

WHO	Patient's physician, including the oncologist, pathologist, and/or surgeon, may request testing.
WHAT	Comprehensive Somatic Tumor Test (DNA). Next-generation sequencing assay covering all coding regions of 277 key cancer genes for both solid tumors and hematologic malignancies.
HOW	Employs next-generation sequencing (NGS) for comprehensive genomic profiling of a patient's tumor sample.
WHY	<p>To identify potential clinically actionable targets and associated therapies</p> <ul style="list-style-type: none"> • Diagnostic/disease classification • Prognostic risk stratification • Informs targeted treatment selection • Clinical trial opportunities
WHEN	Difficult to treat cancers. Rare cancer types. Patients with metastatic, refractory, recurrent, and/or advanced stage cancers. Initial and serial follow-up profiling for hematologic malignancies including acute leukemia and myelodysplastic syndrome.
WHERE	Baylor Genetics in conjunction with Baylor College of Medicine, 20+ MDs and PhDs.
SAMPLE TYPES	Blood, bone marrow, FFPE, fresh tissue (frozen or in media), extracted DNA.

WHY CLARIFIND

Unique Molecular Index (UMI)	Allows for confident low-level variant detection (5% down to as low as 1%).
Amplicon-based, single adapter ligation, single primer extension	Low DNA input requirement – key for small biopsy samples.
Optimized gene coverage	Improved coverage of GC-rich regions in genes such as CEBPA and CCND1.
Simplification	One panel for all cancer types and variety of sample types.
Reporting	Report highlights nearby clinical trials by zip code. Color coded and easy to navigate summary page.
Expertise	Interpretive summary provided by board-certified clinical experts who are available for clinical consultation.

ClariFind

- Amplicon-based UMI chemistry
- Low DNA input requirement (minimum 40 ng)
- One test for both solid tumors and hematologic malignancies
- Interpretative summary written by board-certified lab director
- Report follows 2017 AMP/ASCO/CAP classification guidelines for variants in cancer
- Report highlights nearby clinical trials (within 100 mile radius)
- Lower cost

Main Competition

- Capture-based chemistry
- DNA input not disclosed but presumably higher based on published sample requirements
- Separate tests for solid tumors and hematologic malignancies
- No interpretative summary provided
- No AMP/ASCO/CAP classification for variants provided
- Report does not highlight nearby clinical trials
- Higher cost

ADDITIONAL TESTING RECOMMENDATIONS

Solid Tumors: 180K CGH/SNP Array for genomic copy number analysis, Microsatellite Instability (MSI), HNPCC/Lynch Syndrome, by PCR, PD-L1 by immunohistochemistry.

Non-Small Cell Lung Cancer: ALK, MET, RET, and ROS1 FISH, PD-L1 by immunohistochemistry.

Breast Cancer or Gastric Cancer: ERBB2 (HER2/neu) FISH.

Hematologic Malignancies: FLT3 mutation testing by PCR for acute myeloid leukemia, CytoScan HD SNP Array for genomic copy number analysis, Classical chromosomal analysis.

Aggressive/ High-Grade B-Cell Lymphoma: MYC, BCL2, and BCL6 FISH.

We offer other FISH panels and single probes and single gene molecular tests (please refer to requisition).