



**Xpert®**  
BCR-ABL  
Ultra

Sensitive, Standardized and Easy to Use



# Xpert® BCR-ABL Ultra

Delivering confidence with fast and accurate Chronic Myeloid Leukemia molecular monitoring results

**CE** **IVD** *In Vitro* Diagnostic Medical Device Not available in all countries.

 **Cepheid®**  
A better way.



Cepheid's Xpert® BCR-ABL Ultra test solves many of the present challenges in monitoring patients with Chronic Myeloid Leukaemia, including accuracy (remarkably precise International Scale calibration) and speed (in hours) of reporting molecular response. These performance characteristics are important from initiation of therapy to the deep remissions possible with the array of available therapeutic options."

**Michael J. Mauro, M.D.**

Leader, Myeloproliferative Neoplasms Program  
Memorial Sloan Kettering Cancer Center



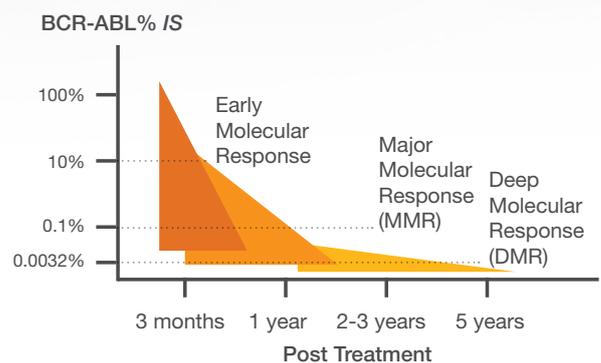
## The Need

Due to the outstanding success of Chronic Myeloid Leukemia (CML) disease treatments, prevalence is estimated to increase at an annual rate of 4%, and the number of individuals living with this disease will double by 2030.<sup>1</sup>

Assessing treatment efficacy for CML requires a molecular diagnostic assay to measure the level of BCR-ABL transcript (RNA). Patients should be tested for BCR-ABL at regular intervals, guided by established international recommendations.<sup>2,3,4</sup>

Recent studies have indicated that patients undergoing the recommended molecular assessments 3–4 times annually, experienced a reduced risk of progression and mortality, had improved TKI adherence, and generated lower health care costs compared to patients who were monitored less frequently.<sup>5</sup>

## Time based Molecular Monitoring Milestones<sup>2</sup>



## The Solution

**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.**

Based on the innovative GeneXpert technology, Xpert BCR-ABL Ultra automates the entire test process including RNA isolation, reverse transcription, and fully-nested real-time PCR of BCR-ABL target gene and ABL reference gene in one automated cartridge.<sup>6</sup>

### Easy to use

Simply add the treated blood sample and an off-board reagent to the GeneXpert® cartridge; no separate extraction needed. Internal controls ensure validity and accuracy, with less than 2.5 hours total process time, sample to result.<sup>6</sup>

### Sensitive

ABL control gene copy number equivalence data highlights high sensitivity with low inter-laboratory variation, and proven linearity from 55-0.0030%/IS.<sup>6</sup> Clinically relevant limit of quantitation (LoQ) 0.0030IS/4.52MR.<sup>6</sup>

### Standardized

Results are automatically aligned to the IS within the cartridge process, and standardized on a lot to lot basis via standards calibrated to the WHO panel.<sup>6</sup>



## The Impact

### Patient: Faster results reduce patient anxiety.<sup>7</sup>

Despite efforts to optimise disease management, only one-third of newly diagnosed CML patients are adequately monitored during the first year of treatment.<sup>8</sup> Therefore, more accessible molecular testing is needed to enhance CML patient outcomes.

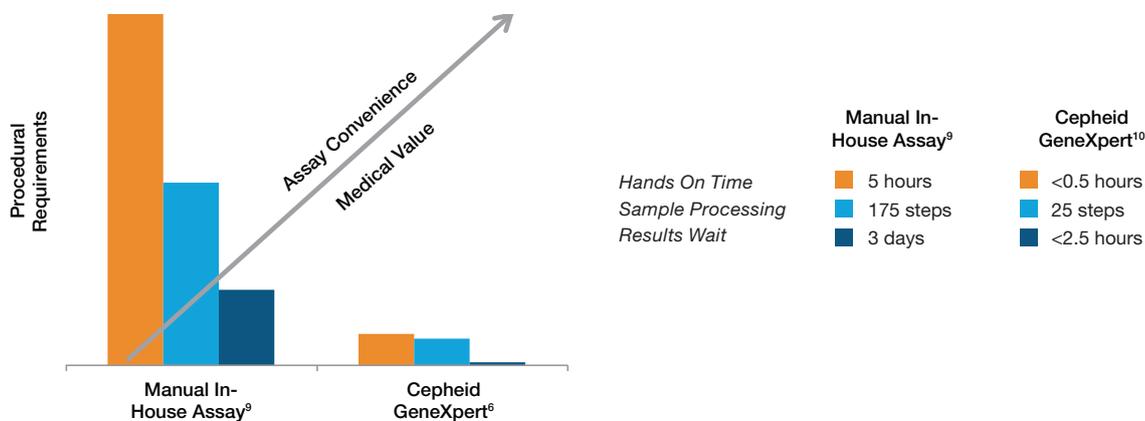
### Clinician: Same day information supports informed clinical decisions.

Timely CML monitoring results ensure that milestone “warning” responses are rapidly identified and acted upon, and may lower patient care costs.<sup>8</sup>

### Laboratory: CE-IVD and FDA cleared test with flexibility and simplicity for an easy, more optimized testing workflow.

- **Flexible:** Any number of samples, any day of the week with a fixed cost per reportable result, no wasted time or reagents from batching requirements.
- **Simple Reporting:** Results align to the IS automatically and are also shown in Molecular Response (MR) format. No additional work is required to align to the International Scale via Conversion Factors.
- **Easy:** Automated processing provides consistent data, eliminates standard curve and replicate testing requirements, enables optimized lab organisation.

## Process Mapping of Different Laboratory Scenarios<sup>9</sup>





## Workflow

# 3 Easy Steps



Prepare sample lysate



Add lysate and wash buffer to cartridge



GeneXpert® System automatically extracts, amplifies, measures, standardizes then reports



➤ **Xpert® BCR-ABL Ultra provides highly sensitive on-demand measurement of BCR-ABL p210 transcript levels directly standardized to the IS, with results in both IS and MR format.**

CATALOG NUMBER

Xpert BCR-ABL Ultra (10 tests) . . . . . GXBCRABL-10

CE-IVD. For *In Vitro* Diagnostic Use. Not available in all countries.

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