

PierianD_x



NGS Gateway Lab Services™

Accelerating Precision Medicine

*Design a Complete Genomic Testing
Portfolio with Turnkey Assays*

About NGS Gateway Lab Services™

Designed to provide a gateway to your own in-house clinical offering, PierianDx NGS Gateway Lab Services deliver clinically validated Next-Generation Sequencing (NGS) tests for inherited diseases, solid tumors, hematopoietic disorders, central nervous system tumors, melanoma and more. This turnkey outsourced testing service allows you to access and customize a full range of NGS assays right out of the box utilizing subsets customized from a wide range of genes. With the NGS Gateway, PierianDx can be your partner to quickly implement any of the following components:

- *Pathology Intake*
- *Sequencing Services (DNA Preparation and Sequencing)*
- *Analytics and Reporting*
- *Medical Review and Sign-Out*

Unlike traditional “send-out” laboratory offerings, the PierianDx NGS Gateway Program is designed to incorporate your brand and transition from our program to your lab as soon as you’re ready.

NGS Gateway Benefits

Clinical Labs

Brand Enhancement Make precision medicine your competitive advantage with a fully branded set of NGS assays and patient reports that kick-start your clinical testing portfolio.

Transition Path Based on your time frame, we'll work with you on a seamless transition of services from our lab to yours. We can assist in training your team to ensure the success of your precision medicine program.

No Capital Outlay You can launch an NGS testing service with no capital commitment. We help get you started while you focus on better diagnoses, treatment and patient care.

Speed to Market Get to market faster by letting us support your precision medicine program while you refine your long-term NGS testing strategy.

Control Data Maintain genomic data essential to the patient lab record and valuable in aggregate for population health initiatives.

Ordering Physicians

Cancer patients who have failed standard treatments, such as chemotherapy, often need more targeted, personalized treatment plans. The genomic tests available in NGS Gateway uncover patient-specific variants that predict response to treatment. Some of the specific benefits and advantages of the tests include:

- *Genomic profiling to enable more personalized patient care and treatment*
- *Comprehensive tests involve sequencing the entire coding region of each gene and selected introns for detecting rearrangements*
- *Efficient, cost-effective and sensitive somatic and constitutional variant analysis*



OncoComplete

About the Assay

OncoComplete™ provides valuable clinical insight to oncologists and pathologists based on targeted molecular profiling of DNA alterations present in each patient's cancer cells. These can include: SNVs, indels, CNVs and gene fusions. The result is that a cancer patient can realize more targeted treatments, diagnoses, prognoses, therapies and clinical trials. OncoComplete:

- Provides comprehensive coverage of most prevalent cancers
- Includes 358 DNA and 301 RNA genes for a total 562 genes



Assay Spotlight

Assay Features

Market-driven assay with feedback from PierianDx Partner Sharing Network

Created to achieve the right balance between gene breadth, depth and affordability

21 days turnaround time (TAT)

Unlike the traditional "send out" model, the partner has the option to retain all data, brand the test as their own, and review and sign out cases

*A comprehensive assay for
a wide range of cancers*

Available NGS Testing

The following set tests are offered through NGS Gateway Lab Services. However, the program allows for the creation of genomic test subsets customized from a broad range of different genes. PierianDx can work with you to customize gene test panels that complement your existing offering and testing roadmap.

Solid Tumor Gene Set

Test includes total exonic coverage for somatic variants arising in 65 genes and six selected translocations that are clinically actionable in a wide range of adenocarcinomas, squamous cell carcinomas, gliomas, sarcomas and melanomas.

Hematopoietic Disorders Gene Set

Test includes total exonic coverage for somatic variants arising in 54 genes, including translocations involving MLL/KMT2A, that are clinically actionable in myeloid, lymphoid and mixed lineage leukemias. It also includes genes that can help establish diagnosis and prognosis for pre-leukemic myelodysplastic and myeloproliferative syndromes.

Melanoma Gene Set

Test includes total exonic coverage for somatic variants arising in 33 genes, including multiple melanoma-specific genes as well as some overlap with the Solid Tumor Gene Set. Indications include cutaneous, mucosal, and ocular melanoma.

CNS Tumor Gene Set

Designed specifically for tumors of the central nervous system, this test includes total exonic coverage for somatic variants arising in 24 genes. Indications include high-grade gliomas and medulloblastomas.

OncoComplete Gene Set

Designed to provide comprehensive coverage of most prevalent cancers, this test includes 358 DNA and 301 RNA genes for a total 562 genes.

OncoPed Select Clinical Gene Set

This pediatric-specific assay includes 117 genes specific to pediatric cancer and was designed to enable diagnosis in a broad range of pediatric solid tumors and hematologic malignancies.

OncoPed Select Research Gene Set

This pediatric research assay includes a total of 573 genes of which 164 are specific to pediatric cancer, including all informative genes from the OncoPed Select Clinical assay.



For a complete list of genes included in these tests, visit [pierianDX.com/gateway](https://www.pierianDX.com/gateway).

NGS Gateway Workflow



PierianDx can also assist in providing medical interpretation and sign-out services with our team of medical directors and genomic scientists.



Additional FAQs

Does PierianDx offer training and support for NGS Gateway assays?

Yes. PierianDx offers training and support to help you launch your NGS Testing Program. The NGS Gateway Kit includes the following materials that can be customized to your brand:

- *Product data sheets*
- *Frequently Asked Questions (FAQs)*
- *Program Launch Training Webinar*

PierianDx can also provide referral sources if additional communications and marketing assistance is needed to launch your testing program.

Can I customize NGS Gateway to my brand?

Yes. PierianDx will customize each signed-out report, so your brand will be front and center.

What CLIA certifications do you have for performing NGS testing services?

All NGS Gateway assays are carried out in CLIA-certified laboratories.

How long do the NGS Gateway assays take to implement?

The NGS Gateway assays were designed to rapidly bring your NGS test offering to market. PierianDx can implement the program within two weeks of the signed contract date. Total implementation timelines may vary depending on partner dependencies and internal training requirements.