LIQUID BIOPSY

Labcorp® Plasma Focus™

An actionable liquid biopsy test for therapy selection with a clear report that focuses on FDA-approved and guideline-driven biomarkers for advanced solid cancers

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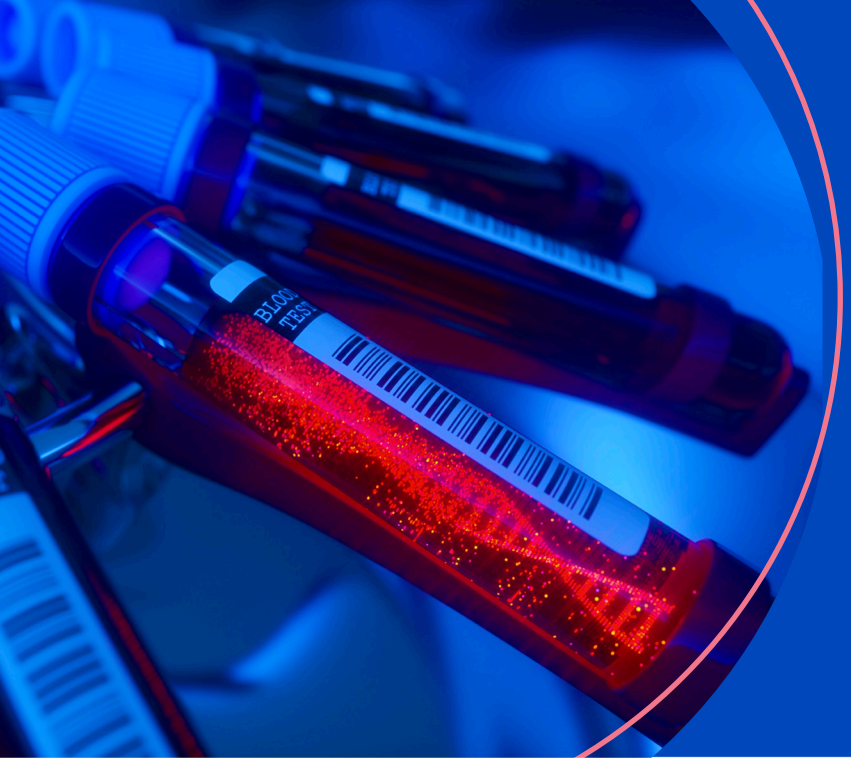

Labcorp Plasma Focus

A guideline-driven targeted liquid biopsy test that delivers actionable results to guide personalized treatment when tissue is not available.

This sensitive and specific multi-solid tumor NGS test focuses on biomarkers for FDA-approved therapies, enabling personalized care based on each patient's unique tumor to help improve outcomes.

When to order the Labcorp Plasma Focus test[1,2]

- When obtaining tissue via biopsy is challenging
- When limited archived tumor tissue is available
- When rapid results are needed for treatment decisions
- When patient is progressing on current therapy
- When OmniSeq INSIGHT® tissue biopsy test result is unavailable due to specimen quality or quantity insufficiency

Why choose the Labcorp Plasma Focus test

Streamlined experience

Simplify your tumor genomic profiling process with a convenient blood draw

Actionable results

A highly curated gene panel that focuses on FDA-approved biomarkers

Fast results

Personalized results within 7-10 days

Advanced cancers*

NSCLC, colorectal, breast, esophageal, gastric, gastroesophageal junction carcinomas, and melanoma

How to order

The Labcorp Plasma Focus test is available on the "Gene Profiling Assays" test requisition form, which can be found on oncology.labcorp.com/test-requisitions, or via your local Labcorp Oncology sales representative. For more information, please visit oncology.labcorp.com/liquid-biopsy

Please direct any questions regarding this test to the Labcorp clinical support team at MedOncSupport@Labcorp.com or Labcorp customer service at 800-781-1259.

*Validated for use in advanced cancers (stage III/IV) and recurrent metastatic cancers

Labcorp Plasma Focus test components

- **SNVs and Indels:**
  33 clinically actionable or relevant genes
- **Amplifications:**
  8 genes (*EGFR, ERBB2 (HER2), MET, MYC, FGFR2, KIT, CCND1, CD274*)
- **Translocations:**
  5 genes (*ALK, ROS1, FGFR2, NTRK1, RET*)
- **MSI status:**
  Only MSI-High status will be reported
- **Geocoded clinical trials:**

Abbreviations: SNVs, single nucleotide variants; Indels, insertion and deletions; MSI, microsatellite instability.

Gene	Translocations	Amplifications	SNV/Indels
AKT1			●
ALK	●		●
APC			●
ARID1A			●
ATM			●
BRAF			●
BRCA1			●
BRCA2			●
BRIP1			●
CCND1		●	●
CD274		●	●
CDH1			●
CSF1R			●
EGFR		●	●
ERBB2		●	●
EZH2			●
FGFR1			●

Gene	Translocations	Amplifications	SNV/Indels
FGFR2	●	●	●
HRAS			●
KIT		●	●
KRAS			●
MET		●	●
MYC		●	●
NRAS			●
NTRK1	●		●
PDGFRA			●
PIK3CA			●
POLD1			●
POLE			●
RAF1			●
RET	●		●
ROS1	●		●
TP53			●

Full coding region will be analyzed in all genes.

Powering better decisions: Clear and concise clinical report

Patient results

Variants of strong clinical significance, Tier 1	FDA - approved treatments in indication	Other treatment considerations
SLC34A2-ROS1: translocation	Crizotinib Entrectinib	NCCN Recommended: ceritinib, lorlatinib **Resistance: afatinib, erlotinib, gefitinib, osimertinib** Trials: 1 Expanded access 2 Phase 3 7 Phase 2
Genomic signatures	**FDA - approved treatments in indication**	**Other treatment considerations**
Microsatellite status: MSI-high	Pembrolizumab	Trials: 8 Phase 2 1 Phase 1/Phase 2 1 Early Phase 1
Variants of potential clinical significance, Tier 2	**FDA - approved treatments in indication**	**Other treatment considerations**
CCND1: amplification	N/A	Trials: 2 Phase 2 1 Phase 1
TP53: p.S241F	N/A	Other Indications: bortezomib/rituximab, lenalidomide/rituximab, Rituximab **Resistance: lorlatinib** Trials: 1 Phase 1
Variants of biological significance, Tier 3	**FDA - approved treatments inindication**	**Other treatment considerations**
No tier 3 variants detected.	N/A	N/A

2 Variants of uncertain significance. See page 21 for details.

Summary of variants of strong clinical significance (Tier 1), FDA-approved therapies within and across indications, therapies associated with resistance, and summary of clinical trials

Summary of MSI status, FDA-approved therapies and clinical trials

Summary of variants of potential clinical significance (Tier 2), other treatment considerations and summary of clinical trials

Summary of variants of biological significance (Tier 3), other treatment considerations, summary of clinical trials, and information on variants of uncertain significance

GUIDELINES

For non-small cell lung carcinoma (NSCLC) patients with tumors harboring a ROS1 rearrangement, the NCCN Guidelines (v.5.2022) highlight entrectinib, crizotinib, and ceritinib as first-line treatment options, with entrectinib and crizotinib identified as preferred options; lorlatinib and entrectinib are highlighted as therapeutic options following progression on crizotinib or ceritinib.

TREATMENT OPTIONS

Therapies with potential clinical benefit (3)

PEMBROLIZUMAB

Pembrolizumab, a programmed death receptor-1 (PD-1)-blocking antibody, is FDA- and EMA-approved for treating patients with unresectable or metastatic melanoma; in combination with pemetrexed and platinum chemotherapy for the first-line treatment of patients with metastatic nonsquamous non-small cell lung cancer (NSCLC), with no EGFR or ALK genomic tumor aberrations; in combination with carboplatin and either paclitaxel or paclitaxel protein-bound, for the first-line treatment of patients with metastatic squamous NSCLC; as a single agent for treating patients with metastatic NSCLC whose tumors express PD-L1 (TPS ≥1%) as determined by an FDA-approved test, with disease progression on or after

Guidelines–recommendations for patient management, summary of therapies with potential clinical benefit and therapies associated with resistance

Expanded Access clinical trials (1)

CRIZOTINIB (XALKORI(REGISTERED)) EXPANDED ACCESS PROTOCOL FOR THE TREATMENT OF ADULT OR PEDIATRIC PATIENTS WITH SOLID OR HEMATOLOGIC MALIGNANCIES THAT HARBOR A CRIZOTINIB-SENSITIVE MOLECULAR ALTERATION BUT WHO ARE UNABLE TO SWALLOW CRIZOTINIB CAPSULES

NCT02473497

Qualifying variant			Contact
Gene	Classification	Variant	United States: CO, GA, MA, NY, PA, RI, TN, WI Pfizer CT.gov Call Center; ClinicalTrials.gov_Inquiries@pfizer.com; 1-800-718-1021;
SLC34A2-ROS1	Tier 1A Pathogenic	fusion	

Summary of available geocoded clinical trials

This is a sample report for informational purposes only. The final clinical report for your patient may vary in the look and layout.

Performance characteristics: High sensitivity and specificity for key genomic alterations and MSI[3]

Variant	Reportable Range	Analytical Sensitivity (LoD)*	Analytical Specificity**
SNVs	≥0.1% VAF	0.6% VAF	99.9%
Indels	≥0.1% VAF	0.6% VAF	100%
CNAs	≥1.2-fold	1.4-fold	100%
Translocations	≥2 fusion reads	0.5% FRF	100%
MSI***	MSI-High	0.6% VAF (100% sensitivity)	100%

*Defined as the detection rate, that is, limit of detection (LOD); **100% means no false positives were detected;
***MSI-High is detected when ≥ 20% tracts are unstable. FRF, fusion read fraction; VAF, variant allele fraction.

Specimen requirements and storage instructions

- Collect a total of 20 mL of whole blood into the 2 Streck BCT® tubes supplied in the Labcorp Oncology Liquid Biopsy Kit
- Only the Labcorp Oncology Liquid Biopsy Kit can be used for collection and shipping
- Sample shipment to testing laboratory must occur within 24 hours of blood draw
- Store at room temperature. Do not refrigerate or freeze. Keep out of direct sunlight

Why choose Labcorp Oncology?

- Trusted by pathologists and oncologists
- Comprehensive testing portfolio supports patients throughout the cancer care continuum
- Single source solution for all your oncology testing
- More than 450 test options beyond NGS, including germline, single gene and pathology support
- Dedicated clinical support team for rapid and reliable response resolution

Powering better decisions

When you need trusted information to make clearer, better health decisions, consider us your source for oncology testing. Whether you are advancing therapies through clinical trials or diagnosing and treating individuals with cancer, we know you are working relentlessly to improve patient outcomes. We can help.

Genetic counseling

We offer a national network of genetic counselors to help inform and support your patients.
Call us at (855) GC-CALLS or (855) 422-2557.

Call us

Arizona: (800) 710-1800
Connecticut: (800) 447-5816
North Carolina: (800) 345-4363
Tennessee: (800) 874-8532

Visit us

oncology.labcorp.com

References
1. Pennell NA, Arcila ME, Gandara DR, West H. Biomarker testing for patients with advanced non–small cell lung cancer: Real-world issues and tough choices. 2019 ASCO Educational Book. May 17, 2019. **2.** Heitzer E, van den Broek D, Denis MG, et al. Recommendations for a practical implementation of circulating tumor DNA mutation testing in metastatic non-small-cell lung cancer. ESMO Open. 2022;7(2):100399. doi:10.1016/j.esmoop.2022.100399. **3.** Validation of genomic profiling by PGDx Plasma Focus to facilitate precision oncology through cell-free DNA testing of solid tumors. Association for Molecular Pathology (AMP) Annual Meeting, 2022.

For more information about Labcorp Plasma Focus, visit **oncology.labcorp.com/liquid-biopsy** or contact your Labcorp Oncology sales representative.

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