Overview

Useful For

Identifying solid tumors that may respond to targeted therapies by assessing multiple gene targets simultaneously

Identifying specific variants within genes known to be associated with response or resistance to specific cancer therapies

Identifying variants that may help determine prognosis forpatients withsolid tumors

Assisting in establishing a diagnosis (eg, *KIT* and *PDGFRA* alterations for gastrointestinal stromal tumors)

Aiding in the determination of clinical trial eligibility for patients with genetic variants not amenable to current FDA-approved targeted therapies

This test is **not intended** for use for hematological malignancies or assessment of germline variants

Genetics Test Information

This test uses targeted next-generation sequencing to evaluate for somatic variants within 50 genes associated with cancer: *ABL1, AKT1, ALK, APC, ATM, BRAF, CDH1, CDKN2A, CSF1R, CTNNB1, EGFR, ERBB2, ERBB4, EZH2, FBXW7, FGFR1, FGFR2, FGFR3, FLT3, GNA11, GNAQ, GNAS, HNF1A, HRAS, IDH1, IDH2, JAK2, JAK3, KDR, KIT, KRAS, MET, MLH1, MPL, NOTCH1, NPM1, NRAS, PDGFRA, PIK3CA, PTEN, PTPN11, RB1, RET, SMAD4, SMARCB1, SMO, SRC, STK11, TP53,* and *VHL*. See Targeted Gene Regions Interrogated by Solid Tumor Targeted Cancer Gene Panel by Next-Generation Sequencing in Special Instructions for details regarding the targeted gene regions identified by this test.

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.

Special Instructions

- Targeted Gene Regions Interrogated by Solid Tumor Targeted Cancer Gene Panel by Next Generation Sequencing
- Tissue Requirements for Solid Tumor Next-Generation Sequencing

Method Name

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

NY State Available

Yes

Specimen

Specimen Type

Varies

Ordering Guidance

Multiple oncology (cancer) gene panels are available. For more information see Oncology Somatic NGS Testing Guide.

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 Required

This assay requires at least 20% tumor nuclei.

-Preferred amount of tumor area with sufficient percent tumor nuclei: tissue144 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 Special Instructions. 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 slide

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.

Specimen Type: Cytology slide (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.

Forms

If not ordering electronically, complete, print, and send an Oncology Test Request (T729) with the specimen.

Specimen Minimum Volume

See Specimen Required

Reject Due To

Specimens that have been decalcified (all methods); Specimens that have not been formalin-fixed, paraffin-embedded	Reject

Specimen Stability Information

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

Clinical and Interpretive

Clinical Information

Targeted cancer therapies are defined as antibody or small molecule drugs that block the growth and spread of cancer by interfering with specific cell molecules involved in tumor growth and progression. Multiple targeted therapies have been approved by the FDA for treatment of specific cancers. Molecular genetic profiling is often needed to identify targets amenable to targeted therapies and to minimize treatment costs and therapy-associated risks.

Next-generation sequencing has recently emerged as an accurate, cost-effective method to identify variants across numerous genes known to be associated with response or resistance to specific targeted therapies. This test is a single assay that uses formalin-fixed paraffin-embedded tissue to assess for common variants in 50 genes known to be associated with cancer. .

See Targeted Gene Regions Interrogated by Solid Tumor Targeted Cancer Gene Panel by Next-Generation Sequencing in Special Instructions for details regarding the targeted gene regions identified by this test.

Reference Values

An interpretive report will be provided.

Interpretation

An interpretive report will be provided.

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 (wild-type) result does not rule out the presence of a variant that may be present but below the limits of detection of this assay (approximately 5%-10%).

This test does not detect large single or multi-exon deletions or duplications or genomic copy number variants.

Rare polymorphisms may be present that could lead to false-negative or false-positive results. Test results should be interpreted in the 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 updated interpretation. Misinterpretation of results may occur if the information provided is inaccurate or incomplete.

Clinical Reference

1. Targeted Cancer Therapies. National Cancer Institute Fact Sheet. Updated July 17, 2020. Accessed September 15, 2020. Available at www.cancer.gov/cancertopics/factsheet/Therapy/targeted

2. Vogelstein B, Papadopoulos N, Velculescu VE, Zhou S, Diaz Jr LA, Kinzler KW: Cancer genome landscapes. Science 2013;339:1546-1558

3. Beadling C, Neff TL, Heinrich MC, et al: Combining highly multiplexed PCR with semiconductor-based sequencing for rapid cancer genotyping. J Mol Diagn. 2013;15:171-176

Performance

Method Description

Next-generation sequencing is performed to test for the presence of a mutation in targeted regions of the following 50 genes: *ABL1, AKT1, ALK, APC, ATM, BRAF, CDH1, CDKN2A, CSF1R, CTNNB1, EGFR, ERBB2, ERBB4, EZH2, FBXW7, FGFR1, FGFR2, FGFR3, FLT3, GNA11, GNAQ, GNAS, HNF1A, HRAS, IDH1, IDH2, JAK2, JAK3, KDR, KIT, KRAS, MET, MLH1, MPL, NOTCH1, NPM1, NRAS, PDGFRA, PIK3CA, PTEN, PTPN11, RB1, RET, SMAD4, SMARCB1, SMO, SRC, STK11, TP53,* and *VHL*. See Targeted Gene Regions Interrogated by Solid Tumor-Targeted Cancer Gene Panel by Next Generation Sequencing in Special Instructions for details regarding the targeted gene regions identified by this test.(Unpublished Mayo method)

PDF Report

No

Day(s) Performed

Monday through Friday

Report Available

12 to 20 days

Specimen Retention Time

Unused portions of blocks will be returned to the client. Unused slides are stored indefinitely.

Performing Laboratory Location

Rochester

Fees and Codes

Fees

- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their Regional Manager. For assistance, contact Customer Service.

Test Classification

This test was developed, and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the US Food and Drug Administration.

CPT Code Information

81445-Targeted genomic sequence analysis panel, solid organ neoplasm

Slide Review

88381-Microdissection, manual

LOINC® Information

Test ID	Test Order Name	Order LOINC Value
CAPN	Solid Tumor Targeted Cancer Panel	73977-1

Result ID	Test Result Name	Result LOINC Value
52611	Result Summary	50397-9
52612	Result	82939-0
52613	Interpretation	69047-9
52614	Additional Information	48767-8
52615	Specimen	31208-2
52616	Source	31208-2
52617	Tissue ID	80398-1
52618	Released By	18771-6