



Laboratory Service Manual

Lab Dept: Anatomic Pathology

Test Name: BCR-ABL, p210, RNA QUANT, MONITOR CML

General Information

Lab Order Codes: BCRR

Synonyms: Chronic Myelogenous Leukemia (CML); CML RT-PCR; Philadelphia.

CPT Codes: 83891 – Molecular diagnostics; isolation or extraction of highly purified nucleic acid
83898 x2 - Molecular diagnostics; amplification, target, each nucleic acid sequences
83902 – Molecular diagnostics; reverse transcription

Test Includes: Detect the presence or absence of BCR/ABL mRNA fusion form producing the p210 protein.

Logistics

Test Indications: Useful for monitoring response to therapy in patients with CML who are known to have the e13/a2 or e14/a2 fusion form.

Lab Testing Sections: Anatomic Pathology – Sendouts

Referred to: Mayo Medical Laboratory (MML Test#: 89007)

Phone Numbers:

Minneapolis: 612-813-6280

Saint Paul: 651-220-6550

Test Availability: Daily, 24 hours

Turnaround Time: Results are reported in 2-4 days, testing performed Mon-Fri

Special Instructions: Complete and submit "[MayoConnect Additional Test Information Form](#)" with the specimen. Include information: patient's name, referring (ordering) physician, specimen submitted & pertinent clinical history (include if the patient has a diagnosis of CML or other bcr/abl-positive neoplasm).

Specimen

Specimen Type: Whole blood or Bone marrow



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Container:	Lavender top (EDTA) tube
Draw Volume:	4 mL (Minimum: 1 mL) blood 3 mL (Minimum: 1 mL) bone marrow
Processed Volume:	Same as Draw Volume
Collection:	Routine venipuncture; Routine bone marrow collection.
Special Processing:	Lab Staff: Do Not Centrifuge. Specimen should remain in the original collection container. Label specimen appropriately (blood or bone marrow). Store and ship at room temperature. Forward promptly. Specimen must arrive at Mayo within 72 hours of collection.
Patient Preparation:	N/A
Sample Rejection:	Mislabeled or unlabeled specimens; specimen other than blood or bone marrow; anticoagulant other than EDTA; specimens >3 days old

Interpretive

Reference Range:	Interpretive report – the presence or absence of BCR/ABL mRNA fusion form producing the p210 fusion protein is reported. If positive, the level is reported as the ratio of bcr/abl (p210) to abl with conversion to a percentage (i.e., bcr/abl (p210) as a percentage of total abl).
Critical Values:	N/A



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Limitations:

This test detects only the e13/a2 and e14/a2 fusion forms, which code for the p210 protein. Other fusion forms are not detected, including those containing the BCR e1 exon, which codes for the p190 protein commonly found in acute lymphoblastic leukemia (ALL). If the patient is known to carry an e1/a2 (p190) fusion form, #83336 "BCR/ABL, p190, mRNA Detection, Reverse Transcription-PCR (RT-PCR), Quantitative, Monitoring Assay" should be used for monitoring.

this test should not be used to screen for bcr/abl fusions at the time of diagnosis. Test #89006 "BCR/ABL, mRNA Detection, Reverse Transcription-PCR (RT-PCR), Qualitative, Diagnostic Assay," which is designed to detect all reported and theoretical BCR/ABL fusion variants, should be ordered for this purpose.

The precision of this assay at low bcr/abl levels is relatively poor, such that inter-run variation can be as high as 0.5 log. Only level changes >0.5 log should be considered clinically significant. For example, if a result is given as 0.1% bcr/abl:abl, then any result between 0.05% and 0.5% should be considered essentially equivalent.

If the results are being used to make major therapeutic decisions, significant changes during monitoring should be verified with a subsequent specimen.

In general, the results of this assay cannot be directly compared with results generated from other PCR assays, including identical assays performed in other laboratories. Monitoring should be performed using the same method and laboratory for each subsequent specimen.

However, the results may be directly compared with results obtained from laboratories reporting results using the international scale. The results of this assay cannot be directly compared with bcr/abl results obtained using FISH technology. FISH measures DNA alleles and PCR-based assays measure mRNA transcripts. Because a single DNA allele can produce many mRNA transcripts, the values are not directly comparable.

Blood is the specimen of choice for monitoring. While most patients show similar bcr/abl levels in blood and bone marrow drawn at the same time, some patients have a consistent difference in the levels in blood and bone marrow such that alternating specimen types during monitoring can lead to confusion.

Assay precision does not appear to be significantly affected by specimen transport or moderate delays in processing. However, in specimens with very low levels of bcr/abl these conditions may cause sufficient RNA degradation to produce false-negative results. Thus, specimens should be shipped as quickly as possible and specimens >3 days old at the time of receipt will be considered unacceptable.

Methodology:

Reverse Transcription-Polymerase Chain Reaction (RT-PCR) with Fluorescent-Bead Array Analysis Allele-Specific Primer Extension (ASPE) and Detection by Luminex Bead Array.



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References:

[Mayo Medical Laboratories](#) July 2009