BCR/ABL1, p210 Test Offers Improved Results and Turnaround Time

WHAT’S NEW?
Effective Wednesday, December 10, PeaceHealth Laboratories will offer the quantitative BCR/ABL1 p210 monitoring test with detailed test result graphs and improved turnaround time. This new test replaces the previously-offered quantitative BCR/ABL test, unit code 80844.

OVERVIEW
This test only detects the BCR/ABL1 p210 RNA transcripts. Other related testing includes BCR/ABL – Minor Breakpoint and ABL1 Kinase Mutation Analysis.

BACKGROUND
Methodology: BCR/ABL1 p210 RNA transcript levels are evaluated using quantitative, reverse transcription PCR. The assay detects the two most common fusion forms in Chronic Myelogenous Leukemia: e13/a2 and e14/a2, which code for the p210 protein. The assay does not detect other fusions including those for the p190 protein commonly present in Ph+ acute lymphoblastic leukemia and rare cases of CML in chronic phase (<2%).

CLINICAL SIGNIFICANCE
Log reduction of BCR/ABL1 can provide important information to manage CML patients. Patients who achieve only one log reduction in BCR/ABL1 level at three months of imatinib therapy have a significantly lower probability of achieving a major molecular response.

Patients who report more than two log reductions achieve a major molecular response. In addition, patients who achieve three log reductions in BCR/ABL1 level by twelve months on imatinib are more likely to have durable response. Half-log increase in BCR/ABL1 level has been reported to be a significant risk factor for relapse. Negative BCR/ABL1 results in patients being treated for CML represent at least five log reductions. Negative log reduction indicates a BCR/ABL1 fusion transcript level higher than is usually detected in previously untreated patients.

TEST RESULTS
The results are reported using a standardized international scale (IS), which is a calculated ratio between the quantities of total BCR/ABL1 transcripts to the ABL1 internal control transcript x100, multiplied with a correction factor. The log reduction is calculated as follows:
Log Reduction = Log10(average BCR-ABL1/ABL1 of newly diagnosed CML) - Log10(BCR-ABL1/ABL1)

The patient monitoring graph summary will be updated for each subsequent sample and faxed to the provider each time a new sample is tested (as shown in the example on page 2).

Previous patient results may be incorporated into the patient monitoring graph upon request.

continued on next page
BCR/ABL1, p210 Test Offers Improved Results and Turnaround Time (continued)

BCR/ABL1 P210 TRANSCRIPT MONITORING SUMMARY
Example of patient graph faxed to provider for each sample tested.

### Patient Name: Sample
### DOB: 1/2/1932

<table>
<thead>
<tr>
<th>Test #</th>
<th>Specimen Type</th>
<th>Draw Date</th>
<th>Specimen ID</th>
<th>% BCR-ABL</th>
<th>Log Δ from Previous Specimen</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>pb</td>
<td>2/4/92</td>
<td>v87654</td>
<td>80.0%</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>pb</td>
<td>12/3/92</td>
<td>v6543</td>
<td>60.0%</td>
<td>-0.12</td>
</tr>
<tr>
<td>3</td>
<td>bm</td>
<td>1/4/93</td>
<td>v765432</td>
<td>10.0%</td>
<td>-0.78</td>
</tr>
<tr>
<td>4</td>
<td>pb</td>
<td>2/3/14</td>
<td>v765432</td>
<td>2.0%</td>
<td>-0.70</td>
</tr>
</tbody>
</table>

![Graph showing bcr/abl as a percentage of total abl](image-url)
QUESTIONS?
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ORDERING INFORMATION

58135: BCR/ABL1 p210 Quantitative RTPCR, Monitoring, CML
Methodology: Quantitative, Reverse Transcription Polymerase Chain Reaction (PCR)
Performed: Tuesday and Friday
Released: 48–72 hours
CPT Code: 81206

SPECIMEN REQUIREMENTS

Collect: Peripheral blood or bone marrow in two 4 mL lavender top tubes (EDTA)
Handling: Ambient or refrigerated
Stability: Specimen must arrive at testing laboratory within 72 hours of collection
Standard Volume: 8 mL peripheral blood or bone marrow
Minimum Volume: 4 mL peripheral blood or bone marrow
Transport: Ambient or refrigerated
Rejection Criteria: Delayed transport >72 hours, hemolyzed, frozen, clotted, anticoagulants other than EDTA
Retention: RNA extract will be stored for two months

REFERENCES