

# Xpert® BCR-ABL Ultra p190

## *Sensitive Acute Lymphoblastic Leukemia (ALL) and Chronic Myeloid Leukemia (CML) Monitoring*



### The Need

The Philadelphia (Ph) chromosome is observed in patients with chronic myeloid leukemia (CML), acute lymphoblastic leukemia (ALL), and acute myeloid leukemia (AML).<sup>1</sup>

Guidelines recommend periodic monitoring of BCR::ABL 190 transcript as a significant predictor of relapse in Ph+ ALL and CML patients.<sup>2-4</sup>

Lack of international standard methods make comparison of BCR::ABL p190 quantification from laboratory-to-laboratory challenging.

### The Solution

The Xpert® BCR-ABL Ultra p190 is an automated test for quantifying the amount of BCR::ABL1 p190 transcript as a ratio of BCR::ABL p190/ABL1 with high sensitivity.<sup>7</sup>

Proprietary in-house RNA control materials are used to calibrate and standardize and align indirectly with the WHO IS (NIBSC-09/138) for BCR::ABL p210.<sup>6,7</sup>

### The Impact

- Meet guideline requirements to monitor treatment response and Minimum Residual Disease (MRD) for Ph-positive (Ph+) ALL and CML patients.<sup>8</sup>
- Timely monitoring ensures the identification of high-risk patients associated with an inferior outcome to therapy.<sup>5</sup>
- Optimize lab organization with standardized reporting.<sup>6</sup>

1 Reckel, S., Hamelin, R., Georgeon, S. et al. Differential signaling networks of Bcr-Abl p210 and p190 kinases in leukemia cells defined by functional proteomics. *Leukemia* 31, 1502–1512 (2017)

2 NCCN Guidelines for Patients Acute Lymphoblastic Leukemia, 2021

3 ESMO Clinical Practice Guidelines for diagnosis, treatment, and follow-up of Acute Lymphoblastic Leukaemia

4 Canadian Cancer Society Follow-up after treatment for acute lymphocytic leukemia.

5 Gandhe N, Vekaria M, Dabak V. A Rare Case of p190 BCR-ABL Chronic Myeloid Leukemia With a Very Good Response to Tyrosine Kinase Inhibitors. *Cureus*. 2021 Aug 5;13(8):e16914. doi: 10.7759/cureus.16914. PMID: 34513487; PMCID: PMC8418323.

6 Yuanyuan Liu, Tran Tran, Phat Nguyen, Huilin Wei, Gwo-Jen Day, Lin Yuan; Development of Reference Control Material for the Evaluation of the Cepheid Prototype \* Xpert® BCR-ABL P190 Ultra Assay. *Blood* 2019; 134 (Supplement\_1): 5213

7 Xpert BCR-ABL Ultra Instructions for Use

8 Soverini S, Bassan R, Lion T. Treatment and monitoring of Philadelphia chromosome-positive leukemia patients: recent advances and remaining challenges. *J Hematol Oncol*. 2019 Apr 23;12(1):39. doi: 10.1186/s13045-019-0729-2. PMID: 31014376; PMCID: PMC6480772.



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## Product Reference Sheet — CE-IVD

<b>Test Reagent Kit</b>	Xpert BCR-ABL Ultra p190	
<b>Catalog Number</b>	<b>CE-IVD</b> GXBCRABLP190-CE-10	
<b>Technology</b>	Nested RT-qPCR	
<b>Targets</b>	BCR-ABL1 p190 mRNA Transcript (e1a2)	
<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>Sensitivity (EDTA)</b>	0.0065%	
<b>Linear Range</b>	0.0065%-25% BCR-ABL p190/ABL	
<b>System &amp; Software</b>	<b>GeneXpert Dx System</b> GeneXpert Dx software version 6.2 or higher	
<b>Sample Stability</b>	2–8 °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	

CE-IVD. *In Vitro* Diagnostic Medical Device. May not be available in all countries. Not available in the United States.

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