

Title: QA Analyst

CERTIFICATE OF ANALYSIS

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

Directive and the Canadian Medical Device Regulations (CMDR).				
Product Name: Xpert® vanA/vanB				
Cepheid Catalogue Part No.: GXVANA/B-CE-10				
Kit Lot No.: 1000	154123			
Cartridge Lot No.: 126	502			
Kit Expiration Date: 2	:020-04-26			
Legal Manufacturer		Manufacturing Facility	€ Solna €	Sunnyvale
Cepheid AB Röntgenvägen 5 SE-171 54 Solna Sweden		Cepheid AB Röntgenvägen 5 SE-171 54 Solna Sweden	(Some	Juliyvale
Sweden		Sweden		
Functional Testing				
Test Description	Acceptance Criteria			Test Result
Positive	vanA Positive; vanB Positive			Passed
Negative	vanA Negative; vanB Negative			Passed
				2
Kambie Maule: 20190513				
Signature of Quality Assurance Date				
Name: Kambiz Ghaderi				