

# Xpert® BCR-ABL Ultra

*Delivering MORE confidence with fast, accurate Chronic Myeloid Leukemia molecular monitoring results*



## The Need

Chronic myeloid leukemia (CML) accounts for approximately 15% of adult leukemias.<sup>1</sup>

Successful treatments with Tyrosine Kinase Inhibitors (TKIs) have greatly improved the outcome for most patients, significantly decreasing annual mortality and increasing prevalence.<sup>2,3</sup>

International guidelines recommend monitoring BCR::ABL1 transcript levels on an international reporting scale (IS) by quantitative RT-PCR (qPCR) at regular intervals to assess the efficacy and safety of the treatment.<sup>4-6</sup>

## The Impact

- Delivers same day results to support informed and timely clinical decisions which can aid in the reduction of patient anxiety and improving patient care.<sup>7,8</sup>
- Flexibility and simplicity of an optimized and on-demand testing workflow improves overall cost and efficiency.<sup>9</sup>
- Eliminates the need for standard curve and replicate testing freeing up technician time for other lab services.<sup>10</sup>

## The Solution

The Xpert BCR-ABL Ultra is a quantitative test for BCR::ABL major breakpoint (p210) transcripts that provides highly sensitive and on-demand molecular results, reporting on both the International Scale (IS) and Molecular Response (MR) formats.<sup>10</sup>

Accurate, on-demand process with results aligned to the IS in a one-page report in approximately 3 hours.<sup>10</sup>

1 Jabbour E, Kantarjian H. Chronic myeloid leukemia: 2020 update on diagnosis, therapy and monitoring. *Am J Hematol*. 2020 Jun;95(6):691-709. doi: 10.1002/ajh.25792. Epub 2020 Apr 10. PMID: 32239758.

2 Sacha, Tomasz et al. The Outcomes of Ponatinib Therapy in Patients With Chronic Myeloid Leukemia Resistant or Intolerant to Previous Tyrosine Kinase Inhibitors, Treated in Poland Within the Donation Program. *Clinical Lymphoma, Myeloma and Leukemia*, Volume 22, Issue 6, 405 – 415. Published: November 20, 2021. DOI: <https://doi.org/10.1016/j.clml.2021.11.012>.

3 Huang X, et al. Estimations of the increasing prevalence and plateau prevalence of chronic myeloid leukemia in the era of tyrosine kinase inhibitor therapy. *Cancer*. 2012 Jun 15;118(12):3123-7.

4 Hochhaus A et al. European LeukemiaNet 2020 recommendations for treating chronic myeloid leukemia. *Leukemia*, March 2020

5 Hochhaus A, et al. Chronic myeloid leukaemia: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow up. *Annals of Oncology*. 2017 May; 28(4):iv41-iv51.

6 NCCN. Clinical Practice Guidelines in Oncology: Chronic Myelogenous Leukemia (Access Version 2.2024, December 2023).

7 Emily S Winn-Deen, Bret Helton, Reuel Van Atta, Wendy Wong, Jeffrey Peralta, James Wang, Gregory J Tsongalis, Dorothy Belloni, David Chan, James R Eshleman, Christopher D Gocke, Zsolt Jobbagy, Lan Beppu, Jerald P Radich, Development of an Integrated Assay for Detection of BCR-ABL RNA, *Clinical Chemistry*, Volume 53, Issue 9, 1 September 2007, Pages 1593–1600, <https://doi.org/10.1373/clinchem.2007.085472>

8 Maria Teresa Bochicchio, Barbara Izzo, Enrico Gottardi, Biagio De Angelis, Roberta Lorenzatti, Claudia Venturi, Francesca Crasto, Caterina De Benedittis, Filomena Daraio, Emanuela Ottaviani, Alessandro Volpengo, Giuseppe Saglio, Fabrizio Pane, Giovanni Martinelli; Evaluation of Cepheid Xpert® BCR-ABL Monitor Assay in Three Italian Reference Centers for Monitoring of BCR-ABL Transcript Levels in CML Patients. *Blood* 2014; 124 (21): 1809. doi: <https://doi.org/10.1182/blood.V124.21.1809.1809>

9 S Haydon-Bradford et al. Implementing Quantitative BCR-ABL P210 Testing in a Rural Healthcare Setting. Poster session presented at Association for Molecular Pathology (AMP) 2023 Annual Meeting & EXPO; 2023 November 14-18; Salt Lake City, Utah.

10 Xpert BCR-ABL Ultra Instructions for Use



# Xpert® BCR-ABL Ultra

## Product Reference Sheet — US-IVD & CE-IVD

<b>Test Reagent Kit</b>	Xpert BCR-ABL Ultra	
<b>Catalog Number</b>	<b>US-IVD</b> GXBCRABL-US-10	<b>CE-IVD</b> GXBCRABL-10
<b>Technology</b>	Nested RT-qPCR	
<b>Targets</b>	BCR-ABL mRNA Transcript [e13a2 (b2a2), e14a2 (b3a2)]	
<b>Batch or On-Demand</b>	On-demand	
<b>Minimum Batch Size</b>	1	
<b>Sample Type</b>	Peripheral blood (EDTA)	
<b>Sample Volume</b>	4 ml	
<b>Sample Extraction</b>	Automated/integrated	
<b>Precision Pipetting</b>	Not Required	
<b>Off-board Sample Preparation Time</b>	Approximately 30 minutes	
<b>TAT</b>	Approximately 2.5 hours	
<b>Internal Controls</b>	<b>Endogenous control (ABL1)</b> ✓	<b>Probe Check Control (PCC)</b> ✓
<b>Alignment to WHO Reference Panel for BCR-ABL Standards using Secondary Standards</b>	Yes, with every lot	
<b>Sensitivity (EDTA)</b>	0.0030% (IS) / MR 4.52	
<b>Specificity (Analytical)</b>	100% for non-CML EDTA blood specimens	
<b>Linear Range</b>	0.0030%–55% (IS) / MR 4.52–0.26	
<b>System &amp; Software</b>	<b>GeneXpert Dx System</b> GeneXpert Dx software version 5.1 or higher	<b>GeneXpert Infinity</b> Xpertise software version 6.6 or higher
<b>Sample Stability</b>	5 ± 3 °C for up to 72 hours	
<b>Kit Storage</b>	2–8 °C	
<b>Commercial Controls</b>	Refer to Instructions for Use (IFU) or Contact Cepheid Technical Support	

IVD. In Vitro Diagnostic Medical Device. May not be available in all countries.

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