Launching new molecular tests can't wait

Assay validation readiness service–a pathway to process validation

Molecular testing laboratories are faced with several challenges when bringing on new assays. One critical, time-consuming, and costly challenge can be planning and executing the analytical validation process (a requirement of process validation).

To identify opportunities that help reduce risk and streamline your new assay addition, we've developed a prevalidation evaluation process that will help save you time and additional financial investment by determining whether your workflow is ready to move on to validation. Guided by experienced compliance professionals, our assay validation readiness (AVR) service enables you to evaluate your workflow on a controlled scale and helps you improve your chances for success before investing in a full-scale assay workflow.

AVR service helps speed your workflow towards proficiency with:

- An assay validation readiness evaluation checklist
- Workflow guidance by a field applications specialist (FAS)
- Data analysis assistance with a global compliance services specialist (GCSS)
- Evaluation consultation with a GCSS
- Custom control kit data analysis and consultation with a GCSS

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AVR service offers comprehensive prevalidation solution

Our AVR service provides a comprehensive prevalidation solution to get you closer to launching your next new assay. A custom control kit containing extracted nucleic acids and workflow controls to evaluate assay variant types is included in the service. Using the custom AVR control kit, our experienced team will provide your laboratory staff with assistance in running the controls to demonstrate efficacy of the workflow.

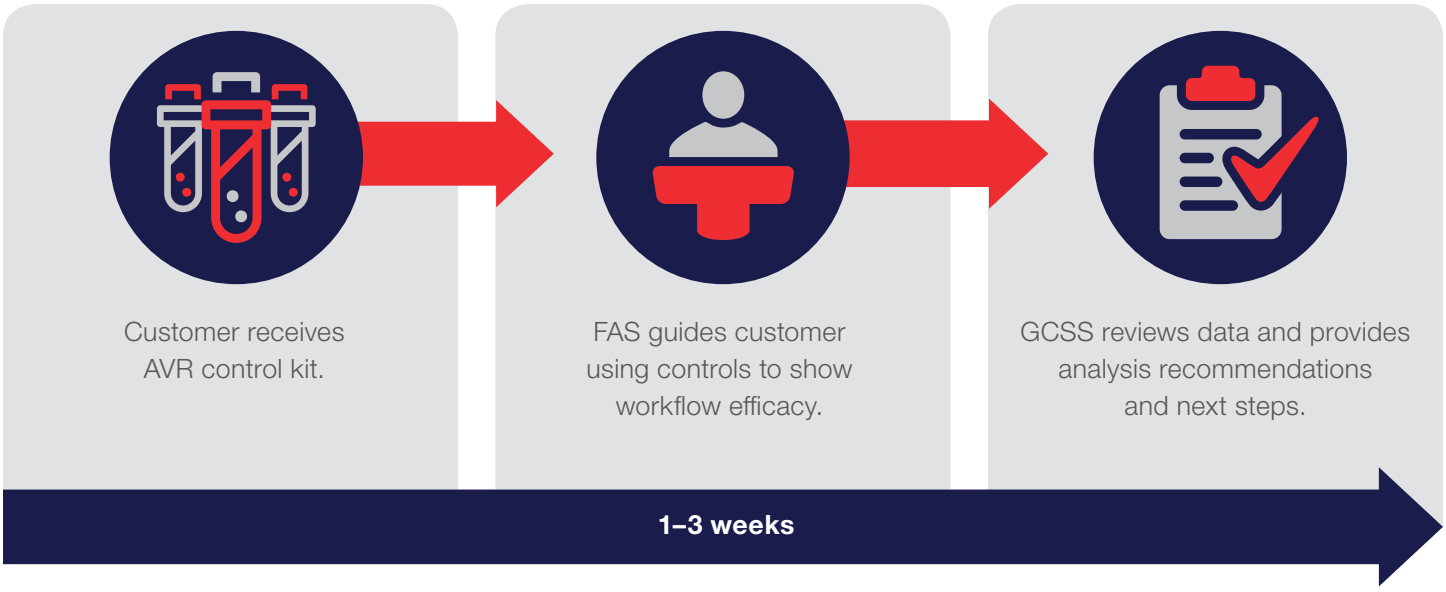
As part of the comprehensive service, our highly trained GCSS will assist you with the analysis of the control data and schedule an online conference to review the results with your team. During the discussion, the GCSS will present a comprehensive assessment to determine your lab's validation readiness and provide a run report and final readiness checklist. The entire AVR process can be completed in just 1 to 3 weeks, helping you save valuable time, resources, and expense.

AVR workflows available

The AVR service is currently available for Ion GeneStudio™ systems with Ion Torrent™ Oncomine™ molecular profiling assay packages. Our AVR service offering is expanding to include additional workflows. Please contact your local compliance specialist to learn more.

We also offer a selection of predefined analytical validation (AV) consulting services for various assays as well as custom consulting service solutions to supplement your molecular testing service needs. For more information on these service solutions, please contact your local compliance specialist.

The AVR service process



Ordering information

Product	Cat. No.
Assay Validation Readiness Service for NGS Instruments	A43330

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

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