Overview

Useful For
Identification of melanoma tumors that may respond to BRAF-targeted therapies

Additional Tests

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

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

Method Name
Polymerase Chain Reaction (PCR) Analysis

NY State Available
Yes

Specimen

Specimen Type
Varies

Specimen Required
Pathology report must accompany specimen in order for testing to be performed.

Preferred:
Specimen Type: Tissue
Container/Tube: Tissue block

Collection Instructions: Submit a formalin-fixed, paraffin-embedded tissue block.

Acceptable:
Specimen Type: Tissue
Container/Tube: Slides
Specimen Volume: 1 stained and 5 unstained

Collection Instructions: Submit 1 slide stained with hematoxylin and eosin and 5 unstained, nonbaked slides with 5-micron thick sections of the tumor tissue.
Forms
If not ordering electronically, complete, print, and send an Oncology Test Request (T729) with the specimen.

Specimen Minimum Volume
Formalin-fixed, paraffin-embedded (FFPE) tissue block (preferred) or 1 slide stained with hematoxylin-and-eosin and 5 unstained, nonbaked slides (5-microns thick sections) of the tumor tissue.

Reject Due To

<table>
<thead>
<tr>
<th>Condition</th>
<th>Rejected Specimens</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemolysis</td>
<td>NA</td>
</tr>
<tr>
<td>Lipemia</td>
<td>NA</td>
</tr>
<tr>
<td>Icterus</td>
<td>NA</td>
</tr>
<tr>
<td>Other</td>
<td>Specimens that have been decalcified (all methods); specimens that have not been formalin-fixed, paraffin-embedded; bone marrow in EDTA</td>
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</tbody>
</table>

Specimen Stability Information

<table>
<thead>
<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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<tr>
<td></td>
<td>Frozen</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>Refrigerated</td>
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Clinical and Interpretive

Clinical Information
Assessment for BRAF V600 mutations has clinical utility in that it is a predictor of response to antimitotic BRAF therapy. BRAF is a member of the mitogen-activated protein/extracellular signal-regulated (MAP/ERK) kinase pathway, which plays a role in cell proliferation and differentiation. Dysregulation of this pathway is a key factor in tumor progression. Targeted therapies directed to components of this pathway have demonstrated some success with increases both in progression-free and overall survival in patients with certain tumors. Effectiveness of these therapies, however, depends in part on the mutation status of the pathway components.

Malignant melanoma, one of the most aggressive forms of skin cancer, has a high frequency of BRAF mutations. Approximately 44% to 70% of melanoma cases have a BRAF mutation, and of those, approximately 50% to 90% are the V600E mutation. Current data suggest that the efficacy of BRAF-targeted therapies in melanoma is confined to patients with tumors with activating BRAF mutations, such as V600E, which leads to increased activation of the kinase pathway. While this test was designed to evaluate for the V600E alteration, cross-reactivity with other alterations at the V600 codon have been described.

At this time, this test is approved specifically for melanoma tumors. Please refer to BRAFT / BRAF Mutation Analysis (V600E), Tumor for BRAF testing in nonmelanoma tumors.

Interpretation
An interpretative report will be provided.
Cautions
Not all patients that have *BRAF* mutations respond to *BRAF*-targeted therapies.

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

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.

Clinical Reference


Performance

Method Description
A PCR-based assay that targets the *BRAF* V600E mutation with *BRAF* wild-type and V600E target specific fluorescent dye-labeled TaqMan probes. (Package insert: Cobas 4800 V600 Mutation Test. Roche Molecular Systems, Inc., Branchburg, NJ; February 2011)

PDF Report
No

Day(s) and Time(s) Test Performed
Monday through Friday; Varies

Analytic Time
5 days

Maximum Laboratory Time
7 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 has been cleared or approved by the U.S. Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

CPT Code Information
81210-BRAF (v-raf murine sarcoma viral oncogene homolog B1), Melanoma FDA approved Cobas assay

Slide Review
88381-Microdissection, manual

LOINC® Information

<table>
<thead>
<tr>
<th>Test ID</th>
<th>Test Order Name</th>
<th>Order LOINC Value</th>
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<td>BRAFC</td>
<td>BRAF Mutation AnalysisV600 Melanoma</td>
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<table>
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<td>Result</td>
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