THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

PUBLIC ASSESSMENT REPORT FOR XPERT® HCV VIRAL LOAD (XPERT® HCV VIRAL LOAD)

Version number 2.0, 18.05.2026

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1. Introduction

XPERT® is a class C in-vitro diagnostic device belonging to the immunology specialty category. It is approved in Tanzania as a kit for use in adults, children, elderly etc by healthcare professionals.

1.1. Administrative Information

Registration number	TAN 23 MDR 0115
Brand Name (if relevant)	XPERT®
Common name	HCV Viral Load
Class of the device and rule applied	Class C as per Rule 3 for classification of In Vitro Diagnostic Devices
GMDN code and term	48374, Hepatitis C virus nucleic acid IVD, kit, nucleic acid technique (NAT)
Name and complete address of the Market Authorization Holder	Cepheid AB Rotagenvagen 5 Solna Sweden, SE 17154
Name and address(es) of local responsible person (LRP).	KAS MEDICS Unit UF09 & UF10, UMOJA COMPLEX Plot number 11, Nyerere Road, Vingunguti Industrial AREA,12019, Dar es Salaam,Tanzania Email: kasregulatory@artemislife.com

1.2. Assessment Procedure

The application for registration of XPERT® was submitted on 28.03.2023. The product underwent full assessment. Assessment was completed in one round of evaluation. XPERT® was registered on 19.07.2023

2. Technical information

2.1. Intended use

The intended use of XPERT® as declared by the manufacturer and approved by TMDA is rapid quantitation of Hepatitis C Virus (HCV) RNA in human serum or plasma (EDTA) from HCV-infected individuals. XPERT® is approved for use in healthcare settings, point of care by trained professionals only.

2.2. Device details and features

XPERT® has been registered as a kit which consists of 10 HCV VL Assay Cartridges with Integrated Reaction Tubes, 10 Disposable 1 mL Transfer Pipettes, and a CD.

It is used to aid in the management of HCV infected patients undergoing antiviral therapy. XPERT® operates by reverse transcriptase polymerase chain reaction (RT-PCR). The test out-put is quantitative.

The type of specimen used is human serum or plasma and is collected by venous blood collection.

The Xpert HCV VL is a rapid, automated in vitro diagnostic test for quantification of hepatitis C virus (HCV) RNA in human serum or plasma. The assay is performed on the Cepheid GeneXpert® Instrument Systems (GeneXpert DX and GeneXpert Infinity).

The GeneXpert Instrument Systems automate and integrate specimen purification, nucleic acid amplification, and detection of the target sequence in simple or complex specimens using real-time reverse transcription PCR (RT-PCR) and real-time PCR methods. The systems consist of an instrument, personal computer, and preloaded software for running tests and viewing the results. The systems require the use of single use disposable GeneXpert cartridges that hold the RT-PCR and PCR reagents and host the RT-PCR and PCR processes. Because the cartridges are self-contained, cross contamination between specimens is minimized. For a full description of the systems, refer to the appropriate GeneXpert Instrument System Operator Manual.

The Xpert HCV VL includes reagents for the quantitation of HCV RNA in human serum or plasma. High (IQSH) and low (IQSL) internal controls and a Probe Check Control (PCC) are also included. The IQSH and IQSL are present to control for adequate processing of the target specimen and to monitor the presence of inhibitors in the RT and PCR reactions as well as for quantitation of HCV. The PCC verifies reagent rehydration, PCR tube filling in the cartridge, probe integrity, and dye stability.

2.3. Commercial presentation

There is one approved commercial presentation as follows: Ten labeled cartridges are loaded in a 9-1/2” long x 6-3/16” deep by 2-3/4” tall printed paperboard carton. Each carton is labeled and lined with one 10-1/4 long x 5” wide recycled polypropylene (PP) absorbent pad, one 9-1/4” long x 2-1/4” tall white paperboard divider pad to separate the cartridges from one another and one 9-1/4” long x 2-1/4” tall x 3” deep white paperboard divider pad to separate the cartridges from the other components in the carton.

Additional contents include Twelve low density polyethylene (LDPE) transfer pipets, each individually sealed in a 7-1/4” long x 1” wide low-density polyethylene (LDPE) pouch, are then packed in a 10” long x 4-1/2” high low-density polyethylene (LDPE) bag and loaded in the carton in the compartment adjacent to the cartridges, An Assay Definition CD.

2.4. Items required but not submitted

GeneXpert Dx System or GeneXpert Infinity Systems (catalog number varies by configuration): GeneXpert Instrument, computer with proprietary GeneXpert Dx Software Version 4.7b or higher (GeneXpert Dx systems); or Xpertise 6.4b or higher (Infinity-80/Infinity-48s), barcode scanner, and operator manual.
• Printer: If a printer is needed, contact Cepheid Technical Support to arrange for the purchase of a recommended printer.
• Bleach or sodium hypochlorite

3. Storage instructions

3.1.1. Shelf-life

The approved shelf-life is 18 months.

3.1.2. Storage conditions

The recommended storage conditions is for 2–28 °C cartridges and reagents, .

3.1.3. Shipping conditions

The recommended shipping conditions is 2°C-28°C, 35°C for summer and winter shipping

4. Manufacturing site audit

The manufacturer of the device is Cepheid AB, Rotagenvagen 5 Solna, Sweden

Quality audit of the manufacturing facility was conducted through site visit on 27-28 December, 2025. The site was found to be compliant to ISO 13485 requirements.

5. Performance Evaluation

5.1. Analytical Performance

The analytical performance characteristics of the device was established through the following test parameters: analytical specificity.

5.2. Clinical Performance

Clinical performance was conducted at UCSF The Human Research Protection Program The Committee on Human Research (CHR) PAENASSUS Committee (FWA#00000068; IRB Registration 00000229), NRES (Tayside Research Ethics Committee B) NHS LOTHIAN SAHSC BIORESOURCE Ethical status: 13/ES/0126, The following parameters were tested specificity in HCV negative blood donors and performance of the Xpert HCV VL assay was compared to results from an established CE marked device Abbott RealTime HCV assay in an EU representative population.

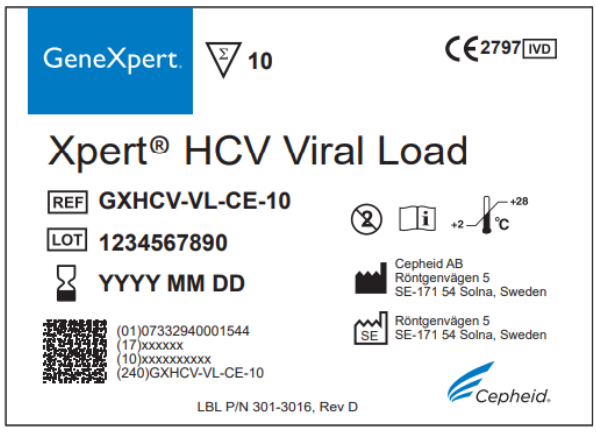
Based on results of the performance studies, it was concluded that the test specificity is 100%. The studies further concluded that XPERT® is capable of consistently producing accurate and reliable test output.

6. Product label and instructions for use

The content of the primary and secondary labels is in line with TMDA labeling requirements in terms of content, layout and design. The label contains sufficient information for proper identification of the device and post marketing follow up of the product in the market.

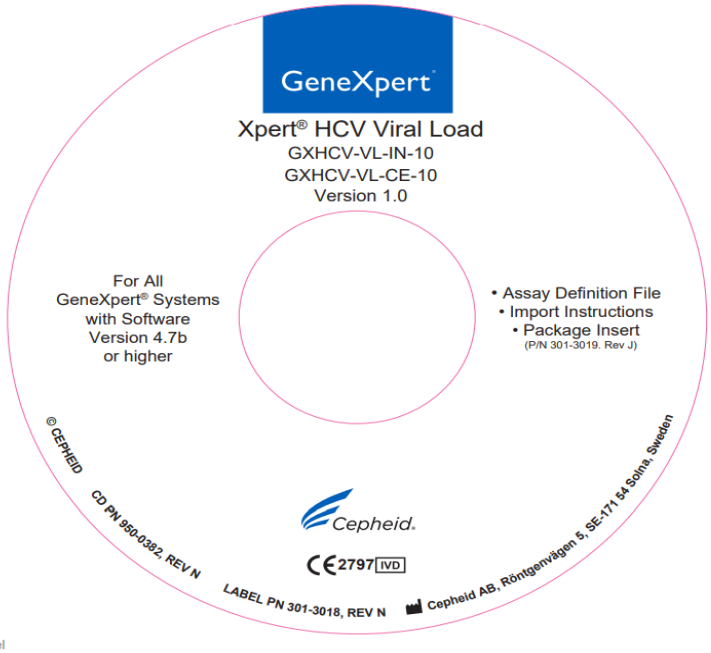
The package insert includes all the relevant information to ensure correct and safe use of the device by intended user.

6.1. Primary pack



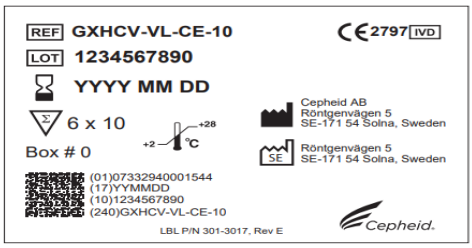
Ten-Test Kit Label
Stock Label p/n 300-5445, (latest revision)
Imprint Label p/n 301-3016, Rev D

Cartridge
Stock Label p/n 300-5505, (current rev)
Imprint Label p/n 301-3015, Rev B

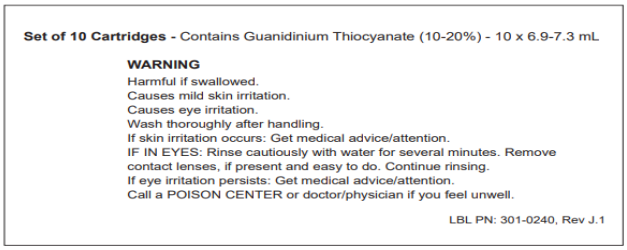


CD Label
Stock Label p/n 950-0639, (latest revision)
Imprint Label p/n 301-3018, Rev N

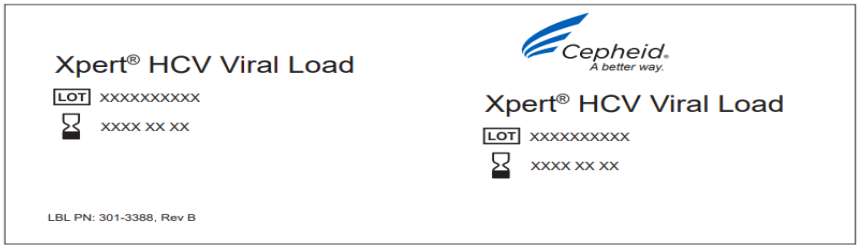
6.2. Secondary pack



Outer Box
Stock Label p/n 301-7666, (latest revision)
Imprint Label p/n 301-3017, Rev E



Hazard Warning Label
Stock Label p/n 301-0240, Rev J.1



Kit Side-Panel Label
Stock Label p/n 301-2307, (latest revision)
Imprint Label p/n 301-3388, Rev B

6.3 Instructions for use/Package insert

Click here.

Attachment 9 - Xpert HCV VL CE IVD ENGLI

7. Risk – Benefit Analysis

On basis of the data submitted, the current state of knowledge and compliance of the manufacturer to ISO 13485, the benefit of the product outweighs the risks associated with its use when used in accordance to the manufacturer instruction. Xpert® HCV Viral Load is recommended for registration.

8. Post-approval updates

8.1. Variation applications

Reference number	Date submitted	Change requested	Recommendation	Granting date
NA	NA	NA	NA	NA

8.2. Feedback from pharmacovigilance, post marketing surveillance and enforcement activities

Type of feedback	Impact	Response
No any recorded Adverse Event	NA	NA

8.3. Re-registration applications

NA

CHANGE HISTORY

Version number	Date	Description of update	Section(s) Modified	Approval date

Xpert® HCV Viral Load

Highly Sensitive Results for Effective Treatment

CE IVD *In Vitro* Diagnostic Medical Device

Not available in all countries. Not available in the United States.

Cepheid®
A better way.

> Cepheid's Xpert® HCV Viral Load test delivers results in hours rather than days — with the simplicity and ease of use of a point-of-care test. It is a very sensitive test for confirmation of infection and monitoring of HCV, and will assist in better patient management."

Pr. Jean-Michel Pawlotsky M.D., Ph.D.
Professor of Medicine at the University of Paris-Est
Director of the National Reference Center for Viral Hepatitis B, C and Delta
Director of the Department of Virology at the Henri Mondor University Hospital in Créteil, France
Director of the Department of Molecular Virology and Immunology at the Institut Mondor de Recherche Biomédicale

The Need

An estimated 185 million people, 3% of the world's population, have been infected with HCV.[1] An estimated 399,000 people died from HCV in 2016.[2]

The primary objective of anti-HCV treatment is the sustained virologic response (SVR), defined as undetectable HCV RNA by a sensitive test 12 or 24 weeks after the end of treatment.[3] With increasing numbers of patients achieving SVR following treatment, eradication of HCV is being discussed for the first time.[4]

The need for a rapid HCV viral load test with flexibility to adapt to any throughput requirements and random access for urgent samples is greater than ever.

An ultrasensitive, easy to use HCV viral load test with the flexibility to adapt to any throughput is critical as a companion test for newly developed drug regimens.

The Solution

Xpert HCV Viral Load is a quantitative test that provides on-demand molecular testing for diagnosis* and monitoring of HCV.

Based on the GeneXpert® technology, Xpert HCV Viral Load utilises automated reverse transcriptase polymerase chain reaction (RT-PCR) using fluorescence to detect and quantify RNA.

Xpert HCV Viral Load quantifies HCV genotypes 1–6 over the range of 10 to 100,000,000 IU/mL.

Redefining Simple

Ultrasensitive[5]

- LOD of 4.0 IU/mL in EDTA plasma (95% CI 2.8 – 5.2)^
- LOD of 6.1 IU/mL in serum (95% CI 4.2 – 7.9)^

Easy

- Minimal hands-on time
- Run daily or on-demand
- No requirements for PCR room settings
- No daily maintenance or liquid waste management

Flexible

- 105 minutes run time with a viral load trend report#
- Provide timely results for 1 to 345 tests on demand†
- Random access 24/7 availability
- Quantification standards run in every test for fixed cost per reportable result independent of daily volume

* Interpretation in conjunction with other clinical and laboratory findings.
^ HCV genotype 1 (WHO 4th International standard).
# Trend report available for patients' viral load measured multiple times on the same GeneXpert System.
† Operational throughput on Infinity-80; internal analysis..

The Impact

- **Increase Efficiency:** Simplified workflow and on demand testing reduces hands-on time
- **Improve Patient Care:** Fast results enable earlier adjustment to appropriate therapy
- **Better for Patients:** Same day results and treatment decisions reduces anxiety and time for multiple clinical appointments

Move Your Lab Forward

- **No Waiting:** Run any test anytime with 24/7 random access
- **Flexible:** Adaptable to meeting throughput requirements
- **Improve Sample Processing:** Speed up results turnaround time to meeting clinical need and deliver a better service

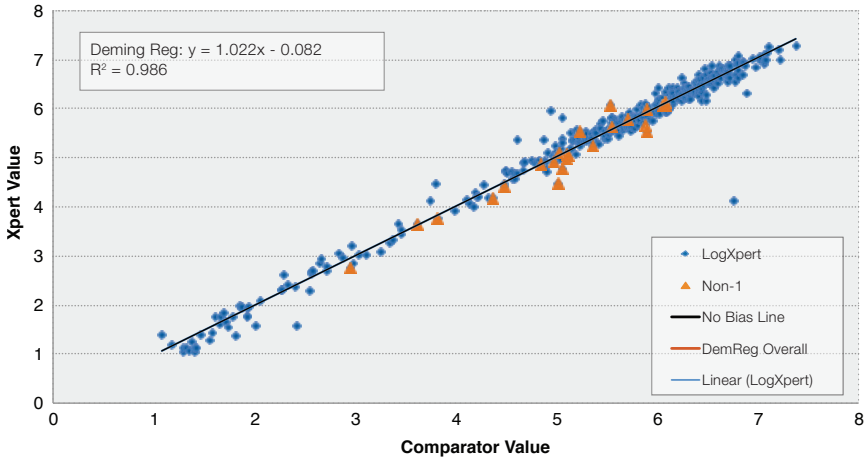
Performance[5]

A multisite study was conducted to evaluate the performance of Xpert® HCV Viral Load relative to a comparator method using fresh and frozen human plasma specimens collected from HCV infected individuals. Of the 607 specimens, 389 were within the quantitation range of the both assays including 23 specimens that were HCV non-1 genotypes (2, 2a, 2b, 2c, 3, 3a, 4 & 6) and one mixed genotype (HCV 1 & 6).

The limit of detection (LOD) of the HCV VL was determined by testing eight different dilutions prepared from a HCV genotype 1 reference standard in HCV negative EDTA plasma and serum with 3 reagents lots. The HCV RNA concentration that can be detected with a positivity rate of greater than 95% was determined by Probit regression analysis.

- The maximum observed LOD with Probit analysis for HCV genotype 1 in EDTA plasma is 4.0 IU/mL (95% CI 2.8 – 5.2)
- The maximum observed LOD with Probit analysis for HCV genotype 1 in serum is 6.1 IU/mL (95% CI 4.2 – 7.9)

Xpert vs. Comparator (LOG cp/mL)



HCV non-1 genotypes are represented as triangles. A single outlier was not included in the analysis.

Specimen	Concentration (IU/mL)	Positivity Rate (%)
WHO (Plasma)	0.5a	49
	1	65
	2	85
	3	96
	4	93
	6	99
	8	100
	10	100
WHO (Serum)	0.5[a]	40
	1	64
	2	88
	3	96
	4	97
	6	99
	8	97
	10	100

a 0.5 IU/mL was added day 2 due to the high positivity rate observed at 1 IU/mL after day 1

Workflow:

2 Easy Steps

1

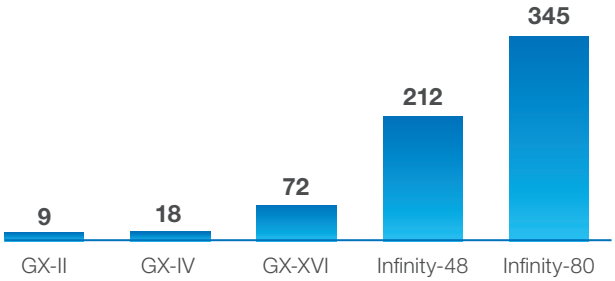
Transfer at least 1 mL of plasma into the cartridge

2

Scan, load cartridge and start test

System Throughput*

8-hr shift



* Operational throughput per 8-hr shift based on HCV Viral Load testing, internal analysis.

GeneXpert® Infinity-80

GeneXpert® II GeneXpert® IV GeneXpert® XVI

CATALOG INFORMATION

Xpert® HCV Viral Load	10 tests	GXHCV-VL-CE-10

References:

1. Mohd Hanafiah K, et al. Global epidemiology of hepatitis C virus infection: new estimates of age-specific antibody to HCV seroprevalence. Hepatology 2013; 57(4): 1333-42.
2. WHO. Hepatitis C. Accessed Jul 2021. https://www.who.int/en/news-room/fact-sheets/detail/hepatitis-c
3. Ghany MG, et al. Diagnosis, management, and treatment of hepatitis C: an update. Hepatology 2009 Apr;49 (4):1335-74.
4. Graham CS, et al. A Path to Eradication of Hepatitis C in Low-and-Middle-Income Countries. Antiviral Res. 2015 Jan 20; pii: S0166-3542(15)00005-4.
5. Xpert HCV Viral Load. Package Insert. 301-3019 Rev J February 2021

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