Lab Dept:	**Anatomic Pathology**
Test Name:	**BCR-ABL, p190, QUANTITATIVE, MONITOR**

General Information

Lab Order Codes:	BCRP
Synonyms:	Philadelphia Chromosome
CPT Codes:	81207 – BCR/ABL1 (t(9;22)), translocation analysis, minor breakpoint, qualitative or quantitative
Test Includes:	Detect the presence or absence of BCR/ABL mRNA fusion form producing the p190 fusion protein.

Logistics

Test Indications:	Monitoring response to therapy in patients with known e1/a2 bcr/abl (p190) fusion forms.
Lab Testing Sections:	Anatomic Pathology – Sendouts
Referred to:	Mayo Medical Laboratories (MML Test: BA190)
Phone Numbers:	MIN Lab: 612-813-6280 STP Lab: 651-220-6550
Test Availability:	Daily, 24 hours
Turnaround Time:	Results are reported in 4-8 days, testing performed Monday -Friday
Special Instructions:	Complete and submit "Hematopathology Patient Information Sheet" 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

Container:	Blood: Lavender top (EDTA) tube Alternate tube: yellow top (ACD) tube Bone marrow: Aspirate collected in a dry syringe and immediately transferred to a lavender top EDTA vacutainer (alternate: ACD yellow top tube) to prevent clotting.
Draw Volume:	10 mL (Minimum: 8 mL) blood 4 mL (Minimum: 2 mL) bone marrow
Processed Volume:	Same as Draw Volume
Collection:	Routine venipuncture; Routine bone marrow collection.
Special Processing:	Lab Staff: Do not centrifuge. Blood specimen should remain in the original collection container; bone marrow specimen from dry syringe should be in an EDTA tube. Label specimen appropriately (blood or bone marrow). Store and ship refrigerated (preferred). Forward promptly. **Refrigerated specimens must arrive at Mayo within 120 hours of collection, ambient specimens within 72 hours.**
Patient Preparation:	None
Sample Rejection:	Mislabeled or unlabeled specimens; specimen other than blood or bone marrow; anticoagulant other than EDTA; specimens past stability timeframe; gross hemolysis

Interpretive

Reference Range:	Interpretive report – the presence or absence of BCR/ABL mRNA fusion form producing the p190 fusion protein is reported. If positive, the level is reported as the ratio of bcr/abl (p190) to abl with conversion to a percentage (i.e., bcr/abl {p190} as a percentage of total abl).
Critical Values:	N/A
Limitations:	This test detects only the e1/a2 bcr/abl (p190) fusion form. Other fusion forms are not detected by this assay, including those containing the BCR e13 and e14 exons, which code for the p210 protein commonly found in CML. This test should not be used to monitor patients carrying bcr/abl fusion forms coding for the p210 protein, which includes most CML patients; #89007 "BCR/ABL p210, mRNA, Reverse Transcription-PCR (RT-PCR), Quantitative, Monitoring CML" should be ordered for this purpose.

This test should not be used to screen for bcr/abl fusions at the time of diagnosis; #89006, "BCR/ABL, mRNA, Detection, Reverse Transcription-PCR (RT-PCR), Qualitative, Diagnostic Assay" 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(p190):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.

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.

The results of this assay cannot be directly compared with bcr/abl results obtained using FISH technology. FISH measures DNA alleles and this PCR-based assay measures mRNA transcripts. Because a single DNA allele can produce man 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 altering 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 specimen with very low levels of bcr/abl, these conditions may cause sufficient RNA degradation to produce false-negative results. Thus, specimen should be shipped as quickly as possible and specimens >3 days old at the time of receipt will be considered unacceptable.

Methodology: Quantitative Reverse Transcription-Polymerase Chain Reaction (RT-PCR)

References: Mayo Medical Laboratories April 2023

Updates:

1/29/2013: CPT 2013 update
5/19/2016: Moved from room temp to refrigerated storage.
4/27/2022: Updated volume per Mayo.
4/24/2023: Updated specimen volumes per Mayo catalog, added specimen stability for ambient temperature