TMDA/DMD/MDA/F/…..
Rev #:00

THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

PUBLIC ASSESSMENT REPORT FOR FASTEP TB-W23 TUBERCULOSIS RAPID TEST DEVICE

Version number 2.0, 11/09/2024

TMDA Headquarters, Plot No. 56/1, Block E, Kisasa B Centre, Swaswa Road, P. O. Box 1253, Dodoma – Tanzania, Telephone: +255 (26) 2961989/2061990/+255 (22) 2450512/2450751/2452108, Email: info@tmda.og.tz, Website: **www.tmda.go.tz**

Toll free: 0800110084

1. Introduction

Fastep TB-W23 is a class *C in-vitro diagnostic device* belonging to the *clinical laboratory* specialty category. It is approved in Tanzania as a *kit* for use in Children, A*dults & Elderly* by *healthcare professionals*.

1.1. Administrative Information

Registration number	TAN 23 MDR 0113
Brand Name (if relevant)	*Fastep TB-W23*
Common name	*Tuberculosis Rapid Test Device*
Class of the device and rule applied	*Class C according to rule 3*
GMDN code and term	*51172, Mycobacterium tuberculosis complex species antigen IVD, kit, rapid ICT, clinical*
Name and complete address of the Market Authorization Holder	*Anudha Ltd,* *P. O. Box* *Dar es Salaam.* *Tanzania* *Telephone: +255 22 21 25 746* *E-mail: anudha@anudha.com*
Name and address(es) of local responsible person (LRP).	*Anudha Ltd,* *P. O. Box* *Dar es Salaam.* *Tanzania* *Telephone: +255 22 21 25 746* *E-mail: anudha@anudha.com*

1.2. Assessment Procedure

The application for registration of *Fastep TB-W23* was submitted on *09/02/2023*. The product underwent *full* assessment. Assessment was completed in *one* round of evaluation. *Fastep TB-W23* was registered on *13/07/2023*.

2. Technical information

2.1. Intended use

The intended use of *Fastep TB-W23* as declared by the manufacturer and approved by TMDA is *for* detecting anti-TB antibodies (Isotypes IgG, IgM and IgA) in whole blood,

serum or plasma specimens. *Fastep TB-W23* is approved for use in *healthcare settings* by *trained professionals only*.

2.2. Device details and features

Fastep TB-W23 has been registered as a kit of 25 test cards which consists of individually packed test devices, buffer, disposable pipettes and package insert. It is a closed system.

Fastep TB-W23 is a manually operated device. It is used to aid diagnosis of Tuberculosis. Fastep TB-W23 operates by detecting anti-TB antibodies in whole blood, serum or plasma specimen. TB antigens are immobilized on the test region of the membrane. During testing, the specimen reacts with TB antigen conjugated to colored particles and precoated onto the sample pad of the test. The mixture then migrates through the membrane by capillary action, and interacts with reagents on the membrane. If there are sufficient antibodies to TB in the specimen, a colored band will form at the test region of the membrane. The presence of this colored band indicates a positive result, while its absence indicates a negative result. The test out-put is qualitative.

The type of specimen used is whole blood or serum or plasma and is collected by venipuncture or fingerstick method.

Figure 1: Test Principle

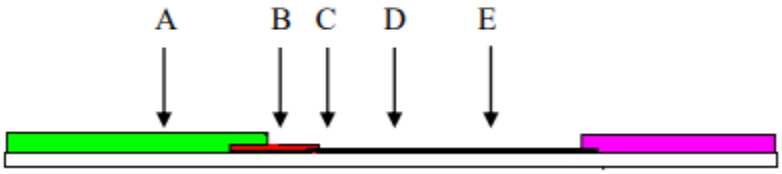
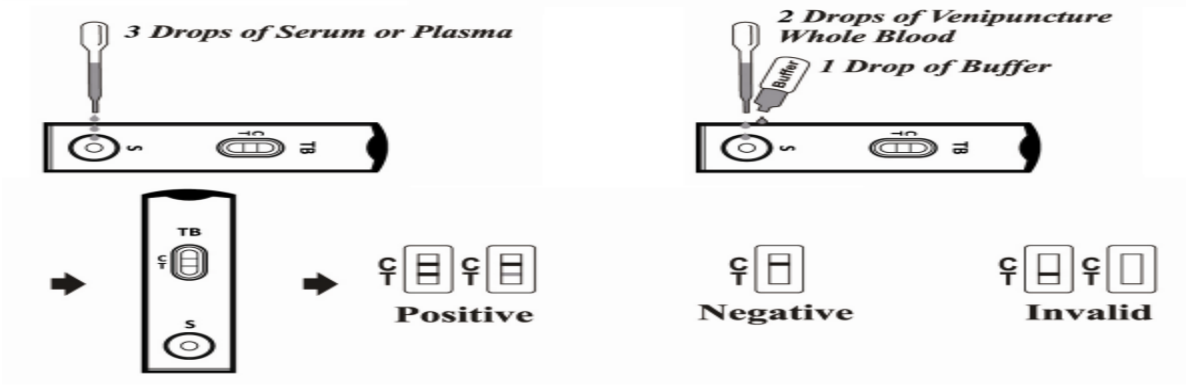


Figure 2: Interpretation of Results



2.3. Commercial presentation

There is 01 approved commercial presentations as follows: 01 units in the primary packaging material. 25 Test Cards are placed in <secondary packaging material.

Additional contents include:

- *Individually packed test devices*
- *Buffer*
- *Disposable pipettes*
- *Package insert*

2.4. Items required but not submitted

- *Specimen collection container*
- *Timer*
- *Centrifuge*

3. Storage instructions

3.1.1. Shelf-life

The approved shelf-life is *24* months.

3.1.2. Storage conditions

The recommended storage condition is *2 – 30^{0}C. Do not freeze.*

3.1.3. Shipping conditions

The kit should be shipped under controlled temperatures between 2°C and 30°C to maintain stability. Short-term excursions within this range are acceptable based on real-time stability data up to 27 months.

4. Manufacturing site audit

The manufacturer of the device is *Assure Tech. (Hangzhou)., Ltd, Building 4, No. 1418-50, Moganshan Road, Gongshu District, Hangzhou, 310011 Zhejiang, P.R. China*

The quality audit has not been conducted yet, but the application and payment have already been completed.

5. Performance Evaluation

5.1. Analytical Performance

The analytical performance characteristics of the device was established through the following test parameters; *analytical sensitivity and analytical specificity.*

5.2. Clinical Performance

Clinical performance was conducted in *three clinical centers; Henan Provincial Chest Hospital, Jiangxi Provincial Chest Hospital and Chest Hospital of Xinjiang Urghur Autonomous Region of PRC*. The following parameters were tested; *accuracy, sensitivity and specificity.*

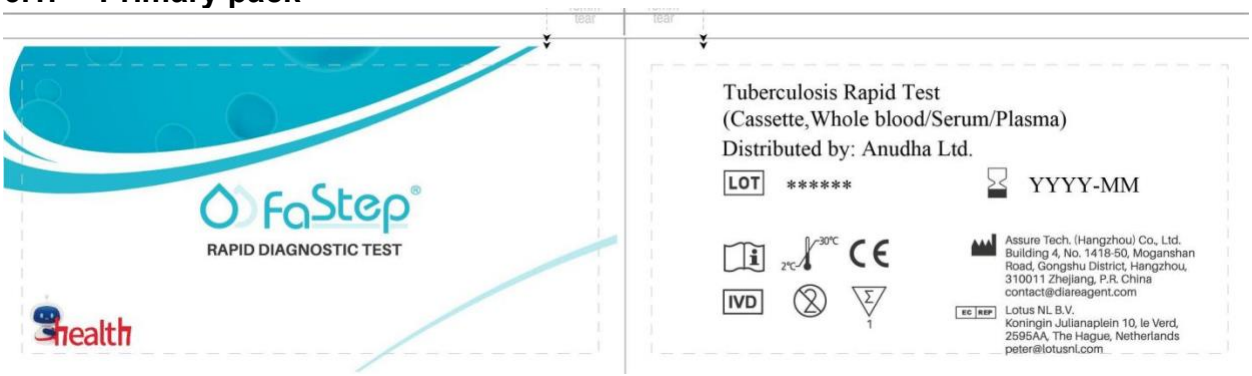
Based on results of the performance studies, it was concluded that the test sensitivity and specificity is *99.2%* and *83.2%* respectively. The studies further concluded that *Fastep - TB-W23* is capable of consistently producing accurate and reliable test output.

6. Product label and instructions for use

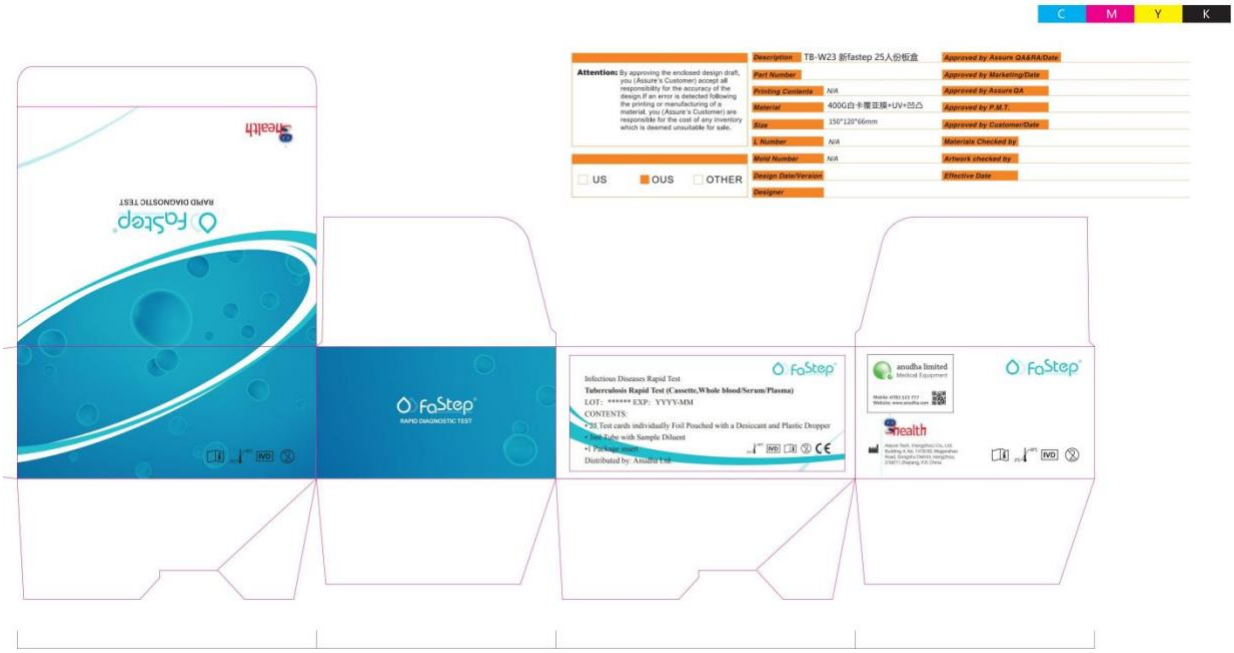
The content of the primary and secondary labels is in line with TMDA labeling requirements in terms of content, layout and design. The label contains sufficient information for proper identification of the device and post marketing follow up of the product in the market.

The *instruction for use* includes all the relevant information to ensure correct and safe use of the device by intended user.

6.1. Primary pack



6.2. Secondary pack



6.3 Instructions for use/Package insert

Instructions for use can be accessed by clicking here

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. *Fastep TB-W23* was 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 recorded Adverse Event	NA	NA

8.3. Re-registration applications

NA

CHANGE HISTORY

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

FaStep®

TB-W23

Tuberculosis Rapid Test Device (Whole Blood/Serum/Plasma)

INTENDED USE

The Tuberculosis Rapid Test Device (Whole Blood/Serum/Plasma) is a rapid visual immunoassay for the qualitative presumptive detection of anti-TB antibodies (Isotypes IgG, IgM and IgA) in whole blood, serum or plasma specimens. This kit is intended for use as an aid in the diagnosis of Tuberculosis.

INTRODUCTION

Tuberculosis (TB) is spread primarily via airborne transmission of aerosolized droplets developed by coughing, sneezing and talking. Areas of poor ventilation pose the greatest risk of exposure to infection. TB is a major cause of morbidity and mortality worldwide, resulting in the greatest number of deaths due to a single infectious agent. The World Health Organization reports that more than 8 million new cases of active tuberculosis are diagnosed annually. Almost 3 million deaths are attributed to TB as well. Timely diagnosis is crucial to TB control, as it provides early initiation of therapy and limits further spread of infection. Several diagnostic methods for detecting TB have been used over the years including skin test, sputum smear, and sputum culture and chest x-ray. But all these methods have some limitations. Newer tests, such as PCR-DNA amplification or interferon-gamma assay, have been recently introduced. However, the turn-around time for these tests is long, they require laboratory equipment and skilled personnel, and some are neither cost effective nor easy to use. These tests are also expensive and not practical for developing countries. Serological methods constitute an attractive alternative, since TB serodiagnosis is simple, inexpensive, relatively non-invasive, and it does not depend on detection of mycobacteria.

PRINCIPLE

The Tuberculosis Rapid Test Device (Whole Blood/Serum/Plasma) detects anti-TB antibodies through visual interpretation of color development on the internal strip. TB antigens are immobilized on the test region of the membrane. During testing, the specimen reacts with TB antigen conjugated to colored particles and precoated onto the sample pad of the test. The mixture then migrates through the membrane by capillary action, and interacts with reagents on the membrane. If there are sufficient antibodies to TB in the specimen, a colored band will form at the test region of the membrane. The presence of this colored band indicates a positive result, while its absence indicates a negative result. The appearance of a colored band at the control region serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS

Materials Provided

- Individually packed test devices
- Disposable pipettes
- Buffer
- Package insert

Materials Required but Not provided

- Specimen collection container
- Centrifuge
- Timer

PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse tests.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious, and handled observing usual safety precautions (e.g., do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to testing.
- Do not eat, drink or smoke in the area where the specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Do not interchange or mix reagents from different lots.
- Humidity and temperature can adversely affect results.
- Used testing materials should be discarded according to local regulations.

STORAGE AND STABILITY

- The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- **Do not freeze.**
- Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipments, containers or reagents can lead to false results.

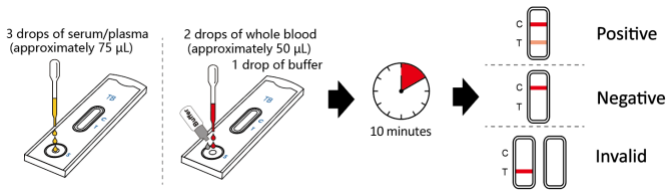
SPECIMEN COLLECTION AND STORAGE

- The Tuberculosis Rapid Test Device (Whole Blood/Serum/Plasma) is intended for use with human whole blood, serum, or plasma specimens only.
- Only clear, non-hemolyzed specimens are recommended for use with this test. Serum or plasma should be separated as soon as possible to avoid hemolysis.
- Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
- Containers containing anticoagulants such as EDTA, citrate, or heparin should be used for whole blood storage.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
- If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.
- Icteric, lipemic, hemolysed, heat treated and contaminated specimens may cause erroneous results.

PROCEDURE

Bring tests, specimens, buffer and/or controls to room temperature (15-30°C) before use.

1. Remove the test from its sealed pouch, and place it on a clean, level surface. Label the device with patient or control identification. For best results, the assay should be performed within one hour.
2. Transfer 3 drops of serum/plasma (approximately 75 µL) to the specimen well (S) of the device with the provided disposable pipette, and start the timer.
   OR
   Allow 2 drops of whole blood (approximately 50 µL) to fall into the center of the specimen well(s) of the test device then add 1 drop of buffer, and start the timer.
   Avoid trapping air bubbles in the specimen well (S), and do not add any solution to the result area.
   As the test begins to work, color will migrate across the membrane.
3. Wait for the colored band(s) to appear. The result should be read at 10 minutes. Do not interpret the result after 30 minutes.



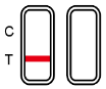
INTERPRETATION OF RESULTS



POSITIVE: Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).



NEGATIVE: Only one colored band appears, in the control region (C). No apparent colored band appears in the test region (T).



INVALID: Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:

1. The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered positive. Note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.
2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

- Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique.
- External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS OF THE TEST

1. The Tuberculosis Rapid Test Device (Whole Blood/Serum/Plasma) is for professional *in vitro* diagnostic use, and should only be used for the qualitative detection of anti-TB antibodies. No meaning should be inferred from the color intensity or width of any apparent bands.
2. A positive result suggests only the presence of antibodies specific to TB, and does not distinguish between active and past infections. A positive result is not necessarily indicative of TB.
3. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time rule out the possibility of TB, as antibodies to TB may be present below the minimum detection level of the test.

PERFORMANCE CHARACTERISTICS

Table: TB Rapid Test vs. Smear/Culture

Relative Sensitivity:
83.6% (75.6%-89.4%)*
Relative Specificity:
99.2% (97.7%-99.7%)*
Overall Agreement:
95.7% (93.5%-97.2%)*

***95% Confidence Interval**

		TB Rapid Test +	TB Rapid Test -	Total
Smear/ Culture	+	92	18	110
	-	3	372	375
		95	390	485

LITERATURE REFERENCES

1. Global tuberculosis control (2003). WHO Report 2003: 1-40.
2. Raviglione M.C., Snider, Jr., D.E., and Kochi, A. Global epidemiology of tuberculosis. JAMA (1995), 273: 220-225.
3. Laszlo A. Tuberculosis: laboratory aspects of diagnosis. CMAJ (1999), 160: 1725-1729.
4. Bothamley G.H. Serological diagnosis of tuberculosis. Eur. Resp. J. (1995), 8: 676s-688s.
5. Lyashchenko K., Colangeli R., Houde M., Jahdali H.A., Menzies D., and Gennaro M.L. Heterogenous antibody responses in tuberculosis. Infect. Immun. (1998), 66: 3936-3940.
6. Lyashchenko K.P., Singh M., Colangeli R., and Gennaro M.L. A multi-antigen print immunoassay for the serological diagnosis of infectious diseases. J. Immunol. Methods (2000), 242: 91-100.

GLOSSARY OF SYMBOLS

ρ	Catalog number	0	Temperature limitation
ι	Consult instructions for use	A	Batch code
I	In vitro diagnostic medical device	ε	Use by
µ	Manufacturer	T	Contains sufficient for <n> tests
σ	Do not reuse	A	Authorized representative in the European Community
Y	CE marking according to IVD Medical Devices Directive 98/79/EC		

FaStep®

µ
Assure Tech. (Hangzhou) Co., Ltd.
Building 4, No. 1418-50, Moganshan Road,
Gongshu District, Hangzhou,
310011 Zhejiang, P.R. China

Y A
Lotus NL B.V.
Koningin Julianaplein 10, le Verd,
2595AA, The Hague, Netherlands

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