TEST UPDATE

BCR/ABL Quantitation (for non-CML patients)

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PathGroup has instituted the International Scale for testing of confirmed CML patients (see the Test Update BCRIS) and will continue to offer BCR/ABL quantitation for non-CML patients. The clinical utility of this assay includes: (1) the determination of a baseline level of BCR/ABL fusion gene expression in non-CML (typically ALL) patients; and (2) the monitoring of patients for molecular evidence of response to therapy. This assay detects the three BCR/ABL transcripts (p210, major breakpoint e13a2, e14a2 and p190, minor breakpoint e1a2). The level of BCR/ABL present in a specimen is expressed as a percentage relative to the housekeeping gene ABL1. Comparison of the results of this assay with other assays using different genes for the relative quantitation is not recommended.

The specimen requirements for this assay have increased to 10 ml of EDTA peripheral blood or 0.5 ml to 1 ml of EDTA bone marrow. This increase is necessary to provide a higher analytic sensitivity. The use of heparin-collected specimens is prohibited due to the strong PCR inhibitory effects of heparin.

Sensitivity and Specificity:
The assay has sensitivity (limit of detection) of 1-2 copies of the BCR/ABL fusion gene, a linear reference range of approximately 5 logs, and a specificity of 99%.

Ordering Information:

| New Test Name: BCR/ABL Quant for non-CML | Previous Test Name: BCR/ABL |
| New Test Code: BCRQ | Previous Test Code: BCR |

Specimen Collection and Storage:
Specimen requirements **HAVE CHANGED**:
- Specimen: **10 ml** EDTA (purple top) Whole Blood (5 mL minimum) or **0.5-1 ml** EDTA (purple top) bone marrow aspirate.
- Temperature: Store refrigerated and transport with cold pack as soon as possible.
- Stability: 24-48 hours

Resulting:
- Result format: BCR/ABL p210 or p190 fusion product will be “Detected” or “Not Detected”.
- Breakpoint reported as “Major” or “Minor”.
- BCR/ABL to ABL ratio will be reported as a %.

For further questions, please contact Client Services at 615-562-9300 or 1-888-474-5227