

MayoComplete Chronic Lymphoid Neoplasms, Next-Generation Sequencing, Varies

Test ID: NGCLN

Useful for:

Aiding in establishing diagnosis, refining prognosis, and potentially identifying targeted therapies for the optimal management of patients with chronic or low-grade B-cell lymphoid neoplasms

Genetics Information

This test includes next-generation sequencing to evaluate the following 25 genes and select intronic regions: ATM, BCL2, BIRC3, BRAF, BTG1, BTK, CCND1, CDKN2A, CXCR4, DDX3X, EZH2, FBXW7, KLF2, KRAS, MAP2K1, MYD88, NOTCH1, NOTCH2, NRAS, PIK3CA, PLCG2, SF3B1, TNFAIP3, TP53, and XPO1. For a list of genes and exons targeted by this test, see [Targeted Genes Interrogated by MayoComplete Chronic Lymphoid 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 chronic or clinically "low grade" lymphoid 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 (mL) at 20 ng/mL

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 25 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 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.