

## 1. WHAT IS ANTHOLOGY DIAGNOSTICS?

In July 2020, Hackensack Meridian Health established the Anthology Diagnostics laboratory at Hackensack Meridian Health in Edison, New Jersey. Anthology Diagnostics offers a first-of-its-kind genomic profiling service that combines state-of-the-art lab technology and advanced, oncology-focused artificial intelligence (AI) analysis.

The Anthology Diagnostics laboratory provides physicians in the HMH network — as well as physicians and hospitals along the entire East Coast — with access to next-generation genomic sequencing technology and analysis.

## 2. MEET OUR JOINT VENTURE PARTNER – GENOMIC TESTING COOPERATIVE (GTC).

Anthology Diagnostics has teamed up with our joint venture partner, Genomic Testing Cooperative (GTC), based in Irvine, California. GTC was founded in 2018 by Maher Albitar, M.D., GTC chief executive officer and chief medical officer.

Dr. Albitar is a certified AP/CP Pathologist, Hematopathologist and Molecular Pathologist who has extensive experience in the field of genomic profiling with next-generation sequencing. He has served in senior roles at major diagnostic laboratories and as a tenured full professor at MD Anderson Cancer Center in Houston, Texas.

[Learn more about GTC.](#)

## 3. HOW DO ANTHOLOGY DIAGNOSTICS AND GTC WORK TOGETHER?

Anthology Diagnostics performs on-site genome sequencing and uploads the genomic data to GTC. GTC then uses their algorithms to analyze and interpret the data, creating usable information and generating a report that will help the treating physician develop a personalized care plan for the patient.

## 4. WHAT ONCOLOGY-SPECIFIC TESTS ARE PERFORMED AT THE ANTHOLOGY DIAGNOSTICS LABORATORY AT HMH JFK?

The Anthology Diagnostics lab performs on-site, oncology-focused, comprehensive hematologic molecular profiling and solid tumor molecular profiling.

### HEMATOLOGIC MOLECULAR PROFILING

Anthology Diagnostics offers oncology-specific next-generation sequencing of DNA and RNA. Comprehensive genomic profiling enables the detection and differentiation of driver and sub-clonal mutations and chromosomal structural abnormalities, confirms diagnosis and classification, determines prognosis, and identifies targeted therapies for personalized medicine. Tests include:

**Hematology Profile** provides DNA-only testing of 177 genes involved in hematologic neoplasms.

- Determines the aggressiveness and prognosis of myelodysplastic syndromes (MDS).
- Determines if the patient has reactive cytopenia (while dysplasia in hematologic cells is an indication of the diagnosis of MDS, the presence of mutations along with cytopenia is the most conclusive evidence for the diagnosis of MDS).
- Confirms diagnosis of acute myeloid leukemia (AML) and determines eligibility for treatment with FLT3 and IDH1/2 inhibitors.
- Includes quantitative analysis of all exons of JAK2, CALR and MPL.
- Analysis of mutations reported in lymphoma, including follicular, DLBCL, CLL and T-cell lymphoma.

**Hematology Profile Plus** combines expression and fusion with mutation analysis in DNA (177 genes) and RNA (1,408 genes) to provide a comprehensive evaluation of all hematologic neoplasms.

- Acute lymphoblastic leukemia (ALL) – this assay can confirm the diagnosis of Ph-ALL and Ph-like ALL.
- Diffuse large B-cell lymphoma (DLBCL) – this assay can distinguish between ABC vs. GCB, double hit lymphoma and is also useful in the differential diagnosis of various types of B-cell lymphoma and T-cell neoplasms.
- Acute myeloid leukemia (AML) – Translocations in AML are very important for diagnosis, prognosis and selecting therapy.
- Detects various translocations involving ABL1, RUNX1, BCL2, RARA, PAX5, JAK2, CBFβ, NUP98 and other genes involved in leukemia, lymphoma and myeloma.
- RNA expression/fusion profiling provides data on alternative splicing and levels of expression, which helps in the classification of various neoplasms.
- RNA sequencing offers a superior method to identify gene fusion variants known to have prognostic and predictive significance in treatment.

**Liquid Biopsy Hematology Profile** utilizes DNA only (177 genes) to detect mutations and chromosomal abnormalities in hematologic diseases, which may reduce the need for bone marrow biopsy. Liquid biopsy can provide:

- Improved capability to monitor hematologic neoplasms.
- High-sensitivity evaluation of molecular abnormalities in bone marrow.
- Distinguish between CHIP/CCUS and MDS.
- Diagnosis and follow up of MDS, CMML, AML, MPN, and lymphoma.
- Monitoring of minimal residual disease (MRD).

### SOLID TUMOR MOLECULAR PROFILING

Anthology Diagnostics offers comprehensive next-generation sequencing of DNA and RNA for solid tumors, including cancers of the lung, pancreas, brain, colon, breast, ovary, endometrium, thyroid, head and neck, and soft tissue (sarcoma and GIST). Anthology Diagnostics assays cover all clinically relevant genes, including tumor mutation burden (TMB), MSI, fusion/translocations, and copy number amplification and deletions. Tests include:

- **Solid Tumor Profile** describes the molecular abnormalities in various solid tumors covering abnormalities in single nucleotide and indels in 434 genes. This profile also detects MSI and TMB, and provides clinically actionable information.
- **Solid Tumor Profile Plus** combines the analysis of DNA (434 genes) with RNA (1,408 genes) to provide a comprehensive evaluation of cancer that includes detection of single nucleotide variation, copy number variation, expression and fusion. This test also provides targeted therapy and immunotherapy matching.
- **Solid Tumor Monitoring Liquid Biopsy Profile** is performed on circulating DNA (275 genes) in peripheral blood to identify molecular abnormalities implicated in solid tumors. This test is recommended for monitoring patients with cancer and when tissue biopsy is not possible.

## 5. IS THE LABORATORY ONLY FOCUSED ON ONCOLOGY?

Yes. By focusing only on the genes and tests relevant to oncology, Anthology Diagnostics can offer a practical, cost-effective, and efficient molecular profiling and analysis solution for patients and physicians. Although Anthology Diagnostics is currently focused on cancer only, the lab hopes to expand testing to include other diseases in the future.

## 6. WHAT IS THE BENEFIT OF SENDING LAB SPECIMENS TO THE ANTHOLOGY DIAGNOSTICS LABORATORY AT HMH JFK?

The Anthology Diagnostics lab offers a one-of-a-kind molecular profiling service. There are several benefits to using the Anthology Diagnostics lab at HMH JFK, including:

- **Comprehensive genomic profiling.** Comprehensive genomic profiling includes DNA and RNA analysis and interpretation using algorithms and AI-based software.
- **Faster turnaround time.** Using the Anthology Diagnostics lab at HMH JFK reduces sample shipping time and allows GTC to interpret data and deliver a comprehensive electronic report in 7 days for DNA and 7-10 days for RNA.
- **Comprehensive solid tumor analysis.** Solid tumor analysis includes microsatellite instability, tumor mutation burden (TMB), single nucleotide mutations, indels, chromosomal structural analysis, gene amplification, genes fusions, expression levels, and determining primary tumor.
- **Comprehensive analysis of hematologic neoplasms.** Hematologic analysis includes single nucleotide mutations, indels, chromosomal structural analysis (cytogenetics), genes fusions, expression and determining immunophenotypes, determining cell of origin in diffuse large B-cell lymphoma, determining Ph-like acute lymphoblastic leukemia, and complete classification and diagnosis of myeloid and myeloid neoplasms.
- **Comprehensive RNA analysis.** RNA analysis goes beyond fusions, providing data on precise diagnosis, immunophenotyping and classification, alternative splicing and information on expression levels of PD-L1 and other biomarkers.
- **More complete, actionable results.** Through its partnership with GTC, the Anthology Diagnostics lab provides more precise reporting that can be used in making treatment decisions that promote optimal patient outcomes. Reports are easy to read and information is provided in a simple and concise fashion. Reports also include information on potential clinical trials that match the detected abnormalities.
- **Cost-effective testing.** Anthology Diagnostics' efficient, practical approach to genomic testing and analysis is approved by Medicare and reimbursed by many commercial insurances, reducing or eliminating out-of-pocket costs for patients.
- **Minimal sample requirement.** Anthology Diagnostics can perform molecular profiling using minimal samples, such as those obtained from needle aspiration and core biopsy. The lab's "inadequate quantity" rejection rate is less than 1 percent compared to 20 percent at competing labs.

## 7. HOW DOES THE ANTHOLOGY DIAGNOSTICS LABORATORY DIFFER FROM OTHERS IN THE MARKET?

Unlike other labs that only analyze DNA or focus on the whole genome, Anthology Diagnostics performs next-generation genetic sequencing of DNA and RNA that relevant to oncology — providing a complete picture of the biology that drives cancer in a practical, efficient, and cost-effective way.

Combining Anthology Diagnostics' advanced testing and sequencing technology with high-quality algorithms, AI-based software, and expert interpretation of results allows Anthology Diagnostics to provide a detailed assessment of each patient's condition by:

- **Confirming a diagnosis and understanding the molecular subtype of a cancer** — not just what it looks like under a microscope.
- **Identifying drivers of cancer growth**, including genetic mutations and structural abnormalities, such as chromosomal translocations or fusions, that may guide the choice of targeted cancer therapies — promoting a precision medicine approach that may not only help in the selection of the most effective therapies, but avoid the use of less effective treatments. RNA profiling also yields more information than DNA sequencing if multiple molecular pathways are driving a cancer's growth, enabling clinicians to take aim at the cancer from a variety of angles by using a combination of targeted therapies.

- **Understanding the aggressiveness of a patient's cancer** so doctors know how intensively they need to treat it, or if it needs to be treated at all (some can just be monitored).
- **Predicting a patient's prognosis** and generating volumes of data on patient outcomes.
- **Monitoring response to therapy**, allowing physicians to change to a different treatment if genomic testing shows another approach is not working.
- **Detecting signs of relapse earlier**, before it can be seen on an imaging exam or causes symptoms.
- **Refining the selection of patients for clinical trials** that require participants to have certain molecular features in their cancers.

## 8. WHAT IS THE INSURANCE COVERAGE FOR PATIENTS? ARE THERE ANY OUT-OF-POCKET EXPENSES?

Anthology Diagnostics' Hematology and Solid Tumor profiles are covered by Medicare. Many commercial insurances also cover hematology and solid tumor genomic testing. If genomic testing is not covered by insurance, Anthology Diagnostics' cost-effective approach minimizes out-of-pocket expenses for patients while delivering complete, actionable results for physicians.

## 9. HOW QUICKLY DO THE RESULTS COME BACK TO THE PHYSICIAN?

Physicians receive a complete report in 7-10 days. Physicians can receive reports via fax, or view and download each patient's report online using the Anthology Diagnostics physician portal. Additionally, the reports will be scanned into the patient's EPIC record.

Anthology Diagnostics does not provide patients with direct access to their reports. However, physicians may provide patients with a copy of their report if requested.

## 10. WILL SUPPLIES/KITS BE PROVIDED TO THE PROVIDERS WHO WOULD LIKE TO UTILIZE THE LABS?

Yes. Providers who wish to use the Anthology Diagnostics lab must register online on the Anthology Diagnostics physician portal and download the Test Requisition Form. After the required information is received, the lab will send kits to the providers.

## 11. HOW DO SPECIMENS GET TRANSPORTED TO THE LAB?

This varies depending on where the referring physician is located – local specimens will be picked up by a courier. For long distance, specimen kits will be provided with a Fedex return label to send back to Anthology Diagnostics. In case of solid tumor testing and tissue paraffin block is at a pathology laboratory, please provide the pathology report and the Anthology Diagnostic laboratory will contact the pathology laboratory or hospital where the tissue is stored and request the tissue block.

## 12. HOW WILL I RECEIVE RESULTS FOR MY PATIENTS?

Registered providers can view and download patient reports online via the Anthology Diagnostics physician portal. Reports can also be provided via fax upon request.

## 13. WHERE IS THE LAB LICENSED?

The lab is licensed by the state of New Jersey and accredited by the College of the American Pathologists.

