis: ~$41K
- Our qPCR AV consulting cost: $17–$25K

Critical timing for success (missed revenue)

- Our proven AV consulting model helps customers complete their AV faster through dedicated project management
  - Our typical AV consulting engagement: 8–9 weeks
- Unrelated or competing laboratory priorities can delay internally managed validations 3–6 months on average
- Internal laboratory delays can result in missed or unrealized revenue of ~$100–$300K

We help you save time, money, and headaches

Time

You need flexibility to meet your clients' needs

Balancing laboratory priorities can be a challenge as you try to:

- Launch a qPCR assay or panel quickly
- Make time to complete AV due to competing priorities
- Remain relevant with the most current set of biomarkers
- Run a lab profitably for faster return on investment

Cost

Launching new assays with limited staffing resources can pose a risk to your laboratory's bottom line

Considerations include:

- Developing an effective validation strategy
- Training your staff
- Executing the plan
- Return on investment
- Upfront costs of controls and control preparation

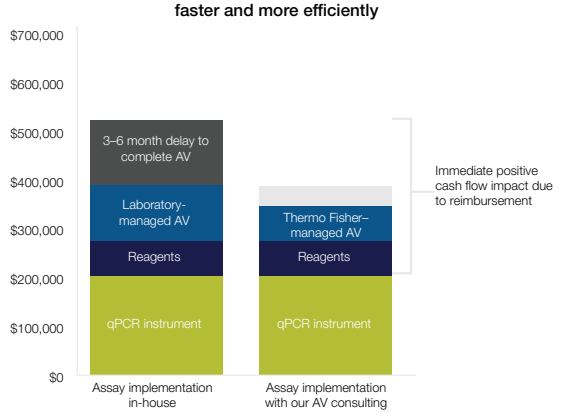
Compliance

Your laboratory faces the constant pressure of meeting compliance requirements

Changes in compliance are often broad, making them hard to navigate and apply, such as:

- Adapting to variability in the compliance environment
- Applying requirements to molecular assays
- Knowing the documentation your lab needs

Our AV consulting helps you implement new assays faster and more efficiently



Why choose us for your validation services?

- **Transparency**—complete visibility into the AV process, data analysis, and summary to facilitate regulatory compliance
- **Integrated support**—complete end-to-end support from highly experienced AV specialists and project managers as well as on-site support from application scientists
- **Flexibility and acceleration**—an adaptable solution based on your needs
- **Technical acumen**—we have completed over 350 AV consulting engagements

What happens when you purchase our AV consulting services?

Thermo Fisher Scientific AV solution

AV consulting services*

Project management and training

- Dedicated AV specialist and project manager
- Workflow optimization
- Data analysis onboarding

Validation

According to relevant guidelines:

- CAP
- CLIA
- ISO 15189
- CLSI
- NYSDoH

Assay implementation and test enablement**

* Thermo Fisher Scientific AV consulting services include end-to-end project management, training, and analytical validation consulting. Documentation templates and guidance are provided.

** Clinical validation and assay implementation are the responsibility of the customer.

Contact your sales representative or customer service at **(800) 955-6288**

applied biosystems