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CERTIFICATE OF ANALYSIS

This letter is provided to confirm that the diagnostic kit specified below conforms to the production and testing specifications required by Cepheid's Quality System. The Cepheid Quality System is in compliance with the US Food and Drug Administration's Quality System Requirements, ISO 13485:2016, European IVD Directive and the Canadian Medical Device Regulations (CMDR).


Product Description : KIT,BCR-ABL ULTRA,10-TESTS,GX,CE-IVD

Cepheid Part # : GXBCRABL-CE-10

Kit Lot #: 1000152186

Cartridge Lot #: 09101

Test Description	Specifications	Results	Acceptance Criteria
Functional Test	Negative samples tested	Negative results meet specifications	PASS
	Positive samples tested	Positive results meet specifications	

 8/23/2019
Signature of Quality Assurance, Date

Name: ThuyTien Nguyen

Title: Quality Systems Specialist