

October 2021

To: Clients of the New York Hospital Laboratories (NYHL)

From: NYHL Management

Subject: Circulating tumor DNA – Lung

Dear Valued NYHL Client,

We are happy to announce the availability of a new in-house test, Circulating Tumor DNA Lung (cell free DNA) assay by targeted next generation sequencing (NGS), for detecting gene mutations in patients with lung cancer. Circulating Tumor DNA Lung (cell free DNA) test is a targeted, next-generation sequencing (NGS) assay that interrogates plasma for clinically relevant somatic variants including 169 hotspot single nucleotide variants (SNVs) and insertions and deletions (indels) in 11 genes that commonly mutate in lung cancer. Variants identified by the Circulating Tumor DNA Lung NGS assay have clinical relevance with therapeutic, diagnostic and/or prognostic significance. The Circulating Tumor DNA Lung test targets key genes including: *ALK*, *BRAF*, *EGFR*, *ERBB2*, *KRAS*, *MAP2K1*, *MET*, *NRAS*, *PIK3CA*, *ROS1*, and *TP53*.

This assay provides important information regarding the presence of cancer gene hot spot variants detected in circulating tumor DNA in the patient's blood. Mutation information obtained by this assay may be used for monitoring or establishing eligibility for certain therapies. For example, an *EGFR* mutation identified from an adenocarcinoma of the lung may support an oncologist's decision to treat the patient with a tyrosine kinase inhibitor (TKI). Moreover, mutation analysis for certain genes including *EGFR*, *KRAS* and *ALK* is an important component of the National Comprehensive Cancer Network guidelines for non-small cell lung cancer due to targeted treatment implications (NCCN guidelines version 2.2021, www.nccn.org). A variant may also provide prognostic information that influences patient management/treatment decisions.

Circulating Tumor DNA Lung assay should not be used as the sole basis for the diagnosis of cancer or patient management decisions. These results must be taken into consideration along with multiple other factors including clinical correlation, surgical pathology and cytopathology morphologic diagnosis, immunohistochemistry, and prior molecular and histologic results.

The test can be ordered in EPIC as: CELL FREE TUMOR DNA LUNG (Code: LAB57596) and MUST be ordered as STAT.

Please send a minimum of 10 mL of fresh peripheral blood collected in EDTA tubes. Preferred collection is 6 mL Lavender tubes Blood. To allow proper processing, blood samples must be received in the laboratory during the day shift by 3pm, Monday through Friday, and the plasma separated within 6 hours of collection. The test is not available on weekends and holidays.

This test is a next-generation sequencing assay with expected turnaround time of 5-10 days.

If you have any questions regarding this test, please do not hesitate to contact Molecular Pathology Lab Director, Dr. Hanna Rennert, at ext. 746-6412, or Dr. John Siple, Molecular Pathology Technical Specialist, at ext. 746-2431.

As always, we appreciate your continued support and partnership with the Laboratories at NewYork-Presbyterian Hospital/Weill Cornell Medical Center.