MAYO CLINIC LABORATORIES

NEW TEST

Notification Date: December 17, 2024
Effective Date: December 17, 2024

MayoComplete Histiocytic Neoplasms, Next-Generation Sequencing, Varies

Test ID: NGHIS

Useful for:
Aiding in establishing diagnosis, refining prognosis, and potentially identifying targeted therapies for the optimal management of patients with histiocytic neoplasms

Genetics Information
This test includes next-generation sequencing to evaluate the following 8 genes and select intronic regions: ARAF, BRAF, CSF1R, KRAS, MAP2K1, NRAS, PIK3CA, and PTEN. For a list of genes and exons targeted by this test, see Targeted Genes Interrogated by MayoComplete Histiocytic Neoplasms Next-Generation Sequencing.

Highlights
This test utilizes next-generation sequencing for the detection of somatic mutations with diagnostic, prognostic, or therapeutic value in a set of genes associated with histiocytic neoplasms.

Methods:
Next-Generation Sequencing (NGS)

Reference Values:
An interpretive report will be provided.

Specimen Requirements:

Submit only 1 of the following specimens:

Specimen Type: Bone marrow aspirate
Container/Tube:
Preferred: Lavender or pink top (EDTA) or yellow top (ACD)
Acceptable: Green top (sodium heparin)
Specimen Volume: 2 mL
Collection Instructions:
1. Invert several times to mix bone marrow.
2. Send bone marrow specimen in original tube. **Do not aliquot.**
3. Label specimen as bone marrow.
Specimen Stability Information: Ambient (preferred) 14 days/Refrigerate

Specimen Type: Whole blood
Container/Tube:
Preferred: Lavender or pink top (EDTA) or yellow top (ACD)
Acceptable: Green top (sodium heparin)
Specimen Volume: 3 mL
Collection Instructions:
1. Invert several times to mix blood.
2. Send whole blood specimen in original tube. **Do not aliquot.**
3. Label specimen as peripheral blood.
Specimen Stability Information: Ambient (preferred) 14 days/Refrigerate

Specimen Type: Paraffin-embedded tissue
Container/ Tube: Paraffin block
Collection Instructions:
1. Send 1 representative slide stained with hematoxylin and eosin.
2. Minimum amount of tumor nuclei is 20%
3. Required amount of tissue area is at least 25 mm(2)
4. Tissue should be fixed in 10% neutral-buffered formalin. Other fixatives are not acceptable.
5. Decalcified specimens (eg, bone marrow core biopsies) are not acceptable.
Specimen Stability Information: Ambient

Specimen Type: Tissue slide
Slides: 10 unstained slides
Container/ Tube: Transport in plastic slide holders.
Collection Instructions:
1. Send 10 unstained, nonbaked slides with 5-micron thick sections of tissue and 1 representative slide stained with hematoxylin and eosin.
2. Minimum amount of tumor nuclei is 20%
3. Required amount of tissue area is at least 25 mm(2)
4. Tissue should be fixed in 10% neutral-buffered formalin. Other fixatives are not acceptable.
5. Decalcified specimens (eg, bone marrow core biopsies) are not acceptable.
Specimen Stability Information: Ambient

Specimen Type: Frozen tissue
Container/Tube: Plastic container
Specimen Volume: 100 mg
Collection Instructions: Freeze tissue within 1 hour of collection
Specimen Stability Information: Frozen

Specimen Type: Body fluid
Container/Tube: Sterile container
Specimen Volume: 5 mL
Specimen Stability Information: Refrigerated 14 days/Frozen

Specimen Type: Extracted DNA
Container/Tube: 1.5- to 2-mL tube
Specimen Volume: Entire specimen
Collection Instructions:
1. Label specimen as extracted DNA and source of specimen
2. Indicate volume and concentration of DNA on label
Specimen Stability Information: Frozen (preferred)/Refrigerated/Ambient

Specimen Minimum Volume:

Whole blood, bone marrow aspirate, body fluid: 1 mL; Frozen tissue: 50 mg; Extracted DNA: 100 microliters (mcL) at 20 ng/mcL

Specimen Stability Information:

Specimen Type	Temperature	Time
Varies	Varies	14 days

Cautions:

This test is a targeted next-generation sequencing (NGS) panel assay that encompasses 8 genes with variable full exon, partial region (including select intronic or noncoding regions), or hot spot coverage (depending on specific genetic locus). Therefore, this test will not detect other genetic abnormalities in genes or regions outside the specified target areas. The test detects single-base substitutions (ie, point mutations), as well as small insertion or deletion type events. This test is not configured to detect structural genomic rearrangements (ie, translocations), gene fusions, copy number alterations, or large-scale (segmental chromosome region) deletions and other complex genomic changes.

This assay does not distinguish between somatic and germline alterations in analyzed gene regions, particularly with variant allele frequencies near approximately 50% or 100%. If nucleotide alterations in genes associated with germline mutation syndromes are present and there is a strong clinical suspicion or family history of malignant disease predisposition, additional genetic testing and appropriate counseling may be indicated. Some apparent mutations classified as variants of undetermined significance may represent rare or low population frequency polymorphisms.

Prior treatment for hematologic malignancy could affect the results obtained in this assay. Particularly, a prior allogeneic hematopoietic stem cell transplant may cause difficulties in either resolving somatic or polymorphic alterations or in assigning variant calls correctly to donor and recipient fractions, if pertinent clinical or laboratory information (eg, chimerism engraftment status) is not provided.

Inadequate samples (eg, insufficient DNA quantity or quality) will preclude further testing and will be noted in the interpretive report. For formalin-fixed paraffin embedded specimens, NGS testing should not be pursued if the quality of the biopsy specimen is poor (eg, limited sample size, presence of extensive necrosis or fibrosis), or the target tumor cell population is low (<20%).

CPT Code:

81450

Day(s) Performed: Monday through Friday

Report Available: 16 to 21 days

Questions

Contact Connie Penz, Laboratory Resource Coordinator at 800-533-1710.