

***TERT* Promoter Mutation Analysis, Droplet Digital PCR, Tumor**

Test ID: TERTD

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	New Specimen Required
This assay requires at least 5% nuclei of tumor cells/cells of interest. -Preferred amount of tumor area with sufficient percent tumor nuclei: tissue 144 mm² -These amounts are cumulative over up to 10 unstained slides and must have adequate percent nuclei of tumor cells/cells of interest. -Tissue fixation: 10% neutral buffered formalin, not decalcified -Cytology fixatives: Cytology smears fixed in alcohol and thin preps fixed with CytoLyt. Preferred: Specimen Type: Tissue block Collection Instructions: Submit a formalin-fixed, paraffin-embedded tissue block with acceptable percent nuclei of tumor cells/cells of interest. Acceptable: Specimen Type: Tissue slides Slides: 1 Hematoxylin and eosin stained and 10 unstained Collection Instructions: Submit 1 slide stained with hematoxylin and eosin and 10 unstained, nonbaked slides with 5-micron thick sections. Note: The total amount of required cell nuclei can be obtained by scraping up to 10 slides from the same block. 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 preferred total of 3000 nucleated cells or a minimum of at least 350 nucleated cells.	This assay requires at least 5% nuclei of tumor cells/cells of interest. -Preferred amount of tumor area with sufficient percent tumor nuclei: tissue 144 mm² -These amounts are cumulative over up to 10 unstained slides and must have adequate percent nuclei of tumor cells/cells of interest. -Tissue fixation: 10% neutral buffered formalin, not decalcified -Cytology fixatives: Cytology smears fixed in alcohol and thin preps fixed with CytoLyt. 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 following 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.

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

Additional Information: Cytology 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.

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

Questions

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