ACME DIAGNOSTICS

ACME Diagnostics
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BCR-ABL1 Gene Rearrangement Report

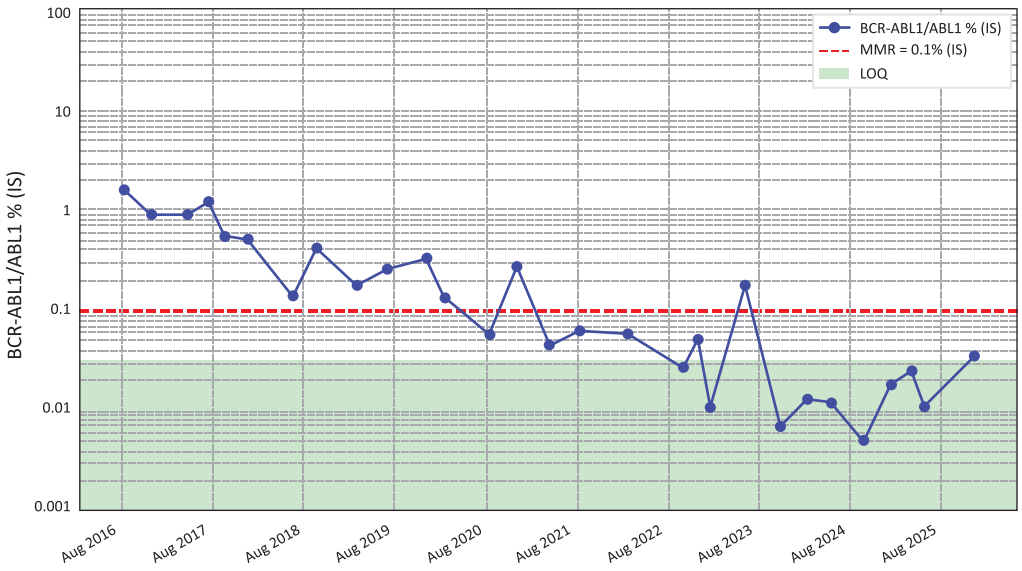
Patient Name **TEST, PATIENT**	Specimen **BLOOD**	Ordering Site **PRAEDIGENE CUSTOMER**
Patient ID **123456**	Specimen Collection Date **August 6, 2025**	Ordering Provider **SHELDON COOPER**
DOB **Jan 1, 1970**	Specimin ID **ACC-25-12345**	REPORTING DATE/TIME **August 7, 2025 08:22AM**

Result

Transcript Tested	Detected?	BCR-ABL/ABL1 % (IS)	BCR/ABL1 Copies	ABL1 Copies
P210 BCR-ABL1	**DETECTED**	**0.0353%**	**35**	**110069**

Trending Details

BCR-ABL1/ABL1 % (IS) Trending Over Time (as of August 2025)



Date	BCR-ABL1/ABL1 (IS)
7-Aug-25	0.035
24-Oct-24	0.011
4-Sep-24	0.025
12-Jun-24	0.018
22-Feb-24	0.005
17-Oct-23	0.012
11-Jul-23	0.013
25-Mar-23	0.007
8-Nov-22	0.176
18-Jun-22	0.011
28-Apr-22	0.051
1-Mar-22	0.027
22-Jul-21	0.059
10-Jan-21	0.062
11-Sep-20	0.045
4-May-20	0.272
13-May-25	0.035
24-Oct-24	0.011
4-Sep-24	0.025

Methods and Limitations

Methods

The quantitative detection of BCR/ABL1 gene rearrangements was performed using the Bio-Rad Droplet Digital PCR (ddPCR) in vitro diagnostic (IVD) system. Extracted RNA from patient samples underwent reverse transcription to generate complementary DNA (cDNA), which was subsequently amplified in a droplet-based PCR reaction. The Bio-Rad QXDx BCR-ABL1 %IS ddPCR kit was utilized, providing absolute quantification of target transcripts without the need for external calibrators. Droplet generation, PCR amplification, and droplet reading were performed according to the manufacturer's validated instructions. Data analysis and absolute quantification were conducted using Bio-Rad QXDxTM Analysis Pro software, version 1.1.0.

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Limitations

This Bio-Rad IVD assay specifically targets BCR-ABL1 p210 major variants (b2/a2 and b3/a2). Rare or alternate rearrangements, including p190 or p230 variants, are not detected by this assay. The assay is subject to inherent limitations associated with RNA-based testing, including variability in RNA extraction quality, potential RNA degradation, and reverse transcription efficiency. Accurate quantification depends on adherence to specified sample handling protocols and recommended storage conditions. The limit of detection (LOD, MR 4.7) and limit of quantification (LOQ, MR 4.56) as defined by the manufacturer should be considered when interpreting results, particularly in samples with low-level target gene expression. Results are reported in Molecular Response (MR) units, which are log10 values based on %BCR-ABL1/ABL1, expressed on the International Scale (IS).

Trending Results

Charted results presented in the Trending Details section may include historical data imported from the patient's medical records. These historical data points carry limitations specific to their original testing methods. If additional context is required or the historical data appear questionable, please review the original corresponding laboratory reports.