

QXDx BCR-ABL %IS Kit

Highly-sensitive ddPCR molecular assay for measuring major breakpoints and complete molecular response

IVD



Elevate your Chronic Myeloid Leukemia monitoring with the Bio-Rad BCR-ABL %IS Kit

Bring high sensitivity and reproducibility to your molecular assay testing

The best way to assess complete molecular response (CMR) is with a highly sensitive molecular assay. The QXDx BCR-ABL %IS Kit elevates chronic myeloid leukemia (CML) monitoring to a new level of reproducibility and precision with the sensitivity of 0.0028%IS and MR 4.56 with 2 wells. Bio-Rad's BCR-ABL assay delivers a reliable and robust workflow for monitoring leukemia patients.

The assay enables:

High precision and accuracy

- Increased sensitivity per patient sample

Absolute quantification

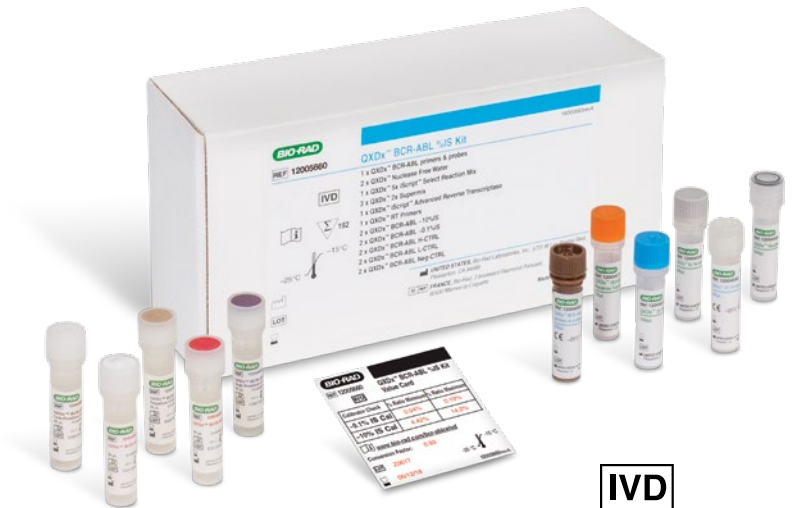
- Eliminates the need for standard curves required with RT-PCR

Simplified and scalable workflow

- Flexibility to process 8 to 48 samples per run
- Flexible kit design to meet your laboratory's throughput and workflow needs

Standardized interpreted output

- Direct reporting on the International Scale (%IS) and Molecular Response (MR) values



IVD

Bio-Rad's first IVD test kit for Droplet Digital PCR

Customer Testimonial

"Bio-Rad's Droplet Digital PCR platform increases the sensitivity and precision of BCR-ABL1 measurements as compared to qPCR. Along with absolute quantification without standard curves (in copies), the system is ideal for use in routine laboratory testing."

– Niels Pallisgaard, Head of Molecular Pathology, Zealand University Hospital

3600+

More than 3600 published studies have described research breakthroughs using Droplet Digital PCR technology.

(May 2019)

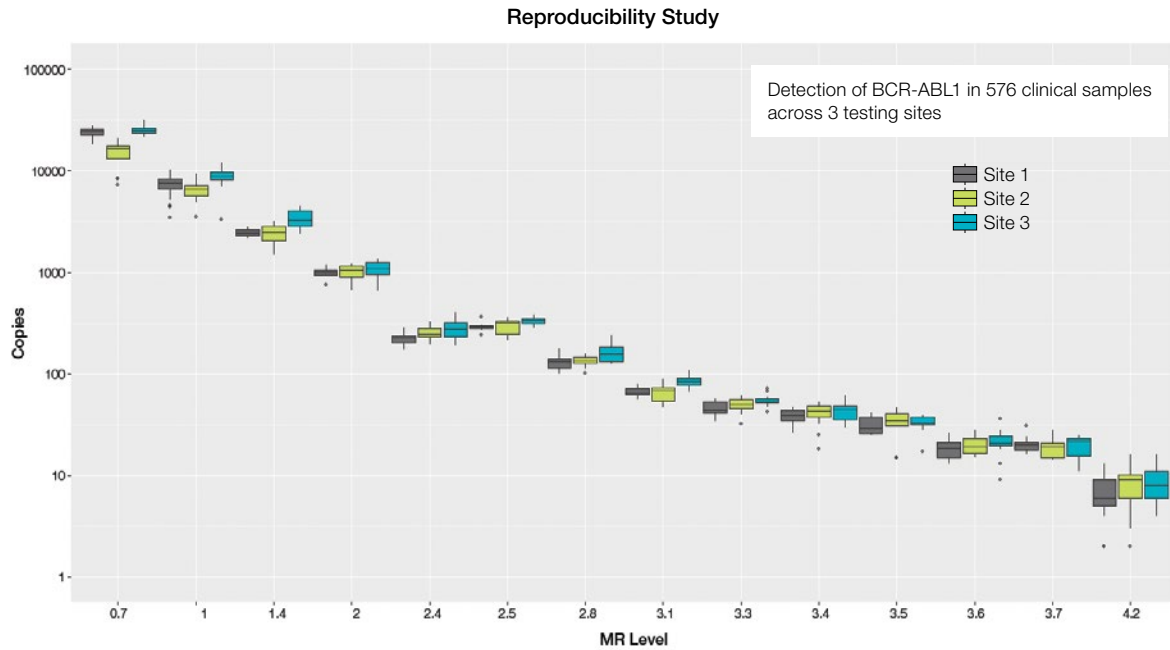
30+

More than 30 published ddPCR studies have expanded the utility of BCR-ABL monitoring.

QXDx Clinical Performance

Discover the advantage of Droplet Digital PCR with the QXDx BCR-ABL clinical trial data.

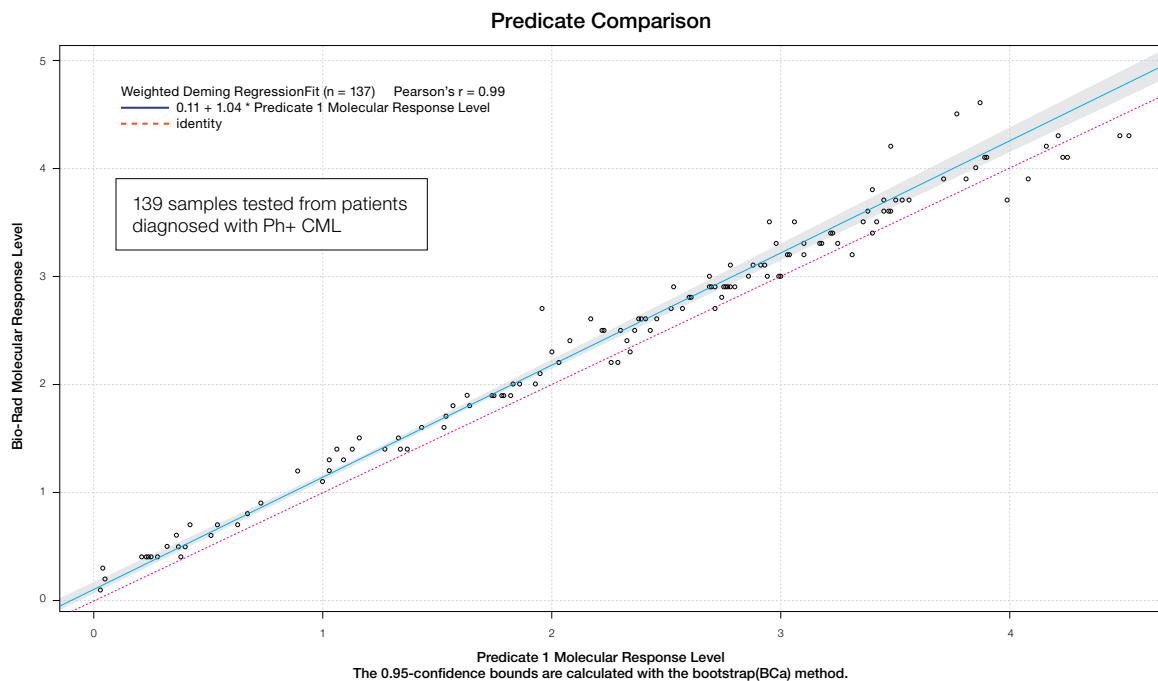
Improves Reproducibility



The BCR-ABL %IS Kit study demonstrated high precision and reproducibility across three test sites showing a Major Molecular Response level of 4.2MR with a mean of 4.23MR and a total variance of 0.04MR.

Same Result – Any Lab, Any Instrument and Any Operator

Demonstrates Equivalence



Clinically validated, the BCR-ABL %IS Kit demonstrated high equivalence (Pearson's $r = 0.99$) and low variability when compared with an FDA-cleared test.

The Droplet Digital PCR Advantage

Unparalleled Reproducibility

Droplet Digital PCR achieves reproducibility, even for complete molecular responses, through absolute quantification of copies of target DNA/RNA. Unlike qPCR, which relies on a standard curve, sample input is the only thing contributing to minimal variability across a dynamic range.

High Precision and Accuracy

Digital PCR is characterized by a high degree of sensitivity and precision that makes it suitable for detection of BCR-ABL transcripts, evidence of the presence of residual malignant cells in minimal residual disease (MRD) when monitoring for chronic myeloid leukemia (CML).

– Maier et al. 2019

QXDx BCR-ABL %IS Kit Workflow



Ordering Information

Catalog No.	Description	
12005660	QXDx BCR-ABL %IS Kit, IVD.....	192 reactions (96 samples)
12001922	QXDx AutoDG Consumable Pack.....	480 reactions
12002526	QXDx Droplet Reader Oil Pack	864 reactions

Required Materials (Not Provided)

17005351	QXDx AutoDG ddPCR System	1 unit <i>(Includes the QXDx Automated Droplet Generator, QXDx Droplet Reader, QXDx Acquisition/Analysis Software and QXDx Laptop)</i>
1814000	PX1 PCR Plate Sealer	1 unit
NA	Thermal cycler with the following specifications:	
	<ul style="list-style-type: none"> ■ Accuracy: +/- 0.2°C ■ Uniformity: +/- 0.4°C well-to-well within 10 sec ■ Adjustable ramp rate: up to 2°C/sec ■ Temperature range: 0-100°C ■ Ability to cool plate to 4°C post run 	

Recommended Materials

1851197	C1000 Touch Thermal Cycler with 96-Deep Well Module.....	1 unit
FIS-HS21	Microscan Barcode Scanner.....	1 unit

REFERENCES

Maier J et al. (2019). Optimized Digital Droplet PCR for BCR-ABL. J Mol Diagn 21, 27-37.

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