Test Definition: TBRAF

BRAF V600 Somatic Mutation Analysis, Tumor, Tissue

Overview

Useful For
Classifying and, possibly, targeting therapies of hematological neoplasms, such as hairy cell leukemia, Langerhans cell histiocytosis, Erdheim-Chester disease, as well as targeting therapies in a variety of cancers, including, melanoma, lung, thyroid, and colon

Method Name
Real Time Polymerase Chain Reaction (PCR) Amplification and Detection with a Qualitative Genotype Call

NY State Available
No

Specimen

Specimen Type
Tissue, Paraffin

Shipping Instructions
Advise Express Mail or equivalent if not on courier service.

Ship paraffin blocks on ice packs during warm months

Necessary Information
1. A pathology report (final or preliminary) **is required for testing to be performed.**
2. At minimum, the following information must be included in the report provided:
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
Submit only 1 of the following specimens:

Preferred:
Specimen Type: Tissue block
Collection Instructions: Submit a formalin-fixed, paraffin-embedded tissue block. Blocks prepared with alternative fixation methods will not be accepted; provide fixation method used

Acceptable:

Specimen Type: Tissue slides
Slides: 1 Hematoxylin and eosin stained and 4 or more unstained
Collection Instructions:
1. A minimum of 10 percent tumor is required.
2. Submit 1 hematoxylin and eosin-stained slide and 4 to 10 unstained, nonbaked slides with 7 to 10-micron thick sections of the tumor tissue with an aggregate of 25 mm squared. 10 microns is preferred.
3. 5-micron sections will be accepted if a 50 mm squared aggregate is cut

Specimen Minimum Volume
Slides: 1 Hematoxylin and eosin-stained slide and 1 unstained slide for each probe set

Reject Due To

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

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Tissue, Paraffin	Ambient (preferred)		
	Refrigerated		

Clinical & Interpretive

Clinical Information
This test uses DNA extracted from tissue to test for the presence of *BRAF* V600E/D and V600K/R/M alterations. *BRAF* mutations occur in many different types of human cancers. Testing for *BRAF* mutation in a blood or bone marrow specimen facilitates classification and possible targeted therapies of hematological neoplasms, such as hairy cell leukemia, Langerhans cell histiocytosis, and Erdheim-Chester disease. This test is not designed for detection of *BRAF* mutations in liquid biopsy for tumors.

Reference Values
An interpretive report will be provided.
Positive and negative for V600, a somatic mutation

Interpretation

The interpretive report includes an overview of the findings.

Results will be characterized as positive, negative, or indeterminate for a V600 somatic mutation.

Cautions

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

Clinical Reference

1. Maitre E, Cornet E, Troussard X. Hairy cell leukemia: 2020 update on diagnosis, risk stratification, and treatment. Am J Hematol. 2019;94(12):1413-1422
2. Rodriguez-Galindo C, Allen CE. Langerhans cell histiocytosis. Blood. 2020;135(16):1319-1331
3. Haroche J, Cohen-Aubart F, Amoura Z. Erdheim-Chester disease. Blood. 2020;135(16):1311-1318

Performance

Method Description

The Idylla is a fully automated real-time polymerase chain reaction-based molecular testing system that uses formalin-fixed, paraffin-embedded slides. This assay detects V600E/E2/D and V600K/R/M mutations in codon 600 of the *BRAF* gene.(Unpublished Mayo method)

PDF Report

No

Day(s) Performed

Monday through Friday

Report Available

1 to 6 days

Specimen Retention Time

Unused slides: 3 months; Extracted DNA: 1 year

Performing Laboratory Location

Mayo Clinic Jacksonville Clinical Lab

Fees & 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 account representative. 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. It has not been cleared or approved by the US Food and Drug Administration.

CPT Code Information

81210

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
TBRAF	BRAF V600 Somatic Mutation, Tumor	97025-1

Result ID	Test Result Name	Result LOINC® Value
616945	Result	97025-1
616943	Interpretation	69047-9
616947	Specimen	31208-2
TBS1	Source	31208-2
616954	Signing Pathologist	18771-6
616951	Method Summary	85069-3
616949	Sample ID	80398-1
616953	Disclaimer	62364-5
616946	Indication for Testing	48767-8