

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).

Cepheid Catalogue Part No.: GXCT/NG-CE-10 Kit Lot No.: 1000335256 Cartridge Lot No.: 29519 Kit Expiration Date: 2023-11-19 Legal Manufacturer Manufacturing Facility Solna Sunnyvale Cepheid AB Cepheid Röntgenvägen 5 904 Caribbean Drive Sunnyvale, CA 94089 USA Sweden Functional Testing Test Description Acceptance Criteria Test Result Positive CT detected; NG detected Passed Negative CT not detected Passed	Product Name: Xpert	® CT/NG			
Cartridge Lot No. 29519 Kit Expiration Date: 2023-11-19 Legal Manufacturer Manufacturing Facility Solna Sunnyvale Cepheid AB Cepheid Röntgenvägen 5 904 Caribbean Drive SE-17154 Solna Sunnyvale, CA 94089 USA Sweden Functional Testing Test Description Acceptance Criteria Test Result Positive CT detected; NG detected	Cepheid Catalogue Part No.: GXCT/NG-CE-10				
Kit Expiration Date: 2023-11-19 Legal Manufacturer Manufacturing Facility Cepheid AB Röntgenvägen 5 SE-17154 Solna Sweden Manufacturing Facility Cosolna Cepheid Sunnyvale Sunnyvale Sunnyvale, CA 94089 USA Functional Testing Test Description Acceptance Criteria Test Result Positive CT detected; NG detected Passed	Kit Lot No.: 10003	335256			
Legal Manufacturer Cepheid AB Röntgenvägen 5 SE-17154 Solna Sweden Functional Testing Test Description Acceptance Criteria Positive Manufacturing Facility Copheid 904 Caribbean Drive Sunnyvale, CA 94089 USA Sunnyvale, CA 94089 USA Test Result Positive CT detected; NG detected Passed	Cartridge Lot No.: 295	519			
Cepheid AB Röntgenvägen 5 SE-17154 Solna Sweden Functional Testing Test Description Acceptance Criteria Positive CEpheid 904 Caribbean Drive Sunnyvale, CA 94089 USA Functional Testing Test Result Positive CT detected; NG detected Passed	Kit Expiration Date: 2	023-11-19			
Röntgenvägen 5 SE-17154 Solna Sweden Functional Testing Test Description Acceptance Criteria Positive CT detected; NG detected Passed	Legal Manufacturer		Manufacturing Facility C	Solna 🌀 Sun	nyvale
Functional Testing Test Description Acceptance Criteria Positive CT detected; NG detected Passed	Röntgenvägen 5 SE-17154 Solna		904 Caribbean Drive Sunnyvale, CA 94089 USA		
Test Description Acceptance Criteria Test Result Positive CT detected; NG detected Passed			. ,		
Positive CT detected; NG detected Passed					
·	Test Description	Acceptance Criteria			Test Result
Negative CT not detected; NG not detected Passed	Positive	CT detected; NG detected			Passed
	Negative	CT not	detected; NG not detected		Passed

Signature of Quality Assurance

Name: Hang Nguyen

Title: Quality Systems Specialist