PathGroup

TEST UPDATE
BCR/ABL - International Scale for confirmed CML

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Effective April 22, 2013

PathGroup is now reporting BCR/ABL \([\text{t}(9;22)(q34;q11)]\) for confirmed CML patients on the International Scale (IS) of measurement. The efficacy of tyrosine kinase inhibitors (TKI) is routinely monitored with serial PCR analysis of BCR/ABL fusion gene expression. The National Comprehensive Care Network goal of therapy is achievement of a “major molecular response” (MMR), defined as a 3-log reduction in BCR/ABL to ABL fusion product. MMR is associated with excellent progression free survival.

The International Scale (\textit{Leukemia} 23:1957-1963, 2009) defines MMR as 0.1% relative ratio. Results calibrated in the International Scale are comparable across laboratories. The International Scale is appropriate for monitoring response to TKI therapy in patients diagnosed with CML with the major BCR/ABL breakpoints (p210, e13a2 and e14a2). For non-CML patients or CML patients with the minor breakpoint (p190, <1% of CML cases), PathGroup has available a BCR/ABL Quantitation assay (please see the Test Update for BCRQT).

The specimen requirements for this assay have increased to 10 ml of EDTA peripheral blood. 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 major breakpoint fusion gene and a linear reference range of 100% of IS to 0.02% of IS.

Ordering Information:
Specimens sent after April 22, 2013 will be tested on both the new assay and the previous assay \textit{one time} to allow for correlation of patient specific values, as appropriate. Both results will be reported in a single report. Parallel testing will be performed on the \textit{first specimen} sent through July 1, 2014.

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<tr>
<th>New Test Name: BCR/ABL IS</th>
<th>Previous Test Name: BCR/ABL</th>
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<tr>
<td>New Test Code: BCRIS</td>
<td>Previous Test Code: BCR</td>
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Specimen Collection and Storage:
Specimen requirements \textit{HAVE CHANGED} due to sensitivity of the assay.

- Specimen: \textbf{10 mL} (preferred) EDTA Whole Blood (5mL minimum).
- Temperature: Store refrigerated and transport with cold pack as soon as possible.
- Stability: 24-48 hours

Resulting:
- Result format: BCR/ABL p210 (210kD) fusion product will be “Detected” or “Not Detected” and if present will be translated automatically into International Scale of measurement.
- International Scale:
  - \(\leq 0.1\%\) = Major molecular response
  - \(>0.1\%\) = No major molecular response

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