



Haematopathology and Oncology Diagnostic Testing

Overcome the challenges and needs of **monitoring leukemia patients** with Cepheid's rapid PCR tests

▸ The Need

Current testing options for monitoring leukemia patients are not only cumbersome, but can be expensive and time-consuming for the lab to implement.

▸ The Solution

Cepheid's advanced Lab in a Cartridge™ technology decreases workflow complexity and hands-on time by automating the entire testing process, delivering faster results.

Accurate and timely results assist clinicians in delivering the most appropriate treatment options, minimising patient worry.

Rapid PCR Testing for Leukemia

Cepheid's Haematology Oncology Tests

Hem Onc Test	Xpert® BCR-ABL Ultra ¹	Xpert® BCR-ABL Ultra p190 ²	Xpert® NPM1 Mutation ³
Leukemia Type	CML	ALL & CML	AML
Targets	e13a2/b2a2 and e14a2/b3a2	e1a2	Types A, B, and D in exon 12
TAT	≤2.5h	≤2.5h	≤3h
LoD	0.0030IS/4.52MR	0.0065%	0.030%
Linear Range	0.0030%-55% (IS) / MR 4.52 – 0.26	0.065% - 25% BCR-ABL p190/ABL	0.03% - 500% NPM1 Mutation/ ABL
Standardisation	WHO IS	Proprietary in-house RNA control materials	Proprietary in-house RNA control materials
Software required	GeneXpert software v5.1 or higher Xpertise software v6.6 or higher	GeneXpert Dx software v6.2 or higher	GeneXpert Dx software v6.2 or higher

HaemOnc Tests Key Features



Fast & Flexible

- ≤2.5-3 hours total testing process (including approximately 30 minutes of off-board sample preparation time)
- Simply add treated blood sample and an off-board reagent to the Xpert® test cartridge



Sensitive & Robust

- Two internal controls in every cartridge
- 4 mL input volume of peripheral blood (EDTA whole blood)
- High sensitivity and low inter-laboratory variation

Haematology and Oncology Workflow



Lyse 4 mL EDTA whole blood using proteinase K and lysis reagent



Perform second lysis step, then add ethanol



Add wash reagent and sample to cartridge



Insert cartridge and start test

Consult the instructions in the systems user manual and individual Cepheid test's' package inserts for complete product information. CE-IVD. *In Vitro* Diagnostic Medical Device. May not be available in all countries.

¹ Xpert® BCR-ABL Ultra IFU 301-2194

² Xpert® BCR-ABL Ultra p190 IFU 302-6673

³ Xpert® NPM1 Mutation IFU 302-8304

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