

Neuro-Oncology Gene Panel, Rearrangements Only, Tumor

Test ID: NONCR

Useful for:

- Identifying rearrangements that may support a diagnosis or help determine prognosis for patients with central nervous system tumors
- Identifying rearrangements within genes known to be associated with response or resistance to specific cancer therapies
- This test is **not intended** for use for hematological malignancies.

Ordering Guidance:

Multiple oncology (cancer) gene panels are available. For more information see [Hematology, Oncology, and Hereditary Test Selection Guide](#).

Testing Algorithm

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

Reflex Tests:

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

Methods:

Targeted Polymerase Chain Reaction (PCR)-Based Next-Generation Sequencing (NGS)

Reference Values:

An interpretive report will be provided.

Specimen Requirements:

This assay requires at least 10% tumor nuclei.

- Preferred amount of tumor area with sufficient percent tumor nuclei: tissue 144 mm(2)
- Minimum amount of tumor area: tissue 36 mm(2)

-If ordered in conjunction with CMAPT / Chromosomal Microarray, Tumor, Formalin-Fixed Paraffin-Embedded, the preferred amount of tissue is 430 mm(2), the minimum amount is 180 mm(2).
 -These amounts are cumulative over up to 15 unstained slides and must have adequate percent tumor nuclei.
 -Tissue fixation: 10% neutral buffered formalin, not decalcified
 -For this test, at least 6 mm x 6 mm areas on 4 unstained slides is preferred: this is approximately equivalent to 144 mm(2). The minimum acceptable area is 6 mm x 6 mm on 1 unstained slides: approximately equivalent to 36 mm(2). For specimen preparation guidance, see [Tissue Requirement for Solid Tumor Next-Generation Sequencing](#).

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 slide
Slides: 1 Hematoxylin and eosin-stained and 15 unstained
Collection Instructions: Submit the followings slides:
 1 Slide stained with hematoxylin and eosin
 AND
 15 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 15 slides from the same block.
Additional Information: Unused unstained slides will not be returned.

Necessary Information:

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 Stability Information:

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

Cautions:

- This test **does not** include evaluation of somatic DNA mutations.
- 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.
- Variants of uncertain significance may be identified.

- A negative result does not rule out the presence of a fusion that may be present below the limits of detection of this assay. The analytical sensitivity of this assay is a minimum coverage of 10 targeted fusion reads with 5 unique fusion molecules in a sample with 10% or greater tumor content.
- Detection of fusion transcripts (RNA) is particularly labile and degrades quickly. Rapid preservation of the tumor sample after collection reduces the likelihood of degradation, but there are sometimes biological factors, such as tumor necrosis that interfere with obtaining a high-quality RNA specimen despite rapid preservation.
- This panel can detect in-frame and out-of-frame fusions. There may be lower sensitivity in detecting out-of-frame fusions, such as exon-intron, intron-intron, or big insertions. This assay will only detect fusions involving at least one gene in the defined gene fusion target list of interest.
- The presence or absence of a variant may not be predictive of response to therapy in all patients.
- 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 or incomplete.
- Reliable results are dependent on adequate specimen collection and processing. This test has been validated on formalin-fixed, paraffin-embedded tissues; other fixatives are discouraged. Improper treatment of tissues, such as decalcification, may cause polymerase chain reaction failure.
- Genes may be added or removed based on updated clinical relevance.

CPT Code:

81456

Day(s) Performed: Monday through Friday

Report Available: 12 to 20 days

Questions

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