

Analytical validation consulting service aids launch of new laboratory-developed tests

Aeon Global Health has a mission to provide actionable information that promotes patient-centric, personalized medical care. This requires that they stay on the cutting edge of diagnostic technologies when aiming to increase their molecular testing options.

Diagnostic testing laboratories like Aeon face multiple challenges when bringing on new assays. From billing and recording services to meeting Clinical Laboratory Improvement Amendments (CLIA) accreditation and compliance requirements, wearing multiple hats at any given time is common for personnel in small to mid-sized labs with lean operating budgets. “Juggling multiple responsibilities and varying priorities can be daunting,” according to Dr. James P. Canner, Laboratory Operations Director at Aeon, who is no stranger to these challenges. When it was time to launch their new vaginal microbiota assay [1], it was an easy decision for Aeon to rely on the unique **Analytical Validation Consulting Service** offered by Thermo Fisher Scientific to help expand their menu of testing services in a more predictable, timely, and cost-effective manner.

Dr. Canner has launched several tests while at Aeon, including a few routine hematology blood panels that were developed and validated in-house, and a pharmacogenomics assay developed in collaboration with Thermo Fisher. It was through this partnership that Aeon first learned about using the Applied Biosystems™ QuantStudio™ 12K Flex system and OpenArray™ platform for women’s health testing [2].



James P. Canner, PhD, is Laboratory Operations Director at Aeon Global Health, where he is responsible for launching new testing services, including the company’s most recent laboratory-developed test (LDT) for women’s health.

We interviewed Dr. Canner to find out more about how choosing an analytical validation (AV) partner enabled his lab to overcome operational challenges and expand the testing portfolio for Aeon.

What are your goals at Aeon Global Health?

As Laboratory Operations Director, I wear two main hats. The first is to oversee the day-to-day operations of the lab, including laboratory testing, hiring personnel, and managing staff. The second part, which I am very excited about, is to bring on new assays.

What problems are you addressing with Aeon's women's health assays?

Many vaginal infections have very similar symptoms but very different causative agents. We feel that getting to the molecular level to identify 34 organisms associated with the vaginal microbiota provides a lot more information to our clients and is faster and more accurate than traditional methods, which in turn improves the therapeutic treatment of patients.

What impact does the analytical validation process have on your lab?

The time it takes to complete analytical validation is a big deal to us. Personnel time is limited, and prolonged downtime isn't something we can easily manage. It's not always possible to have the qualified resources freed up from their day-to-day responsibilities in order to undertake the challenges involved in the validation of new assays.

If issues arise during validation, there are so many variables you have to investigate and troubleshoot. Being able to individually examine all of them in-house is very challenging. If you're getting tied up in the validation from the beginning, it's going to cause a huge time delay for everything else, such as your laboratory information system (LIS) integration, reporting options, billing interface, marketing strategy, and your launch. Being able to use an integrated approach and build an actual timetable for assay development was key to our decision to choose Thermo Fisher as our AV partner [3].

What other factors influenced your decision to choose the solution from Thermo Fisher?

Timing was a big factor. We considered how the Thermo Fisher service team would coordinate with all the other moving pieces when bringing on our women's health test. We needed to make sure the new test flowed properly

into our LIS. We needed to ensure we had viable reporting options and billing systems set up properly to handle everything. We also needed to make sure we were on track with our marketing and sales teams so our providers would know what we were offering. Finally, we considered how much it was going to cost to use the analytical validation services versus trying to do it ourselves, and how much it would cost to continue running the test year after year.

How would you say the Thermo Fisher solution impacted the launch of your test?

Thermo Fisher was able to offer an integrated approach and helped us build a tight timetable that included assay development with all of the other pieces so that everything would fall in line together like a well-orchestrated event. This service made it practical for us to launch without taking time away from our lab personnel, who are needed for test development and running samples, in order to perform non-testing-related functions.

The cost of sourcing was another impact. Having identified source materials to work with on the OpenArray platform really eliminated the burden of having to design and order our own controls. Being able to use plasmid DNA, provided in the correct dilutions for our testing service, saved us about four months of time.

Since the launch of your test, how has the inspection process been?

We adhere to CLIA and are currently seeking accreditation from the Joint Commission. Since launching our women's health assay, we've had a few inspections, including one from the State of California. Having all the paperwork and a complete validation set readily available to show the inspector that our assays have specificity, selectivity, precision, low limits of detection, and the quantifiable range was a huge benefit during the inspection.

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How does this help you expand your testing portfolio and equip your lab for the future?

If you want to provide more value to your existing clients and expand your services, you need to find cost-effective solutions. That opens the door for molecular LDTs using a platform like the QuantStudio 12K Flex system and OpenArray plates, which provides extremely low cost per sample while still offering a service similar to that obtained using the IVD, FDA-cleared device.

The Analytical Validation Consulting Service makes this strategy possible for us by providing training to our staff, managing the process, and delivering the validation on time, alongside all of the other moving parts.

In your opinion, what types of labs would ideally benefit from an AV consulting service?

A variety of labs. Smaller independent laboratories that run a lean operation in terms of personnel would benefit because they could leverage their highly skilled personnel for the day-to-day tasks and processes while utilizing the service team to help launch new assays. Medium to larger labs would benefit from coordination across multiple departments and set project completion dates managed through the AV consulting service (Figure 1).

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What parting advice do you have for other labs looking to develop new assays?

When you're building your timetable for launch, inform everyone that it's flexible and not set in stone. Make sure you allot time for failures and missed deadlines and communicate openly to all parties involved about where you are in the process at any given time. This includes sales, marketing, billing, and senior leadership. Take a holistic view so everyone knows what they should be doing. An expression we like to use is, “Make sure all oars are rowing in the same direction.” Finally, consider seeking help from an experienced team to work through the rigorous analytical validation process with you.

References

1. Aeon Global Health (2016) Aeon clinical laboratories launches the MDx Advantage™ test—an innovative women's health, qPCR-based diagnostic test for STDs and other infections. Press release.
2. Thermo Fisher Scientific Inc. (2017) High-throughput OpenArray solution for vaginal microbiota profiling using Applied Biosystems™ TaqMan® Assays. Application note.
3. Thermo Fisher Scientific Inc. (2017) Analytical validation consulting—helping ensure speed and success through your validation process. Brochure.

Analytical validation workflow completed 75% faster with AV consulting service

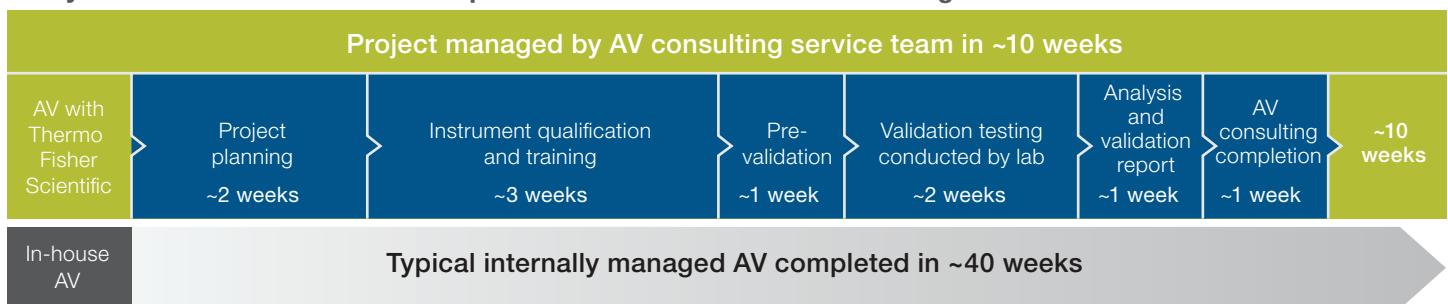


Figure 1. On average, the Analytical Validation Consulting Service helps labs complete their validation process 75% faster than in-house. The service provides project management by a compliance specialist, a dedicated on-site application specialist, workflow training, workflow optimization, technical review, and assistance with confirmatory sequencing. Deliverables include validation plan templates, protocol templates, controls and samples, data analysis workflow, and report template.

Find out more at thermofisher.com/av

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