



Excellent Performance & Streamlined Workflow for BCR-ABL1 Monitoring in CML Patients

The Genovo BCR-ABL1 Duplex One Step RT-digital PCR Assay is designed for the absolute quantification of BCR-ABL1 fusion transcripts (e13a2 and e14a2) in whole blood. It provides a highly sensitive monitoring tool for Chronic Myeloid Leukemia (CML) patients, enabling the detection of Deep Molecular Response (DMR). The BCR-ABL1/ABL1 transcript ratio is converted to the WHO International Scale (%IS), enabling comparable molecular response monitoring across laboratories.

OPTIMIZED WORKFLOW

Complete sample-to-result in under 3 hours with minimal hands-on time:

- Only 2mL EDTA whole blood needed — ACK lysing isolates $>1 \times 10^6$ PBMC in 40 minutes
- TRIzol extraction yields >1000 ng RNA from PBMC in 30 minutes
- One-step duplex RT-dPCR quantifies BCR-ABL1 and ABL1 simultaneously in ~2 hours
- Automation-compatible platform reduces operator technical requirements

REDUCED COMPLEXITY

Ease-of-data analysis and reporting for your laboratory:

- Direct reporting on the WHO International Scale (%IS) with kit-specific conversion factor (CF)
- Results reported as both MR value and %IS — $MR = \log_{10}(100/\%IS)$
- Fully automated data analysis and report generation
- Single-step RT-dPCR — no separate reverse transcription step needed

QUALITY RESULTS

Detecting BCR-ABL1 transcripts robustly with a highly sensitive assay:

- Limit of Detection (LoD): MR 5.0 (0.001% IS) with $\geq 95\%$ detection rate
- Limit of Quantitation (LoQ): MR 4.7 (0.002% IS) with 100% hit rate and $CV \leq 5\%$
- Limit of Blank (LoB): 0 copies — no false positives in 102 negative samples
- Intra-assay and inter-assay precision $CV \leq 5\%$
- Traceable to WHO International Genetic Reference Panel ($R^2 > 0.97$)

KEY PERFORMANCE

LIMIT OF DETECTION

MR 5.0

0.001% IS

LIMIT OF QUANTITATION

MR 4.7

0.002% IS

PRECISION

$CV \leq 5\%$

All levels

PERFORMANCE COMPARISON VS. SIMILAR PRODUCTS

	Suzhou Sniper	Bio-Rad	Genovo (Roche & Dunwill)
Platform	Digital PCR	Digital PCR	Digital PCR
Specimen Type	Whole Blood (EDTA)	Whole Blood (EDTA)	Whole Blood (EDTA)
RNA Input	500ng	1000ng	125ng–5000ng
Linearity	MR 0.3~4.5	MR 0.3~4.7	MR 0.3~5.0
LoD	MR 4.7	MR 4.7	MR 5.0
LoQ	MR 4.5	—	MR 4.7
Precision	CV 10–50%	CV <10%	CV ≤5%

METHOD COMPARISON WITH PREDICATE DEVICE

A method comparison study evaluated the BCR-ABL1 fusion P210 %IS Kit (Genovo) against the QuantideX® qPCR BCR-ABL1 IS Kit (Asuragen) using peripheral blood RNA across multiple MR levels.

0.995

Pearson Correlation (R)

0.956

Regression Slope

0.991

Spearman Correlation

TECHNICAL SPECIFICATIONS

Platform	Roche Digital LightCycler
Sample Type	2mL EDTA Whole Blood
RNA Input	125ng – 5000ng
Targets	BCR-ABL1 P210 (e13a2, e14a2) + ABL1
Workflow Time	~3 hours (sample to result)
Reportable Range	MR 0.3 ~ MR 4.7
LoD	MR 5.0 (0.001% IS)
LoQ	MR 4.7 (0.002% IS)
LoB	0 copies (0.0000% IS)
Precision	CV ≤5% (all levels)
WHO Traceability	R ² >0.97 vs Reference Panel