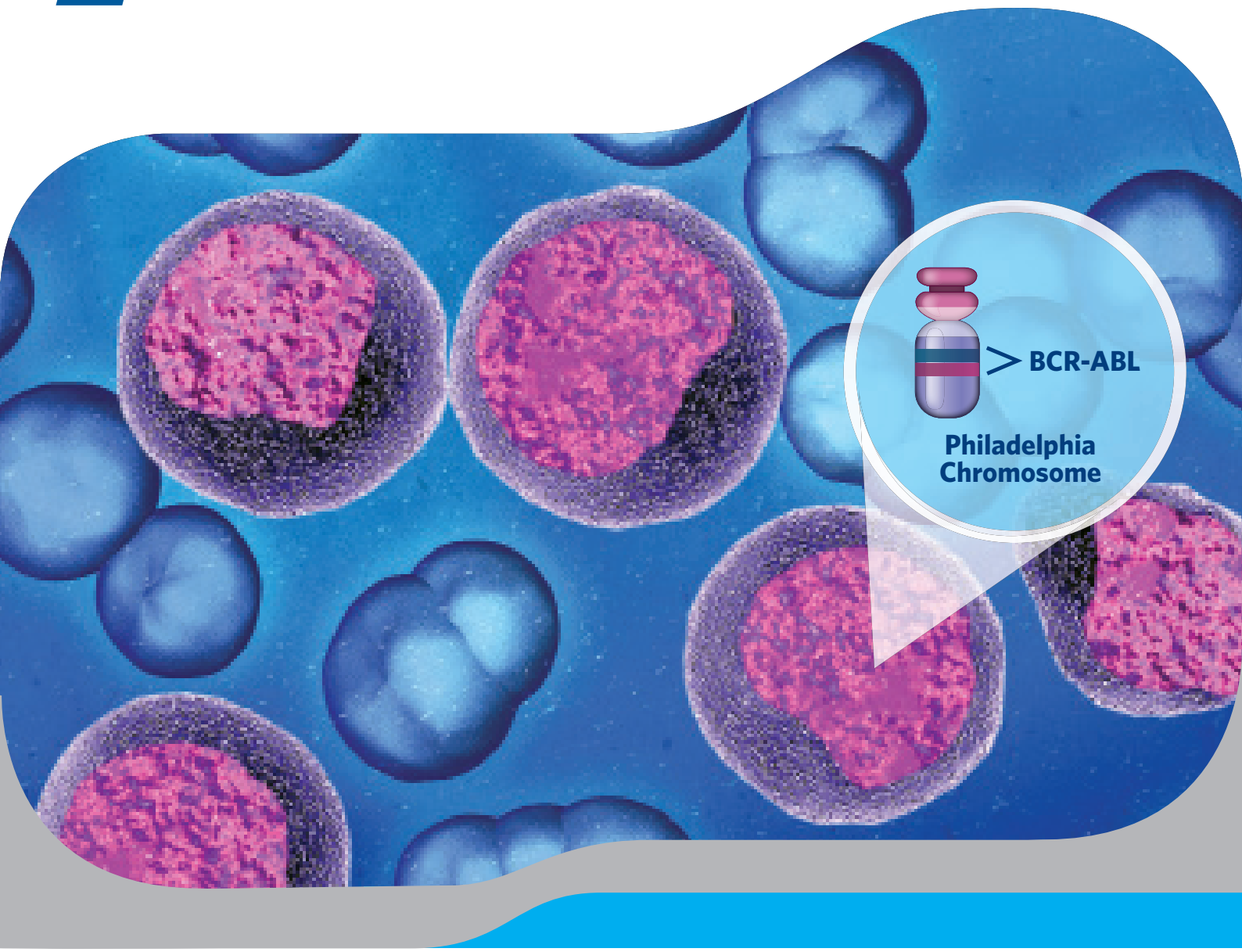
Oncology

Iam BCR-ABL Qualitative



*A one-step, rapid molecular assay for qualitative differential detection of **BCR-ABL** fusion transcripts*

DiaSorin

The Diagnostic Specialist

For use outside of the USA and Canada only

Iam BCR-ABL Qualitative

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BACKGROUND

The **BCR-ABL** fusion gene codes for an oncogenic protein with elevated tyrosine kinase activity, which is responsible for the neoplastic transformation. The timely and accurate molecular detection of the **BCR-ABL** transcripts is mandatory in order to diagnose Philadelphia Positive Leukemias allowing implementation of targeted therapies, which are able to selectively inactivate the **BCR-ABL** chimeric protein.

Iam BCR-ABL Qualitative MAIN FEATURES:

- *A simplified and reliable solution: from 500ng RNA to results in ONE STEP*
- *Simultaneous detection and discrimination of the common isoforms p190 and p210*
- *Easy set-up*
- *Internal control to validate BCR-ABL negative results*
- *Ultra Rapid: first results visible in real-time within 20 minutes*

SPECIFIC AND SENSITIVE

Extraction Method	Total No Replicates	Sample Type	% Analytical Specificity
Qiagen RNeasy Kit	240	cell lines	99.6
Modified TRIzol®	240	cell lines	100
N/A	226	NTC	100

Extraction Method	Limit of Detection
Qiagen RNeasy Kit	K562 10^{-3}
	TOM1 10^{-3}
Modified TRIzol®	K562 10^{-3}
	TOM1 10^{-3}

K562 10^{-4} and TOM1 10^{-4} dilutions extracted with Qiagen RNeasy Kit and TRIzol® were detected 87.5%/92.5% and 72.5%/92.5% respectively.

Detection of rare isoforms
e6a2
e8a2
e19a2
e18a2

Clinical studies have shown that Iam BCR-ABL Qualitative has the potential to detect rare isoforms, results must be correlated to the patient's clinical profile and other clinical laboratory results in making a diagnosis.

ROBUST

Iam **BCR-ABL** is resistant to the common PCR inhibitors. During field evaluations the assay also returned accurate results for samples in which a partial degradation of RNA had occurred.

CLINICALLY VALIDATED

Sample status	% Agreement with laboratory developed PCR method (BIOMED protocol)
p210 positive	100% (N=40)
p190 positive	100% (N=40)
p210 negative	99% (N=100)*
p190 negative	99% (N=100)

** 1 sample was defined as negative by the laboratory developed PCR method (BIOMED protocol) however was subsequently defined as p210 positive with a CE marked commercial quantitative PCR kit.*

IVD CE

Catalog number: *V31BCR* ***Description:*** *Iam BCR-ABL* ***Number of reactions per kit:*** *24*

Product code V31BCR

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