

ESR1 Mutation Analysis, Next-Generation Sequencing, Tumor

Test ID: ESR1T

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 20% tumor nuclei. NOTE: Submit tissue from either local recurrence or metastatic disease collected after endocrine therapy has been administered (see Clinical Information for more details). -Preferred amount of tumor area with sufficient percent tumor nuclei: tissue 216 mm(2) -Minimum amount of tumor area: tissue 36 mm(2) -These amounts are cumulative over up to 10 unstained slides and must have adequate percent tumor nuclei. -Tissue fixation: 10% neutral buffered formalin, not decalcified -For specimen preparation guidance, see Tissue Requirement for Solid Tumor Next-Generation Sequencing. In this document, the sizes are given as 4 mm x 4 mm x 10 slides as preferred: approximate/equivalent to 144 mm(2) and the minimum as 3 mm x 1 mm x 10 slides: approximate/equivalent to 36 mm(2). Preferred: Specimen Type: Tissue block Collection Instructions: Submit a formalin-fixed, paraffin-embedded tissue block with acceptable amount of tumor tissue. Acceptable: Specimen Type: Tissue slides Slides: 1 Stained and 10 unstained Collection Instructions: Submit 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.	This assay requires at least 20% tumor nuclei. NOTE: Submit tissue from either local recurrence or metastatic disease collected after endocrine therapy has been administered (see Clinical Information for more details). -Preferred amount of tumor area with sufficient percent tumor nuclei: tissue 216 mm(2) -Minimum amount of tumor area: tissue 36 mm(2) -These amounts are cumulative over up to 10 unstained slides and must have adequate percent tumor nuclei. -Tissue fixation: 10% neutral buffered formalin, not decalcified -For specimen preparation guidance, see Tissue Requirement for Solid Tumor Next-Generation Sequencing. In this document, the sizes are given as 4 mm x 4 mm x 10 slides as preferred: approximate/equivalent to 144 mm(2) and the minimum as 3 mm x 1 mm x 10 slides: approximate/equivalent to 36 mm(2). 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:

Additional Information: Unused unstained slides will not be returned.

Specimen Type: Cytology slides (direct smears or ThinPrep)

Slides: 1 to 3 Slides

Collection Instructions: Submit 1 to 3 slides stained 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.

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.

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.