EGFR ctDNA

London Health Sciences Centre

Pathology and Laboratory Medicine

Orderable – E-order/Requisition

Turnaround Time: 15 days

STAT: 10 days

<u>Alternate Name(s):</u>

ctDNA EGFR



Laboratory: Molecular Diagnostics Lab Specimen:

Plasma



Requisition: MOLECULAR DIAGNOSTIC REQUISITION



Method of Analysis: Methodology: ctDNA is isolated from a patient's plasma specimen and mixed with reagents that specifically detect, bind to, and make copies of the tumor's EGFR gene. This reaction produces fluorescence, which is then measured to determine presence or absence of the specific EGFR mutations in the

plasma specimen.

Collection Information:

Must be collected in STRECK cell free DNA blood collection tube or other plasma DNA preservation tube.

Reference Ranges:

See report

Interpretive Comments:

The cobas[®] EGFR Mutation Test v2 is an automated molecular assay designed to detect the presence of mutations in the epidermal growth factor receptor (EGFR) gene in cancer-spreading (metastatic) non-small cell lung cancer (NSCLC). In normal tissue, the EGFR protein transmits signals in cells to regulate cell growth and cell death. Mutations in the EGFR gene result in abnormal functioning of the EGFR protein and stimulate cancer cell growth in NSCLC. The cobas[®] EGFR Mutation Test v2 is to aid physicians in selecting patients with metastatic NSCLC with specific EGFR treatment mutations (i.e., exon 19 deletions and exon 21 L858R substitution mutations) in plasma specimens, also called liquid biopsy specimens, and also identify presence of the acquired EGFR TKI inhibitor treatment resistance related T790M mutation.

Special Processing:

EGFR ctDNA



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Sample must be collected in stabilizing blood collection tube specific for cell free DNA analysis.

Critical Information Required:

Sensitizing EGFR mutation must be provided prior to circulating tumuor DNA (ctDNA)test being performed. To conclusively determine that the patient is T790M negative, the patient must be assessed through the standard tissue biopsy and molecular testing process



Test Schedule: As required, Monday to Friday 0800-1600 hours