TEST CHANGE

EGFR Mutation Detection by Pyrosequencing

2002440, EGFR PCR

Specimen Requirements:	
Patient Preparation:	~~For a general FNA collection and smear preparation refer to ARUP's Laboratory Test Directory: Cytology, Fine Needle Aspiration Collection at http://ltd.aruplab.com/tests/pdf/366~~
Collect:	Tumor tissue.
Specimen Preparation:	Tumor Tissue: Formalin fix (10 percent neutral buffered formalin) and paraffin embed tissue. Protect from excessive heat. Tissue block will be returned after testing. Transport tissue block or 5 unstained 5-micron slides. (Min: 3 slides) ~~(Min: 3 slides) Fine Needle Aspirate (FNA): Prepare FNA smear with Diff-Quik or equivalent stain by standard methods (air-dried slides are preferred). Number of slides needed is dependent on the tumor cellularity of the smear. (Min: 1 slide). Slide(s) will be destroyed during testing process and will not be returned to client.~~ Transport block and/or slide(s) in a tissue transport kit (ARUP Supply #47808) available online through eSupply using ARUP Connect(TM) or contact ARUP Client Services at (800) 522-2787.
Transport Temperature:	Room temperature. Also acceptable: Refrigerated. Ship in cooled container during summer months.
Unacceptable Conditions:	Less than 25 percent tumor. Specimens fixed/processed in alternative fixatives (alcohol, Prefer) or heavy metal fixatives (B-4 or B-5). Decalcified specimens. ~~FNA smears with less than 50 tumor cells.~~
Remarks:	Include surgical pathology report. If multiple specimens (blocks or slides) are sent to ARUP, they must be accompanied by one of the following: an order comment indicating that the ARUP pathologist should choose the specimen most appropriate for testing (e.g., "Choose best block"), or individual orders for each sample submitted. A Pathologist Block Selection Fee (ARUP test code 3002076) will be added to orders that utilize the first option. If multiple specimens are sent to ARUP without a request for pathologist block/slide selection or individual orders, they will be held until clarification is provided.
Stability:	Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable

Methodology:	Polymerase Chain Reaction/Pyrosequencing
Performed:	Varies
Reported:	6-14 days
Note:	This test detects mutations in EGFR exons 18, 19, 20 and 21 (codons 719, 745-753, 768, 790, 858, and 861).
CPT Codes:	81235
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

Refer to report.

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.

Reference Interval: