



# Launching new molecular tests can't wait

Accelerate and streamline your validation process with technical project management of your lab's analytical validation

## **Analytical validation consulting services for NGS assays**

Next-generation sequencing (NGS) is quickly becoming the go-to tool for testing labs looking to bring on additional molecular tests to enable smaller tissue samples, reduced time-to-results, and increased efficiencies and profitability. Oncology testing labs are faced with inherent challenges, including adapting to the arduous compliance requirements for validating new assays and panels.

We have decades of experience designing, building, testing, supporting, and integrating our workflows into complex laboratory environments, including experience with various regulatory guidance (e.g., CAP, CLIA, CLSI, and ISO 15189).

To help address your oncology testing needs, we've developed analytical validation (AV) consulting services that help shorten your validation time, control your validation cost, and reduce your compliance risk. With this service, you'll receive end-to-end project management support from a global compliance service specialist (GCSS) to help ensure your lab's molecular testing workflow is executed within the defined assay or panel parameters according to your required regulatory guidance.

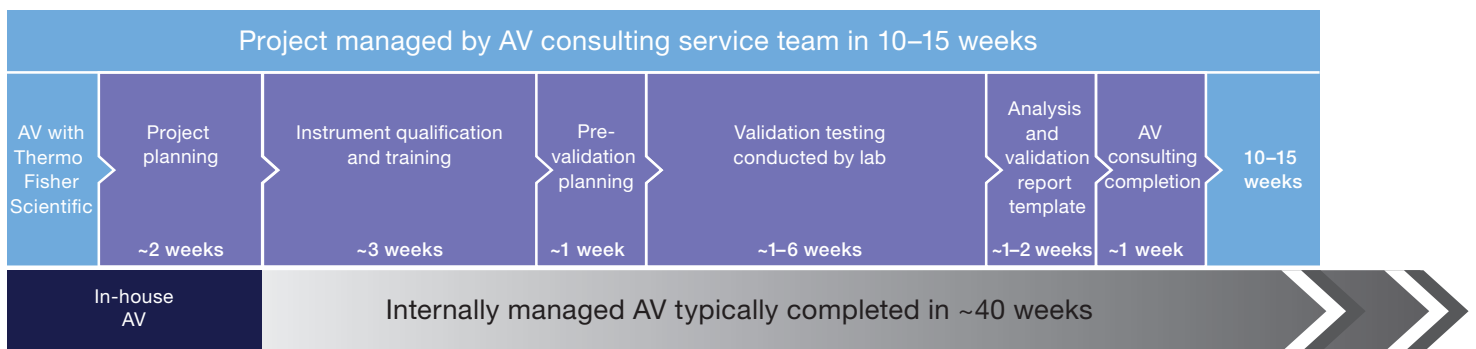
**Our AV consulting service helps accelerate launch time and reduce costs**

AV consulting services provide technical project management to help verify that the assay is tested for the required parameters. We work with you to develop and optimize your validation workflow, while providing data analysis and summary report documentation to fully maximize your instrument and reagent investment. On average, we can help you complete the validation process 62% faster than on your own; and by supplying control samples, data analysis, and reporting, we can help you reduce costs by up to 50% for your completed AV.

**Instruments supported:**

- Ion Torrent™ GeneStudio™ S5, S5 Plus, and S5 Prime Systems
- Ion Personal Genome Machine™ (Ion PGM™) System

**Table 1. Analytical validation workflow completed 62% faster with AV consulting services.**



Our analytical validation consulting services for NGS assays help labs complete their validation process 62% faster than the average in-house AV.

**AV consulting services include:**

- Project management by GCSS specialist
- Dedicated on-site field applications scientist
- Workflow training and optimization
- Technical review with guidance around sequencing metrics
- **Optional:** Confirmatory orthogonal testing support

**What you receive with this service:**

- Validation plan template
- Protocol templates
- Samples and controls
- Data analysis review
- Final report template
- **Optional:** Orthogonal testing review

**Table 2. Oncology assays supported by our AV consulting services.**

OncoPrint™ assay	OncoPrint™ assay
Ion Torrent™ OncoPrint™ Myeloid Research Assay	Ion Torrent™ OncoPrint™ Focus Assay
Ion Torrent™ OncoPrint™ Comprehensive Assay	Ion Torrent™ OncoPrint™ Childhood Cancer Research Assay
Ion Torrent™ OncoPrint™ Tumor Mutation Load Assay	Ion Torrent™ OncoPrint™ Inherited Cancer Assay
Ion Torrent™ OncoPrint™ Immune Response Assay	Ion Torrent™ OncoPrint™ Custom Oncology Assay

\* OncoPrint assays are designed for research use only. Thermo Fisher Scientific cannot support the use of these assays for *in vitro* diagnostic applications.

### References

1. Jennings LJ, Arcila ME, Corless C, et al. (2017) Guidelines for Validation of Next-Generation Sequencing-Based Oncology Panels: A Joint Consensus Recommendation of the Association for Molecular Pathology and College of American Pathologists. *J Mol Diagn* 19: 341–365.
2. New York Department of Health. Next-generation sequencing (NGS) guidelines for somatic genetic detection. Jan 2018 update/revision. Accessed Aug. 16, 2019.

## Ordering information

Product	Cat. No.
<b>AV consulting services for NGS assays</b>	
Oncology complete service	A34088
Oncology consultation only	A39199
Oncology controls only	A39558
Oncology custom assay	A42904
Additional NGS instrument	A41777
<b>Confirmatory testing for NGS assays</b>	
NGS platform	A39200
Sanger sequencing platform	A39201
qPCR platform	A39202
Reagent kit (custom)	A39203

Find out more or contact an AV consulting services specialist at [thermofisher.com/av](https://thermofisher.com/av)