THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

PUBLIC ASSESSMENT REPORT FOR Xpert® MTB / RIF Ultra (GeneXpert)

Version number 2.0,18.05.2026

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1. Introduction

Xpert® MTB/RIF Ultra is a class C in-vitro diagnostic device belonging to the Infectious disease specialty category. It is approved in Tanzania as a kit for use in adults, children and elderly by trained professionals only

1.1. Administrative Information

Registration number	TAN 25 MDR 0143
Brand Name (if relevant)	Xpert® MTB / RIF Ultra
Common name	GeneXpert
Class of the device and rule applied	Class C as per Rule 3 for classification of In Vitro Diagnostic Devices
GMDN code and term	61517 MDR-TB/XDR-TB nucleic acid IVD, kit, nucleic acid technique (NAT)
Name and complete address of the Market Authorization Holder	Cepheid 904 Caribbean Drive Sunnyvale, USA Tel: +27 11 234 9640 www.cepheid.com
Name and address(es) of local responsible person (LRP).	KAS Medics Units UF09 & UF10, Umoja Complex, Plot No. 11, Nyerere Road, Vingunguti Industrial Area, P. O. Box 12019, Dar Es Salaam, Tanzania Tel: +255 22 2861737/8 Email: kasregulatory@artemislife.com

1.2. Assessment Procedure

The application for registration of Xpert® MTB/RIF Ultra was submitted on 28.03.2024. The product underwent full assessment. Assessment was completed in 02 rounds of evaluation. Xpert® MTB/RIF Ultra was registered on 15.07.2025.

2. Technical information

2.1. Intended use

The intended use of Xpert® MTB/RIF Ultra as declared by the manufacturer and approved by TMDA is for semi quantitative detection of Mycobacterium tuberculosis complex DNA and Rifampin-resistance associated mutations of the rpoB gene in sputum

specimens from untreated patients from whom there is clinical suspicion of tuberculosis is approved for use in healthcare settings by trained laboratory personnel.

2.2. Device details and features

The kits contain;

a) Xpert MTB/RIF Ultra Cartridges with Integrated Reaction Tubes,
b) 10 and 50 Sample Reagent Bottles
c) 12 Disposable Transfer Pipettes 10 kits and 60 on 50 kit package and CD 1.

Xpert® MTB/RIF Ultra is automated device. It is used for diagnosis, of detection of Mycobacterium tuberculosis complex DNA and Rifampin-resistance associated mutations of the RPOB gene in sputum. The test out-put is semi-quantitative.

The type of specimen used is sputum or aerosol-induced sputum and is collected by user institution's standard procedures.

Device description

The Xpert® MTB/RIF Ultra is an automated in vitro diagnostic laboratory test for semi quantitative detection of Mycobacterium tuberculosis complex DNA and Rifampin-resistance associated mutations of the rpoB gene in sputum specimens from untreated patients from whom there is clinical suspicion of tuberculosis (TB).

The GeneXpert® Dx/Edge/Infinity Systems integrate and automate sample processing, nucleic acid amplification, and detection of the target sequences in simple or complex samples using real-time PCR and reverse transcriptase PCR.

The system consists of an instrument, personal computer, barcode scanner, and preloaded software for running tests on collected samples and viewing the results. The system requires the use of single-use disposable GeneXpert® cartridges that hold the PCR reagents and host the PCR process.

2.3. Commercial presentation

There is one approved commercial presentation as follows:

	Kit Component	**Xpert® MTB/RIF-Ultra-10**	**Xpert® MTB/RIF-Ultra-50**
1	**Xpert MTB/RIF Ultra Cartridges with Integrated Reaction Tubes**	**10 per kit**	**50 per kit**
	Bead 1 and Bead 2 (freeze-dried)	2 of each per cartridge	2 of each per cartridge

	Bead 3 (freeze-dried)	1 of each per cartridge	1 of each per cartridge
	Reagent 1	4 mL per cartridge	4 mL per cartridge
	Reagent 2	4 mL per cartridge	4 mL per cartridge
2	**Sample Reagent Bottles**	**10 per kit**	**50 per kit**
	Sample Reagent	8 mL per bottle	8 mL per bottle
3	**Disposable Transfer Pipettes**	**12 per kit**	**60 per kit**
4	CD	1 per kit	1 per kit
	Assay Definition Files (ADF)	1	1
	Instructions to import ADF into software	1	1
	Instructions for Use (Package Insert)	1	1

Additional contents include
One (1) CD contains Assay Definition Files (ADF), Instructions to import ADF into the GeneXpert software and Instructions for Use

2.4. Items required but not submitted

- GeneXpert® Dx System or GeneXpert® Infinity Systems (catalog number varies by configuration): GeneXpert® Instrument, computer, barcode scanner, and operator manual
    - For GeneXpert® Dx system: Software version 4.7b or higher
    - For GeneXpert® Edge system: Software version 1.0
    - For GeneXpert® Infinity system: Software version 6.4b or higher
- Printer: If a printer is required, contact Cepheid Sales Representative to arrange for the purchase of a recommended printer.
- Leak-proof, sterile screw-capped collection containers
- Disposable gloves
- Labels and/or indelible labeling market
- Sterile pipettes for sample processing

3. Storage instructions

3.1.1. Shelf-life

18 months.

3.1.2. Storage conditions

a) Store the Xpert MTB/RIF Ultra test cartridges at 2-28 °C.

b) Do not open a cartridge lid until you are ready to perform testing.
c) Do not use reagents or cartridges that have passed the expiration date

3.1.3. Shipping conditions.

The recommended shipping conditions is 2-45°C

4. Manufacturing site audit

The manufacturer of the device is Cepheid AB, Rontgen agen 5, Solna, SE-171 54, Sweden.

Quality audit of the manufacturing facility was conducted through desk review on 27th-28th 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: accuracy (trueness, precision (repeatability and reproducibility), analytical sensitivity and analytical specificity.

5.2. Clinical Performance

Clinical performance was conducted at NICD-National TB Reference Lab,1 Modderfontein Road, Sandringham, Modderfontein, Johannesburg, South Africa and Henan Provincial Chest Hospital, No.1 Weiwu Road Jinshui District, Zhengzhou City, Henan Province, China. The following parameters were tested; Clinical Specificity and Clinical Sensitivity.

Based on results of the performance studies 1594 specimens were tested by both the Xpert MTB/RIF Ultra test and the Xpert MTB/RIF Assay. The overall percent agreement between the assays was 96.5% [(1538/1594) 95% CI: 95.5, 97.3]. The positive percent agreement and the negative percent agreement were 99.2% [(491/495) 95% CI: 97.9, 99.7] and 95.3% (1047/1099) 95% CI: 93.8, 96.4], respectively. The studies further concluded that Xpert® MTB/RIF Ultra is capable of consistently producing accurate and reliable test output.

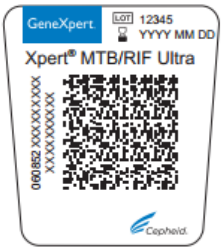
6. Product label and instructions for use

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.

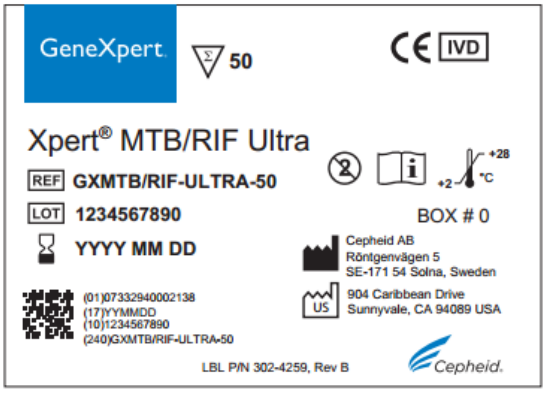
The user manual, package insert, instructions for use includes all the relevant information to ensure correct and safe use of the device by intended user.

6.1. Primary pack

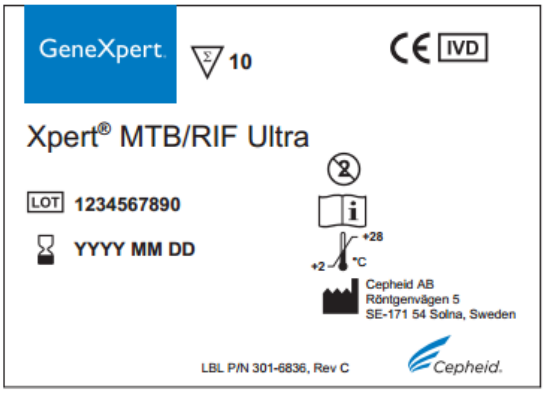
Xpert® MTB/RIF Ultra 50-Test Kits
Catalog # GXMTB/RIF-ULTRA-50
Updated 16 May 2022



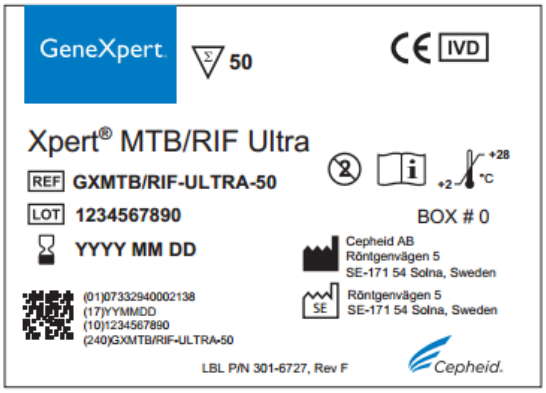
Cartridge Label (SVL and SWE)
Stock Label p/n 300-5505, (latest revision)
Imprint Label p/n 301-9357, Rev B



10-test kit label (US Physical Manufacturing Site)
Stock Label p/n 300-5445, (latest revision)
Imprint Label p/n 302-4259, Rev B

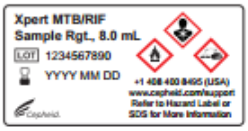


10-Cart (Brick) label
Stock Label p/n 300-5445, (latest revision)
Imprint Label p/n 301-6836, Rev C



6.2. Secondary pack

Xpert® MTB/RIF Ultra 50-Test Kits (pg 2)



Sample Reagent
Stock Label p/n 301-8023, (latest revision)
Imprint Label p/n 301-7198, Rev C

Sample Reagent - Contains Sodium Hydroxide (5-8%) and Isopropyl Alcohol (10-15%) - 10 x 8.0 mL

DANGER

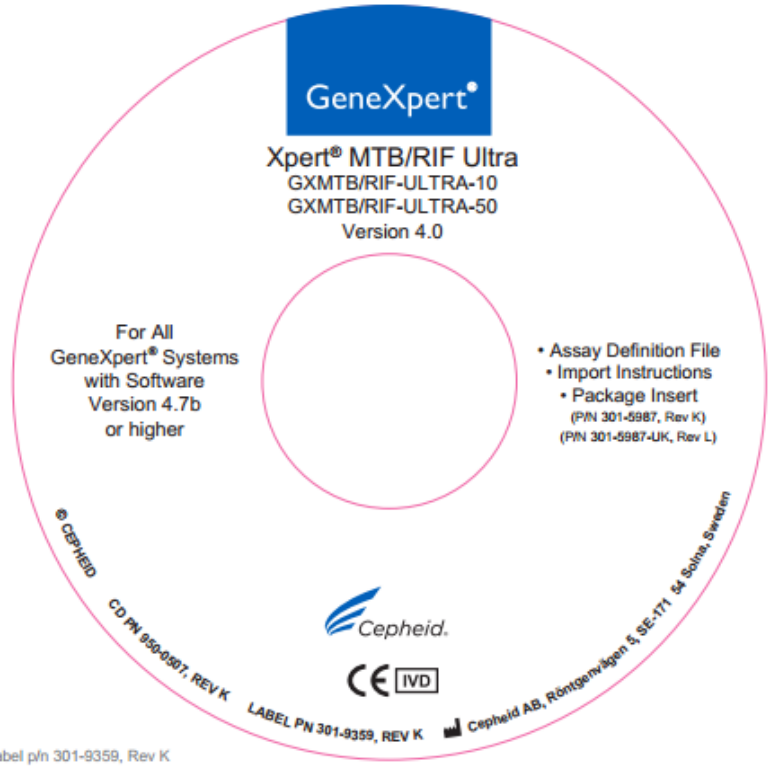
Flammable liquid and vapour.
Causes severe skin burns and eye damage.
Causes serious eye damage.
Suspected of causing genetic defects.
Suspected of damaging fertility or the unborn child.
May cause damage to organs through prolonged or repeated exposure.
Obtain special instructions before use.
Do not handle until all safety precautions have been read and understood.

Keep away from heat, sparks, open flames and/or hot surfaces. No smoking.
Keep container tightly closed.
Do not breathe mists, vapours and/or spray.
Wash thoroughly after handling.
Wear protective gloves/protective clothing/eye protection/face protection.
Use personal protective equipment as required.

In case of fire: Use appropriate media for extinction.
IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Immediately call a POISON CENTER or doctor/physician.
IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. Wash contaminated clothing before reuse.
Specific treatment, see supplemental first aid information.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
If exposed or concerned: Get medical advice/attention.
Get medical advice/attention if you feel unwell.
Dispose of content and/or container in accordance with local, regional, national and/or international regulations.

LBL PN: 301-6700, Rev E

Hazard Label
Stock Label p/n 301-6700, Rev E



CD Label
Imprint Label p/n 301-9359, Rev K

6.3 Instructions for use/Package insert
Instructions for use can be accessed by clicking here

9. Xpert MTB_RIF Ultra CE IVD ENGLISH

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® MTB/RIF Ultra 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