



## CONVERSION SHEET

Xpert®  
BCR-ABL  
Ultra

# PRODUCT COMPARISON

Test Reagent Kit	Xpert® BCR-ABL Ultra* <sup>1</sup>	Xpert® BCR-ABL Ultra* <sup>2</sup>
Catalog Number	GXBCRABL-CE-10	GXBCRABL-10
Registration	CE-IVD	CE-IVD
Targets	Major breakpoint: p210 (e13a2/b2a2 and e14a2/b3a2)	
Assay Chemistry	No change	
Sample Volume Required	4mL peripheral blood	
Specimen Requirement	EDTA or PAXgene	EDTA
White Blood Cell (WBC) Count Suggestion	None	0.15-30 million WBC/mL
Cartridge Prep Workflow	No change	
Total Time to Result	<2.5 hrs	
Linear Range	6-log	0.0030% to 55% (IS)
Result Reporting	Quantitative result reported outside of linear range	Quantitative result only in linear range Addition of MR (Molecular Response)
GeneXpert Software	GeneXpert® Dx version 4.4a-4.8 Infinity Xpertise 6.1-6.5	GeneXpert® Dx version 5.1 or higher Infinity Xpertise 6.6 or higher
LIS Mapping ADF Test Name*	Xpert BCR-ABL Ultra	Xpert BCR-ABL Ultra G2
Alignment to WHO Reference Panel (IS)	Yes with every lot	
Sample Storage and Stability	2-8°C, 72 hours (Blood in EDTA tube) 2-8°C, 120 hours (Blood in PAXgene tube)	4°C, 72 hours (Blood in EDTA tube)
1st Lysate Stability (EDTA only)	2-8°C, 1 hour -20°C or lower, 3 weeks	4°C, 4 hours -20°C, 24 hours
Kit Storage	2-8°C	

CE-IVD. *In Vitro* Diagnostic Medical Device. Not available in all countries.  
Xpert BCR-ABL Ultra is available in the United States.

\* Contact Cepheid Technical Support for assistance (see reverse side for contact details)

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### Example Results Reporting Changes

RESULT RANGE: % (IS) BCR-ABL/ABL	Part Number: GXBCRABL-CE-10 Using Software: GX Dx 4.4a-4.8 / Xpertise 6.1 – 6.5	Part Number: GXBCRABL-10 Using Software: GX Dx 5.1 and higher / Xpertise 6.6 and above
>55%	BCR-ABL has been detected at a level of XX% (IS)	POSITIVE [Above upper LoQ]
0.0030-55%	BCR-ABL has been detected at a level of X.XX% (IS)	POSITIVE [X.XX% (IS) and MR X.XX]
<0.0030%	BCR-ABL has been detected at a level of X.XX% (IS)	POSITIVE [Below LoD;>MR4.52/<0.0030% (IS)]
N/A	BCR-ABL was not detected at a detection limit of X.XXXXX% (IS)	NEGATIVE [Sufficient ABL transcript]
N/A	BCR ABL Invalid	INVALID [Insufficient ABL transcript]
N/A	BCR ABL Invalid	INVALID [Too high BCR-ABL and ABL transcripts]
N/A	BCR ABL Invalid	INVALID [Too high ABL transcript]
N/A	BCR ABL Invalid	INVALID [Too high BCR-ABL transcript]



### Same easy workflow...



If you need further assistance, please contact Cepheid Technical Support by submitting a case online at <http://www.cepheid.com/us/support/support/contact-support-online>.

If you prefer, you can contact your local Technical Support office. This information is available at [www.Cepheid.com](http://www.Cepheid.com) or [www.Cepheidinternational.com](http://www.Cepheidinternational.com) under the SUPPORT tab. Select the Contact Us option.

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1. Xpert BCR-ABL Ultra Package Insert, CE-IVD, 301-2194, Rev. D
2. Xpert BCR-ABL Ultra Package Insert, CE-IVD, 302-0742, Rev. A

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