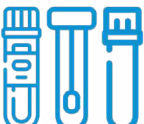





qPCR BCR-ABL1 DIAGNOSTICS CE IVD










Sensitive, accurate, quantitative & qualitative kits

The complete solution for rapid, reliable, qualitative & quantitative detection of all three Major, Minor & Micro transcripts to aid in the diagnosis & monitoring of CML

FAST & FLEXIBLE WORKFLOW

Multiple Sample Types	Multiple Extraction Kits	Platform Agnostic	Result Analysis
			
<ul style="list-style-type: none"> ✓ EDTA Blood ✓ Bone Marrow 	<ul style="list-style-type: none"> ✓ TRUPCR® Total RNA Blood Extraction Kit (3B1200) ✓ QIAamp® RNA Blood Mini Kit 	<ul style="list-style-type: none"> ✓ AB™ QuantStudio/7500/StepOne ✓ Roto-Gene Q ✓ Bio-Rad CFX96/CFX384 ✓ Agilent Aria Mx ✓ Roche LightCycler® 480 - II 	<ul style="list-style-type: none"> ✓ Technical support can be supplied for setting up run templates and run analysis including threshold settings.

KEY FEATURES

		
Platform Agnostic	Aligned to WHO international Reference Panel	Extensively validated kits
		
Multiplex capabilities	All inclusive kits	Easy workflow & Quick Analysis
		
Highly sensitive BCR-ABL1 M Quantitative kit – MR of 4.7	Detection and differentiation of all three Major, Minor and Micro transcripts	Unique Screening kit detecting 12 transcripts



ALL INCLUSIVE KITS

All reagents for Reverse Transcription	RT Mix, Enzyme Mix, Primer Mix, Enhancer Mix, cDNA Control, IS-MMR Calibrator
Master Mix	Hot start mastermix
Primer Probe Mix	Major*/ Minor*/ Micro*/ ABL1*
Standards	BCR ABL1 & ABL1
RNase Free Water	RNase Free Water

*Primer probe mixes included are dependent on kit ordered.

ORDERING INFORMATION

Qual/Quant	BCR-ABL1 Kit	Cat No.		QTY	
Qualitative	Major	3B1201	3B1202	24	48
	Major & Minor	3B1203	3B1204	48	96
	Major, Minor & Micro	3B1205	3B1206	48	96
	Transcript Screening	3B1239	3B1238	48	96
Quantitative	Major (WHO IS)	3B1251	3B1252	48	96
	Major (WHO IS) & Minor	3B1253	3B1254	48	96
	Major (WHO IS), Minor & Micro	3B1267	3B1268	48	96
	Minor	3B1291	3B1292	24	48
	Micro	3B1263	3B1264	24	48

PERFORMANCE CHARACTERISTICS

Regulatory Status	CE IVD
Intended Use	For detection & differentiation of the outlined transcripts to aid in diagnosis & quantification of CML patients in laboratory settings by trained staff
Type of Analysis	Qualitative/Quantitative (dependent on kit)
Detection Channels	FAM
Traceability/Reference Material	Validated on WHO International Genetic Reference Panel / European Reference material
Run Time	~130 minutes
Storage	-20 °C
Shelf-Life	12 months
Analytical Sensitivity-LOD	1.76 copies of BCR ABL1 transcript