MAYO CLINIC
Mayo Medical Laboratories

NEW TEST
NOTIFICATION DATE: October 8, 2018
EFFECTIVE DATE: November 7, 2018

NEXT-GENERATION SEQUENCING ACUTE MYELOID LEUKEMIA, THERAPEUTIC GENE MUTATION PANEL (*FLT3, IDH1, IDH2, TP53*)
Test ID: NGAMT

USEFUL FOR: Evaluation of acute myeloid leukemia (AML) using a focused 4-gene panel at the time of diagnosis, or possibly relapsed or refractory disease, to help determine optimal (eg, targeted) therapeutic approaches.

GENETICS INFORMATION: This test includes next-generation sequencing to evaluate for the following 4 genes: *FLT3*, *IDH1*, *IDH2*, and *TP53*.

METHOD: Somatic Mutation Detection by Next-Generation Sequencing (NGS)

REFERENCE VALUES: An interpretive report will be provided.

SPECIMEN REQUIREMENTS:
Submit only one of the following specimens:

Specimen Type: Bone marrow aspirate (preferred)
Preferred: EDTA or ACD
Acceptable: Heparin
Specimen Volume: 2 mL
Collection Instructions:
1. Invert several times to mix bone marrow.
2. Send specimen in original tube.
3. Label specimen as bone marrow.

Specimen Stability: Ambient (preferred)/Refrigerate
Minimum Volume: 1 mL

Specimen Type: Peripheral blood
Preferred: EDTA or ACD
Acceptable: Heparin
Specimen Volume: 2 mL
Collection Instructions:
1. Invert several times to mix blood.
2. Send specimen in original tube.
3. Label specimen as blood.

Specimen Stability: Ambient (preferred)/Refrigerate
Minimum Volume: 1 mL

Specimen Type: Extracted DNA from blood or bone marrow
Container/Tube: 1.5- to 2-mL tube with indication of volume and concentration of the DNA
Specimen Volume: 100 uL at 20 ng/uL concentration
Collection Instructions: Label specimen as extracted DNA and source of specimen
Specimen Stability: Frozen (preferred)/Refrigerate/Ambient
Minimum Volume: 100 uL at 20 ng/uL concentration

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 4 genes with variable full exon, partial region (including select intronic or non-coding regions), or hot spot coverage (depending on specific 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, but it does not detect gene rearrangements (ie, translocations), gene fusions, copy number alterations, or large scale (segmental chromosome region) deletions and complex changes.

This assay does not distinguish between somatic and germline alterations in analyzed gene regions, particularly with variant allele frequencies (VAF) near 50% or 100%. If nucleotide alterations in genes associated with germline mutation syndromes are present and there is also a strong clinical suspicion or family history of malignant disease predisposition, additional genetic testing and appropriate counseling may be indicated. Mutation cells detected between 5% and 10% VAF may indicate low-level (ie, subclonal) tumor populations, although the clinical significance of these findings may not be clear. A low incidence of gene mutations associated with myeloid neoplasms can be detected in nonmalignant hematopoietic cells in individuals with advancing age (clonal hematopoiesis of indeterminate potential, CHIP) and these may not be clearly distinguishable from tumor-associated mutations. Some apparent mutations classified as variants of undetermined significance (VUS) may represent rare or low frequency polymorphisms.

Prior treatment for hematologic malignancy could affect the results obtained in this assay. In particular, prior allogeneic hematopoietic stem cell transplant (HSCT) may cause difficulties in 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.

Correlation with clinical, histopathologic and additional laboratory findings is required for final interpretation of these results. The final interpretation of results for clinical management of the patient is the responsibility of the managing physician.

CPT CODES: 81120, 81121, 81245, 81246, 81405

DAY(S) SET UP: Monday and Wednesday **ANALYTIC TIME**: 14 days

QUESTIONS: Contact your Mayo Medical Laboratories' Regional Manager or
Amy Nelson, MML Laboratory Technologist Resource Coordinator
Telephone: 800-533-1710