

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

KRAS Somatic Mutation Analysis, Tumor

Test ID: KRASP

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

Preferred:

Specimen Type: Tissue slides with tissue block and cytology slides (direct smears or ThinPrep, if applicable, especially if tissue is small)

Slides: 1 stained and 5 unstained with tissue block and 1-3 cytology slides (direct smears or ThinPrep) Collection Instructions: Submit 1 hematoxylin and eosin (H and E) stained slide and 10 unstained. nonbaked 5-micron thick sections and the tissue block with the remaining material and 1-3 cytology slides (direct smears or ThinPrep) with highest cellularity Note: The total amount of required tumor can be obtained by scraping up to 5 slides from the same block.

Acceptable:

Specimen Type: Tissue block

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

Specimen Type: Tissue slide

Slides: 1 Stained and 10 unstained

Collection Instructions: Submit 1 slide stained with hematoxylin and eosin and 5 unstained, nonbaked slides with 5-micron thick sections of the tumor tissue. Note: The total amount of required tumor nuclei can be obtained by scraping up to 5 slides from the same block.

Additional Information: Unused unstained slides will not be returned.

Specimen Type: Cytology slide (direct smears or

ThinPrep)

Slides: 1 to 3 Slides

Collection Instructions: Submit 1 to 3 slides stained

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 tissue block with acceptable amount of tumor tissue.

Specimen Type: Tissue slide

Slides: 1 Hematoxylin and eosin-stained and 10 unstained

Collection Instructions:

Submit the followings slides:

1 Slide stained with hematoxylin and eosin AND

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

Note: The total amount of required tumor nuclei can be obtained by scraping up to 10 slides from the same block.

Additional Information: Unused unstained slides will not be returned.

Specimen Type: Cytology slide (direct smears or

ThinPrep)

Slides: 1 to 3 Slides

Collection Instructions: Submit 1 to 3 slides stained 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.

and coverslipped with a preferred total of 5000 nucleated cells, or a minimum of at least 3000 nucleated cells.

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

Additional Information: Cytology slides will not be returned.

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Questions

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