Patient: Test Test

DOB/Gender: 10/10/1980 (37 yrs) - Female
MRN/ID: 123456

Provider: John Doe, M.D.
Account: Hematology Oncology Associates
Phone: 800-123-4567 **Fax:** 800-765-4321

PRECIPIO EXPECT MORE.
4 Science Park, New Haven, CT 06511
Phone: 203-787-7888 Fax: 203-901-1289
www.precipiodx.com

Case No: RT18-00001

Collected: 02/15/18
Received: 02/15/18 10:23
Reported: 02/15/18 11:03

Alert Status: Routine
Report Status: Final
Report Category: Positive

Clinical information: Lung cancer

Received information: 1 Streck tube

Molecular

Professional Services Provided By
Yale SCHOOL OF MEDICINE

RESULT:

Peripheral blood:
- T790M mutation in EGFR exon 20 was detected
- C797S mutation in EGFR exon 20 was detected

Electronically Signed By: S. David Hudnall, MD, FCAP 02/15/18 10:52

INTERPRETATION:

Methods and Limitations:
Patient genomic DNA extracted from plasma was used for PCR amplification of codon 790 in exon 20 of the EGFR gene. The sample was evaluated by multiplexed ICE-COLD PCR (MX-ICP) and Allele Specific TaqMan® technology. This testing methodology can only detect mutations within regions of interest (T790M & C797S). A negative (wild type) result does not rule out the presence of a mutation that may be present but below the limits of detection for this assay (approximately 0.10%). Rare polymorphisms exist that could lead to false-negative or false-positive results. Interpretation of test results should be in the context of the patient's clinical and family histories, and other laboratory test results.

National Comprehensive Cancer Network (NCCN) guidelines for non-small cell lung carcinoma (NSCLC) endorse broader molecular profiling in individuals not responding to first-line therapy to determine cause for acquired resistance prior to changing therapy.[1,2] The MX-ICP EGFR test is designed to specifically identify the T790M & C797S mutations in EGFR which can be detected as a "second-site mutation" in more than 50% of EGFR-mutated lung cancers that have developed acquired resistance to anti-EGFR therapies (erlotinib or gefitinib).[3]

References:
1. Prabhakar CN. Epidermal growth factor receptor in non-small cell lung cancer. Transl Lung Cancer Res 2015; 4(2):110-118.
2. NCCN NSCLC Clinical Guidelines. http://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf
3. Pao W et al. Acquired resistance of lung adenocarcinomas to gefitinib or erlotinib is associated with a second mutation in the EGFR kinase domain. PLoS Med. 2005; 2(3):e73.

Disclaimer:
These test results should only be used in conjunction with the patient's clinical history and any previous analysis of appropriate family members. It is strongly recommended that these test results be communicated to the patient in a setting that includes appropriate counseling. The results of this test are not intended to be used as the sole means for patient diagnosis or patient management decisions. The performance characteristics of this test were validated by Precipio, Inc. laboratories. The U.S. Food and Drug Administration (FDA) has not approved this test; however, FDA approval is not currently required for clinical use of this test. This test meets the requirements for high complexity tests under the Clinical Laboratory Improvement Amendments Act and its implementing regulations. Individuals being studied should understand that rare diagnostic errors may occur. Possible sources of diagnostic errors include sample mix-ups, erroneous paternity identification, and genotyping errors. Genotyping errors can result from trace contamination of PCR,

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from maternal contamination of fetal samples, from rare genetic variants which interfere with analysis, from mosaicism at levels below standard detection, and from other sources.

END OF REPORT

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