Quantitative BCR-ABL1 (p210) testing for diagnosis and monitoring of CML and ALL patients

23 January 2018

Valued Clients,

Canterbury Health Laboratories Molecular Oncology group are changing the method of analysis for quantitative BCR-ABL1 on 7th Feb 2018. From this date testing will be performed using the Xpert BCR-ABL Ultra System (GeneXpert, Cepheid). Following extensive evaluation and validation this method will replace the current quantitative BCR-ABL1 p210 RT-PCR method. The multiplex BCR-ABL1 RT-PCR test for qualitative transcript identification (p210-specific and p190-specific) will continue to be offered.

The Assay
This is a cartridge-based assay in which transcripts from the two major breakpoints, BCR-ABL1 e13a2 (b2a2) and e14a2 (b3a2), and an endogenous control ABL1 are amplified. The results are expressed as a ratio percent (BCR-ABL1/ABL1 x 100) according to the International Scale (IS). The Limit of Quantitation for this assay is 0.010% (IS), offering at least 4 logs reduction from baseline.

Benefits
This assay will enable a much faster turnaround time and we anticipate 3 working days from sample receipt to reporting.
All reports are provided as percent ratios (BCR-ABL) % to the international Scale (IS) - the International Scale–Scaling Factor is a lot-specific parameter determined for each assay lot. Thus reports for the new assay are comparable with current reports.
Reports have been simplified and results from up to six previous sequential samples will be displayed.

Samples
Please provide 3 x 4ml EDTA peripheral blood from each patient for this assay.
Sample integrity is maintained up to 72 hours post collection – therefore we are able to accept samples seven days per week. Testing will continue to be performed Monday through Friday only.
Bone marrow has not been validated as a sample type and will not be accepted for this assay. Diagnostic testing on a bone marrow sample may be done by FISH or multiplex RT-PCR.
Please Note:
The new report format will not cumulate results from the previous test method. The reference gene for this assay is ABL (previously BCR). This may cause minor inconsistency in sequential results during the changeover period for some patient. This test will only detect e13a2 (b2a2) and e14a2 (b3a2) BCR-ABL1 p210 gene fusion transcripts. It will not detect other fusion transcripts such as e1a2 (p190) and e19a2 (p230). Diagnostic samples may also to be tested by FISH and/or standard RT-PCR to detect rare BCR-ABL1 gene fusions in addition to providing a quantitative result using the Xpert system.

Example of the report notification.

The price of the test will remain at the current price $513.46 (exclusive of GST)

If you have any enquiries at all, please do not hesitate to contact:
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