Overview

Useful For
Identification of BRAF V600E-mutated protein

Reflex 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>IHTOA</td>
<td>IHC Additional, Tech Only</td>
<td>No, (Bill Only)</td>
<td>No</td>
</tr>
<tr>
<td>IHTOI</td>
<td>IHC Initial, Tech Only</td>
<td>No, (Bill Only)</td>
<td>No</td>
</tr>
</tbody>
</table>

Testing Algorithm
For the initial technical component only immunohistochemical (IHC) stain performed, the appropriate bill-only test ID will be reflexed and charged (IHTOI). For each additional technical component only IHC stain performed, an additional bill-only test ID will be reflexed and charged (IHTOA).

Method Name
Immunohistochemistry

NY State Available
Yes

Specimen

Specimen Type
TECHONLY

Advisory Information
This test includes only technical performance of the stain (no pathologist interpretation is performed). If diagnostic consultation by a pathologist is required order PATHC / Pathology Consultation.

Shipping Instructions
Attach the green pathology address label and the pink Immunostain Technical Only label included in the kit to the outside of the transport container.

Specimen Required
Supplies: Immunostain Technical Only Envelope (T693)

Specimen Type: Tissue

Container/Tube: Immunostain Technical Only Envelope

Preferred: 2 Unstained positively charged glass slide (25- x 75- x 1-mm) per test ordered; sections 4-microns thick

Acceptable: Formalin-fixed, paraffin-embedded (FFPE) tissue block
Digital Image Access
1. Information on accessing digital images of immunohistochemical (IHC) stains and the manual requisition form can be accessed through this website: www.mayocliniclabs.com/test-info/ihc/index.html

2. Clients ordering stains using a manual requisition form will not have access to digital images.

3. Clients wishing to access digital images must place the order for IHC stains electronically. Information regarding digital imaging can be accessed through this website: www.mayocliniclabs.com/test-info/ihc/faq.html

Forms
If not ordering electronically, complete, print, and send a Immunohistochemical (IHC)/In Situ Hybridization (ISH) Stains Request (T763) with the specimen.

Reject Due To

<table>
<thead>
<tr>
<th>Wet/frozen tissue</th>
<th>Cytology smears</th>
<th>Nonformalin fixed tissue</th>
<th>Nonparaffin embedded tissue</th>
<th>Noncharged slides</th>
<th>ProbeOn slides</th>
<th>Reject</th>
</tr>
</thead>
</table>

Specimen Stability Information

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
</tr>
</thead>
<tbody>
<tr>
<td>TECHONLY</td>
<td>Ambient (preferred)</td>
<td>Refrigerated</td>
<td></td>
</tr>
</tbody>
</table>

Clinical and Interpretive

Clinical Information
BRAF is a serine/threonine protein kinase and a member of the Raf family. The BRAF V600E alteration leads to constitutive activation of the mitogen activated protein kinase pathway, which plays a role in cell proliferation and tumorigenesis. This genetic alteration has been detected in a variety of tumors such as melanoma, colorectal cancer, papillary thyroid carcinoma, hairy cell leukemia, Langerhans cell histiocytosis, and pleomorphic xanthoastrocytomas.

Interpretation
This test does not include pathologist interpretation: only technical performance of the stain. If interpretation is required order PATHC / Pathology Consultation for a full diagnostic evaluation or second opinion of the case. The positive and negative controls are verified as showing appropriate immunoreactivity and documentation is retained at Mayo Clinic Rochester. If a control tissue is not included on the slide, a scanned image of the relevant quality control tissue is available upon request. Contact 855-516-8404.

Interpretation of this test should be performed in the context of the patient's clinical history and other diagnostic tests by a qualified pathologist.

Cautions
Age of a cut paraffin section can affect immunoreactivity. Stability thresholds vary widely among published literature and are antigen-dependent. Best practice is for paraffin sections to be cut within 6 weeks.
Clinical Reference


Performance

Method Description

PDF Report
No

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

Analytic Time
1 day

Maximum Laboratory Time
3 days

Specimen Retention Time
Until staining is complete.

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 Definition: BRAFV
BRAF V600E IHC, Tech Only

Test Classification
This test has been cleared, approved or is exempt 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
88342-TC, primary
88341-TC, if additional IHC

LOINC® Information

<table>
<thead>
<tr>
<th>Test ID</th>
<th>Test Order Name</th>
<th>Order LOINC Value</th>
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<tbody>
<tr>
<td>BRAFV</td>
<td>BRAF V600E IHC, Tech Only</td>
<td>Order only; no result</td>
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</tbody>
</table>

<table>
<thead>
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<th>Result ID</th>
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<th>Result LOINC Value</th>
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<tbody>
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<td>70680</td>
<td>BRAF V600E IHC, Tech Only</td>
<td>Bill only; no result</td>
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