

Notification Date: September 9, 2025 Effective Date: September 9, 2025

EGFR Gene, Targeted Mutation Analysis, 51 Mutation Panel, Tumor

Test ID: EGFRS

Explanation: On the effective date, the Specimen Required will be updated to clarify tissue preferences and standardize amongst molecular tissue assays. This update will not affect assay-specific acceptance criteria.

Current Specimen Required

Submit only 1 of the following specimens:

Preferred:

Specimen Type: Tissue, smear stained with Diff Quik, fine needle aspirate (FNA), or pleural fluid in cell

blocks

Container/Tube: Tissue block

Collection Instructions: Submit a formalin-fixed,

paraffin-embedded (FFPE) tissue block.

Acceptable:

Specimen Type: Tissue, smear stained with Diff Quik, FNA, or pleural fluid in cell block or cytology blood

smear

Container/Tube: Slides

Specimen Volume: 1 Hematoxylin and eosin stained

and 5 unstained

Collection Instructions:

- 1. **For FFPE tissue**, FNA or pleural fluid: Submit 1 slide stained with hematoxylin and eosin and 5 unstained, non-baked slides with 5 to 10-micron thick sections of the tumor tissue.
- 2. For cytology blood smear: Submit up to 2 slides stained with Diff Quik

New Specimen Required

Preferred: Submit 3, if available, or 2 of the following specimens.

Acceptable: Submit at least one of the following specimens.

Specimen Type: Tissue block

Collection Instructions: Submit a formalin-fixed, paraffin-embedded (FFPE) tissue block with acceptable amount of tumor tissue.

Specimen Type: Tissue slide

Source: FFPE tissue, cell block (prepared from fine-

needle aspirate, or pleural fluid)

Slides: 1 Hematoxylin and eosin-stained and 5

unstained

Collection Instructions:

Submit the followings slides:

1 Slide stained with hematoxylin and eosin

AND

5 Unstained, nonbaked slides with 5-micron thick sections of the tumor tissue.

Specimen Type: Cytology slide (direct smears; smears stained with Pap stain are not acceptable)

Slides: 2 Slides

Collection Instructions: Submit 2 slides stained with Diff Quik and coverslipped with a total of 5000 nucleated cells (preferred) or at least 3000 nucleated cells (minimum).

Note: Glass coverslips are preferred; plastic coverslips are acceptable but will result in longer turnaround times.

Additional Information: Cytology slides will not be returned. An image of the slides will be stored per regulatory requirements.

Questions

Contact Michelle Raths, Laboratory Resource Coordinator at 800-533-1710.