THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

PUBLIC ASSESSMENT REPORT FOR ACCUQUIK *SYPHILIS AB RAPID DIAGNOSTICS TEST KIT*

Version number 2.0, 29/03/2024

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1. Introduction

AccuQuik is a class C in-vitro diagnostic device belonging to the microbiology specialty category. AccuQuik is approved in Tanzania as a kit for use by healthcare professionals.

1.1. Administrative Information

Registration number	TAN 22 MDR 0203
Brand name (if relevant)	AccuQuik
Common name	Syphilis Ab Rapid Diagnostics Test Kit
Class of the device and rule applied	Class C according to Rule 1
GMDN code and term	63969 Treponema Pallidum Immunoglobulin G (IgG)/IgM Antibody IVD Kit, Immunochromatographic test (ICT), rapid.
Name and complete address of the Market Authorization Holder	Zhejiang Orient Gene Biotech Co., Ltd 787#, East Yangguang Avenue, Dipu Street, Anji 313300, Huzhou, Zhejiang, China. Telephone: +86 572 5303756.
Name and address(es) of local responsible person (LRP).	Serengeti Care (T), P. O. Box 15639, Magomeni Mapipa, Oposite CRDB Bank, Dar es Salaam. Tanzania. Telephone: 0713-246532 E-Mail: Info@Serengeticare.Co.Tz

1.2. Assessment Procedure

The application for registration of AccuQuik was submitted on 07/01/2022. The product underwent full registration procedure assessment. Assessment was completed in 02 rounds of evaluation. AccuQuik was registered on 07/12/2022.

2. Technical information

2.1. Intended use

The intended use of AccuQuik as declared by the manufacturer and approved by TMDA is screening test and as an aid in the diagnosis of infection with Treponema Pallidum (TP). AccuQuik is approved for use in healthcare settings by trained professionals only.

2.2. Device details and features

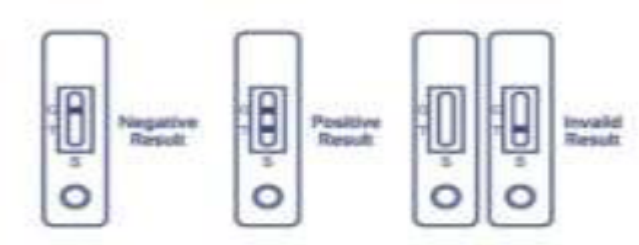
AccuQuik has been registered as a kit which consists of Test devices, buffer, desiccant, dropper and package insert.

AccuQuik is an in vitro diagnostic device. It is used for aiding diagnosis and screening, of Syphilis. AccuQuik operates by detection of IgM and IgG antibodies to Treponema Pallidum (TP) through lateral flow chromatographic immunoassay. The test out-put is qualitative.

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

Device description
The test device contains the following; nitrocellulose membrane strips, sample pad, conjugate releasing pads, absorbent pad, plastic cassette for lateral flow assay, laminated pouch, specimen transfer device and specimen volume

Pictorial diagram



2.3. Commercial presentation

There is one approved commercial presentation as follows: 1 cassette in a pouch. 25 test cassettes are placed in a carton box.

Additional contents include pipette dropper, buffer, and package insert. The test kit is not automated and does not require any additional instrument.

2.4. Items required but not submitted
a) Specimen collection container
b) Timer
c) Centrifuge
d) Lancets
e) Heparinized capillary tubes and dispensing bulb

3. Storage instructions

3.1.1. Shelf-life
The approved shelf-life is 24 months.

3.1.2. Storage conditions

The recommended storage conditions are 4°C -30°C

3.1.3. Shipping conditions

The recommended shipping conditions are 4°C -30°C

4. Manufacturing site audit

The manufacturer of the device is Zhejiang Orient Gene Biotech Co., Ltd, 787#, East Yangguang Avenue, Dipu Street, Anji 313300, Huzhou, Zhejiang, China.

Quality audit of the manufacturing facility was conducted through site visit on 20-21/03/2019. 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: precision (repeatability and reproducibility), analytical sensitivity, analytical specificity.

5.2. Clinical Performance

Clinical performance was conducted at Anji Traditional Medicine Hospital: Address:No 299, West Shenli Road, Dipu Town, Anji,Huzhou City,Zhejiang, China and Anji People's Hospital: Address: No 699 Tianmu Road, Dipu Town, Anji, Huzhou City, Zhejiang, China. The following parameters were tested sensitivity and specificity.

Based on the result of the performance studies, it was concluded that the test sensitivity and specificity is 100% and 99.8% respectively. The studies further concluded that Accuquik 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.

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

6.1. Primary pack

Mock Up Labels for Primary Pack

Pouch:

6.2. Secondary pack

Mock Up Labels for Secondary Pack

Box:

6.3 Instructions for use/Package insert

Instructions for use can be accessed at the Accuquik test kit instruction for use 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's instruction. Accuquik was recommended for registration.

8. Post-approval updates

8.1. Variation applications

Reference number	Date submitted	Change requested	Recommendation	Granting date
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**

AccuQuik Test Kit™

Anti-Syphilis Rapid Test

Anti-Syphilis Rapid Test
Cassette/Whole Blood

INTENDED USE

The Syphilis Rapid Test (Whole Blood) is a rapid visual immunoassay for the qualitative, presumptive detection of IgM and IgG antibodies to Treponema Pallidum (TP) in human whole blood specimens. This kit is intended for use as an aid in the diagnosis of syphilis.

PRINCIPLE

The Syphilis Rapid Test (Whole Blood) detects IgM and IgG antibodies to Treponema Pallidum (TP) through visual interpretation of color development on the internal strip. Specific recombinant TP antigens are immobilized on the test region of the membrane. During testing, the specimen reacts with recombinant TP-specific 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 Treponema Pallidum (TP) 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.

CONTENTS

Materials Provided
- Individually Packed Test Device
- Buffer
- Desiccant
- Dropper
- Package Insert

Materials Not Provided:
- Specimen Collection Container
- Timer
- Centrifuge

SPECIMEN

- The Syphilis Rapid Test (Whole Blood) is intended for use with human whole blood specimens.
- Only clear, non-hemolyzed specimens are recommended for use with this test.
- Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods. Do not freeze whole blood specimens. Whole blood 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, hemolyzed, heat treated and contaminated specimens may cause erroneous results.

DIRECTIONS FOR USE

1. Remove the test device from the foil pouch and place it on a flat, dry surface.

2. Slowly add 2 drops (50µl) of whole blood to the sample well, then add 1 drop (40µl) of buffer to the buffer well 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, you will see color move across the membrane.

3. Wait for the colored line(s) to appear. The result should be read at 10 minutes. Do not interpret the result after 20 minutes.

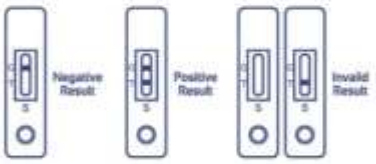
INTERPRETATION OF RESULTS

Positive:
Two colored lines appear on the membrane. One line appears in the control region (C) and another line appears in the test region (T).

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

Invalid:
Control line fails to appear. Results from any test which has not produced a control line 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 the color in test region (T) may vary depending on the concentration of aimed substances present in the specimen. Therefore, any shade of color in the test region should be considered positive. Besides, the substances level can not be determined by this qualitative test.
2. Insufficient specimen volume, incorrect operation procedure, or performing expired tests are the most likely reasons for control line failure.



PERFORMANCE CHARACTERISTICS

The Syphilis Rapid Test has been evaluated with a TPHA test using clinical specimens. The results show that the sensitivity is 99.6%, the specificity is 99.1% and the accuracy is 99.3% relative to the TPHA test.

LIMITATIONS OF THE TEST

1. The Syphilis Rapid Test (Whole Blood) is for professional in vitro diagnostic use, and should only be used for the qualitative detection of TP antibodies. No meaning should be inferred from the color intensity or width of any apparent bands.
2. The Syphilis Rapid Test (Whole Blood) will only indicate the presence of TP antibodies in the specimen and should not be used as the sole criteria for the diagnosis of TP infection.
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 anytime rule out the existence of TP antibodies in blood, as antibodies may be present below the minimum detection level of the test.
4. As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

STORAGE AND STABILITY

- The kit should be stored at 4-30°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.

WARNINGS AND 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 by 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 the proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Humidity and temperature can adversely affect results.
- Used testing materials should be discarded according to local regulations.

AccuQuik™ manufactured exclusively for:
AdvaCare Pharma USA
www.AccuQuikTestKits.com

Made in China

advacare
PHARMA USA