

Notification Date: September 23, 2022 Effective Date: October 24, 2022

B-Catenin Mutations Analysis, Next-Generation Sequencing, Tumor

Test ID: CTNBT

Useful for:

Distinguishing desmoid-type fibromatosis from other soft tissue tumors by assessing gene targets within the beta-catenin (*CTNNB1*) gene

Additional Tests:

Test ID	Reporting Name	Available Separately	Always Performed
SLIRV	Slide Review in MG	No (Bill Only)	Yes

Testing Algorithm:

When this test is ordered, slide review will always be performed at an additional charge.

Methods:

Sequence Capture and Targeted Next-Generation Sequencing (NGS)

Reference Values:

An interpretive report will be provided.

Necessary Information:

A pathology report (final or preliminary), at minimum containing the following information, must accompany specimen for testing to be performed:

- 1. Patient name
- 2. Block number-must be on all blocks, slides, and paperwork (can be handwritten on the paperwork)
- 3. Tissue collection date
- 4. Source of the tissue

Specimen Requirements:

This assay requires at least 20% tumor nuclei.

- -Preferred amount of tumor area with sufficient percent tumor nuclei: tissue 216mm(2)
- -Minimum amount of tumor area: tissue 36mm(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 <u>Tissue Requirement for Solid Tumor Next-Generation Sequencing</u>. In this document, the sizes are given as 4mm x 4mm x 10 slides as preferred: approximate/equivalent to 144 mm(2) and the minimum as 3mm x 1mm x 10 slides: approximate/equivalent to 36mm(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.

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 cover slipped 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.

Specimen Stability Information:

Specimen Type	Temperature	Time	Special Container
Varies	Ambient (preferred)		
	Refrigerated		

Cautions:

- This test cannot differentiate between somatic and germline alterations. Additional testing may be necessary to clarify the significance of results if there is a potential hereditary risk.
- DNA variants of uncertain significance may be identified.
- A negative result does not rule out the presence of a variant that may be present but below the limits of detection of this assay. The analytical sensitivity of this assay for sequence reportable alterations is 5% mutant allele frequency with a minimum coverage of 500X in a sample with 20% or more tumor content.

- Point mutations and small insertion/deletion mutations will be detected in the CTNNB1 gene only. This test
 may detect single exon deletions but does not detect multi-exon deletions, duplications, or genomic copy
 number variants.
- Rare alterations (ie, polymorphisms) may be present that could lead to false-negative or false-positive results.
- Test results should be interpreted in the context of clinical, tumor sampling, histopathological, and other laboratory data. If results obtained do not match other clinical or laboratory findings, contact the laboratory for discussion. Misinterpretation of results may occur if the information provided is inaccurate and/or incomplete.
- Reliable results are dependent on adequate specimen collection and processing. This test has been
 validated on cytology slides and formalin-fixed, paraffin-embedded tissues; other types of fixatives are
 discouraged. Improper treatment of tissues, such as decalcification, may cause polymerase chain reaction
 failure.

CPT Code:

88381 - Microdissection, manual 81479

Day(s) Performed: Monday through Friday Report Available: 12-20 days

Questions

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