LAB ALERT

Date: August 4, 2017

Specimen Requirement and Order Code Changes for BCR/ABL Quantitation p210 Assay

Dear Regional Pathology Services Clients,

On Monday, August 7th, the Molecular Diagnostics Laboratory will be converting to the Cepheid GeneXpert v2.0 quantitative p210 *BCR/ABL1* assay. This assay is designed to detect the BCR/ABL1 translocation transcripts and the ABL endogenous control sequence in peripheral blood and bone marrow samples. Specifically, the *BCR/ABL1* primers and probe are designed for the detection of the *BCR/ABL1* p210 e13a2 (b2a2) and e14a2 (b3a2) major breakpoint translocations.

This assay does **NOT** detect the BCR/ABL1 p190 e1a2 transcript more commonly found in B-cell precursor acute lymphoblastic leukemia.

This assay has improved sensitivity over the current assay, with a quantitative LOD of <0.002% IS (1 *BCR/ABL1* positive cell in 50,000 cells) and a qualitative sensitivity of 1 *BCR/ABL1* positive cell in a background of 93,000,000 normal cells. The current assay quantitative LOD is 0.01% IS.

Please note: Order code and specimen requirements and stability of samples will change, see below:

Test Name- BCR-ABL Quantitative p210 Assay
Test code- BCRQNT (Old Code: BCRQT)
CPT Code- 81206 (unchanged)

Peripheral blood: EDTA anticoagulated, **minimum 5 mL, 10 mL optimum,** stored at $2\text{-}8^{O}C$ and tested **within 72 hours** of collection. Heparin is unacceptable as an anticoagulant because it will inhibit the reaction.

Bone marrow aspirate: EDTA anticoagulated**, minimum 1 mL**, stored at $2\text{-}8^{O}C$ and tested **within 72 hours** of collection.   Heparin is unacceptable as an anticoagulant because it will inhibit the reaction.

If you have any questions about these changes please contact client services at 402-559-6420 and ask to speak with one of the client coordinators.

24/7 Client Services   1-800-334-0459

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