

NEW TEST ANNOUNCEMENT

NOTIFICATION DATE: January 28, 2014 **EFFECTIVE DATE:** January 30, 2014

CEBPA Mutations, Gene Sequencing Test ID: CEBPA

USEFUL FOR: Initial evaluation of acute myeloid leukemia, both for assigning an appropriate diagnostic subclassification and as an aid for determining prognosis.

METHODOLOGY: Mutation Detection in DNA Using Sanger Sequencing (PCR is utilized pursuant to a license agreement with Roche Molecular Systems, Inc.)

SPECIMEN REQUIREMENTS:

The following information is required:

- 1. Pertinent clinical history
- 2. Clinical or morphologic suspicion
- 3. Date of collection
- 4. Specimen source

Forms: Hematopathology Patient Information Sheet: (Supply T676).

Specimen must arrive within 168 hours of collection.

Submit only 1 of the following specimens:

Specimen Type: Peripheral Blood

Container/Tube: Lavender top (EDTA) or yellow top (ACD solution B)

Specimen Volume: 3 mL **Minimum Volume:** 1mL **Collection Instructions:**

- 1. Invert several times to mix blood.
- 2. Send specimen in original tube.
- 3. Label specimen as blood.

Specimen Type: Bone marrow

Container/Tube: Lavender top (EDTA) or yellow top (ACD solution B)

Specimen Volume: 2 mL **Minimum Volume:** 1mL **Collection Instructions:**

- 1. Invert several times to mix bone marrow.
- 2. Send specimen in original tube.
- 3. Label specimen as bone marrow.

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: Entire specimen

Collection Instructions: Label specimen as extracted DNA from blood or bone marrow.

SPECIMEN STABILITY INFORMATION:

Specimen Type	Temperature	Time
Varies	Ambient (preferred)	7 days
	Refrigerated	7 days

CAUTIONS: The assay is performed using Sanger sequencing, which has a sensitivity of 20%. This means that 20% or more of the DNA in the sample must be mutated to be detected. Consequently, this test is intended for use at the time of diagnosis, and not for disease monitoring.

CPT CODE: 81403

DAY(S) SET UP: Monday through Friday **ANALYTIC TIME:** 5 days

NOTE: The following referral test code(s) will become obsolete effective February 27, 2014

Test Name	Test ID	Referral Lab Code	Referral Lab
CEBPA Mutation Analysis	FCEMA	4629	Blood Center of Wisconsin
AML via the CEBPA Gene-	ZW194	996	Prevention Genetics
Sequencing			