Overview

Useful For
Diagnosis and management of patients with melanoma

Simultaneously interrogating multiple gene targets including \textit{BRAF} (e.g., V600E and V600K), \textit{GNAQ}, \textit{GNA11}, \textit{KIT} and \textit{NRAS}

Genetics Test Information

This test uses targeted next-generation sequencing to evaluate for somatic mutations within the \textit{BRAF} (exons 11 and 15), \textit{GNAQ} (exon 5), \textit{GNA11} (exon 5), \textit{KIT} (exon 2, 9, 10, 11, 13, 14, 15, 17, 18), and \textit{NRAS} (exons 2, 3, 4) genes. This includes, but is not limited to, the testing of somatic mutations in \textit{NRAS} codons 12, 13, 61,146; \textit{GNA11} and \textit{GNAQ} codon 209; and \textit{BRAF} codons 594, 596, 600 (e.g. V600E/K). See Targeted Gene Regions Interrogated by Melanoma Panel in Special Instructions for details regarding the targeted gene regions identified by this test.

Additional Tests

<table>
<thead>
<tr>
<th>Test ID</th>
<th>Reporting Name</th>
<th>Available Separately</th>
<th>Always Performed</th>
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<tbody>
<tr>
<td>SLIRV</td>
<td>Slide Review in MG</td>
<td>No</td>
<td>Yes</td>
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</table>

Testing Algorithm

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

Special Instructions

- Targeted Gene Regions Interrogated by Melanoma Panel
- 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

Advisory Information

Mutations in genes interrogated by this test can be seen in neoplasms other than melanoma. For \textit{KIT} Asp816Val mutation analysis in mast cell disease, see KITAS / KIT Asp816Val Mutation Analysis, Qualitative PCR, Varies.

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: tissue 144 mm²

-Minimum amount of tumor area: tissue 36 mm².

-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 4mm x 4mm x 10 slides as preferred: approximate/equivalent to 144 mm² and the minimum as 3mm x 1mm x 10 slides: approximate/equivalent to 36mm².

**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

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

Specimen Stability Information

<table>
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<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
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<tbody>
<tr>
<td>Varies</td>
<td>Ambient (preferred)</td>
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<td></td>
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<tr>
<td>Frozen</td>
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<tr>
<td>Refrigerated</td>
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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 mutations 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 mutations in the following genes known to be associated with melanoma: BRAF, GNA11, GNAQ, KIT, and NRAS. This includes the common BRAF V600E and V600K mutations. The results of this test can be useful for assessing prognosis and guiding treatment of individuals with melanoma.

See Targeted Gene Regions Interrogated by Melanoma Panel in Special Instructions for details regarding the targeted gene regions identified by this test.

Reference Values
An interpretative report will be provided.

Interpretation
An interpretative 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
Test Definition: MELP
Melanoma Panel, Tumor

identified.

A negative (wild-type) result does not rule out the presence of a mutation that may be present but below the limits of detection of this assay (approximately 5%-10%). This test does not detect large single or multixon 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, contact the laboratory for updated interpretation. 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 types of fixatives are discouraged. Improper treatment of tissues, such as decalcification, may cause PCR failure.

Clinical Reference


Performance

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Method Description

Next generation sequencing is performed to test for the presence of a mutation in targeted regions of the \textit{BRAF}, \textit{GNA11}, \textit{GNAQ}, \textit{KIT}, and \textit{NRAS} genes. See Targeted Gene Regions Interrogated by Melanoma Panel in Special Instructions for details regarding the targeted gene regions identified by this test.(Unpublished Mayo method)

PDF Report

No

Day(s) and Time(s) Test Performed

Monday through Friday; Varies

Analytic Time

12 days

Maximum Laboratory Time

20 days

Specimen Retention Time

Unused portions of blocks will be returned. 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 U.S. Food and Drug Administration.

CPT Code Information

81445

88381-Microdissection, manual

LOINC® Information

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