

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).

Product Name: Xpert® TV			
Cepheid Catalogue Part No.: GXTV-CE-10			
Kit Lot No.: 1000176228			
Cartridge Lot No.: 06403			
Kit Expiration Date: 2020-08-02			
Legal Manufacturer	Manufacturing Facility	○ Solna	Sunnyvale
Cepheid 904 Caribbean Drive	Cepheid 904 Caribbean Drive		
Sunnyvale, CA 94089 USA	Sunnyvale, CA 94089 USA		

Functional Testing

Test Description	Acceptance Criteria	Test Result
LOW Positive	TV detected	Passed
HIGH Positive	TV detected	Passed
Negative	TV not detected	Passed

Signature of Quality Assurance	12/11	Date
Name: ThuyTien Nguyen		
Title: Quality Systems Specialist		