MAYO CLINIC LABORATORIES

NEW TEST

Notification Date: April 21, 2020
Effective Date: April 28, 2020

FGFR Mutation and Fusion Analysis, Tumor

Test ID: TFGFR

Genetics Information:

This test is an FDA-approved assay for the evaluation of somatic mutations and fusions in the *FGFR3* and *FGFR2* genes to identify urothelial carcinoma patients that may be eligible for treatment with *FGFR*-targeted therapies such as Balversa (erdafitinib).

This test uses targeted reverse transcriptase (RT)-PCR to evaluate for somatic mutations within the *FGFR3* gene: R248C, S249C, G370C, and Y373C. RT-PCR is also used to identify certain rearrangements (fusions): *FGFR3-TACC3v3* and *FGFR3-TACC3v1.* Furthermore, this test can identify fusions: *FGFR3-BAIAP2L1, FGFR2-BICC1,* and *FGFR2-CASP7*, however detection of these fusions is considered off-label use of the test.

Of note, this test is performed to evaluate for somatic mutations and rearrangements (fusions) within solid tumor samples. This test is not intended for use for hematological malignancies. Additionally, this test does not assess for germline alterations within the genes listed.

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	Yes

Methods:

Reverse Transcriptase-Polymerase Chain Reaction (RT-PCR)

Reference Values:

An interpretive report will be provided.

Specimen Requirements:

This assay requires at least 10% tumor nuclei.

The amount of tissue needed is dependent on a variety of preanalytical factors (eg, cellularity, ischemic time, fixation).

The FFPE input required is equivalent to a 4–5 micron slide thickness with a total tumor surface area between 100 mm(2) and 500 mm(2) (inclusive). This can be created by combining material from multiple slides from one tissue block.

Specimen Type:	Tissue Slide
Acceptable:	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.

Necessary Information:

Pathology report (final or preliminary) at minimum containing the following information **must** accompany specimen in order 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
Varies	Ambient (preferred)
	Frozen
	Refrigerated

Cautions:

A negative (wild-type) result does not rule out the presence of a mutation or rearrangement (fusion) that may be present but below the limits of detection of this assay. It also does not rule out the presence of other activating mutations in the fibroblast growth factor receptor (*FGFR*) gene outside those that the assay was designed to detect.

The predictive value of *FGFR* testing applies to *FGFR*- kinase inhibitors therapy erdafitinib (BALSERVA), not to other therapeutic agents.

Not all patients who have *FGFR* mutations respond to *FGFR*-targeted therapies.

Rare polymorphisms exist that could lead to false-negative or false-positive results.

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 PCR failure.

Test results should be interpreted in context of clinical findings, tumor sampling, and other laboratory data. If results obtained do not match other clinical or laboratory findings, please contact the laboratory for possible interpretation. Misinterpretation of results may occur if the information provided is inaccurate or incomplete.

CPT Code: 0154U
88381 (slide review)

Day(s) Setup: Monday through Friday

Analytic Time: 5 days

Questions

Contact Heather Flynn Gilmer or Melissa Lonzo Green, Laboratory Technologist Resource Coordinators at 800-533-1710.