THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

PUBLIC ASSESSMENT REPORT FOR UMOJA'S HCG STRIP ONE STEP HCG URINE PREGNANCY TEST

Version number 2.0, 25.05.2026

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1. Introduction

Umoja's hCG strip is a class B in-vitro diagnostic device belonging to the immunology specialty category. It is approved in Tanzania as a single invitro diagnostic device for use in women in reproductive age by healthcare professionals.

1.1. Administrative Information

Registration number	TAN 25 MDR 0249
Brand Name (if relevant)	Umoja's hCG strip
Common name	One step HCG Urine Pregnancy Test
Class of the device and rule applied	B, Rule 6
GMDN code and term	33819, Total human chorionic gonadotropin IVD, kit, rapid ICT, clinical
Name and complete address of the Market Authorization Holder	Umoja Pharmaceuticals CO, LTD Lindi/Swahili, Kariakoo, Gerezani- P.O.Box 22787, Dar Es Salaam
Name and address(es) of local responsible person (LRP).	Umoja Pharmaceuticals CO, LTD Lindi/Swahili, Kariakoo, Gerezani- P.O.Box 22787, Dar Es Salaam

1.2. Assessment Procedure

The application for registration of Umoja's hCG strip was submitted on 26.02.2025. The product underwent full assessment. Assessment was completed in three rounds of evaluation. Umoja's hCG strip was registered on 18.11.2025

2. Technical information

2.1. Intended use

The intended use of Umoja's hCG strip as declared by the manufacturer and approved by TMDA is qualitative detection of hCG (human chorionic gonadotrophin) in urine to aid in the early diagnosis of pregnancy. Umoja's hCG strip is approved for use in healthcare settings by trained professionals only.

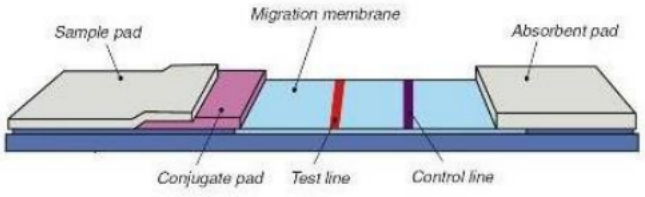
2.2. Device details and features

Umoja's hCG strip has been registered as a single invitro diagnostic device.

Umoja's hCG strip is a rapid test device. It is used to aid diagnosis of pregnancy. Umoja's hCG strip operates by Immuno-chromatography, a two-site immunoassay on a membrane. As the test sample flows through the membrane assembly of the dipstick, the colored anti-hCG-colloidal gold conjugate complexes with the hCG in the sample. This complex moves further on the membrane to the test region where it is immobilized by the anti-hCG antibody coated on the membrane leading to formation of a colored band which confirms a positive test result. Absence of this colored band in the test region indicates a negative test result. The unreacted conjugate and unbound complex if any along with rabbit IgG colloidal gold conjugate move further on the membrane and are subsequently immobilized by the anti-rabbit IgG antibodies coated on the membrane at the control region, forming a colored band. This control band serves as an internal control to validate the test results.The test out-put is qualitative.

The type of specimen used is urine and is collected by micturition in a dry and clean container.

Pregnancy Test (Strip /Dipstick) is an immuno-chromatographic assay. Each pouch contains a test strip. The test strip is composed of followings.



A. Sample pad: It is area of test strip where sample / specimen is applied. Sample pad is made of glass fibre sheet having buffering salts, biological detergents and preservative.

B. Conjugate pad: Conjugate pad is made of glass fibre sheet / special grade of paper having colloidal gold conjugated with monoclonal anti HCG & Rabbit IgG, buffering salts, biological detergents and preservative.

C. Nitrocellulose membrane: Nitrocellulose membrane is immobilised / coated with anti HCG in form of line at Test line region (T) and Goat anti rabbit IgG at control line region (C).

D. Absorbent pad: It made of cellulose paper and it absorbs the applied sample / specimen.

2.3. Commercial presentation

There is one approved commercial presentation as follows: one test strip/dipstick in an aluminum foil pouch as the primary package. 50 aluminium pouches are placed in hard cardboard box as the secondary package.

Additional contents include a desiccant and package insert.

2.4. Items required but not submitted

Specimen collection container and Timer.

3. Storage instructions

3.1.1. Shelf-life

The approved shelf-life is 36 months.

3.1.2. Storage conditions

The recommended storage conditions is 2-30 ºC

3.1.3. Shipping conditions

The recommended shipping conditions is 2 to 45°C and 80% humidity.

4. Manufacturing site audit

The manufacturer of the device is Oscar Medicare Pvt. Ltd, E-92, Bahadrabad Industrial Area, Haridwar- 249402, Uttarakhand, 011-41076195/96, India.

5. Performance Evaluation

5.1. Analytical Performance

The analytical performance characteristics of the device was established through the following test parameters: minimum detection limit, reproducibility, analytical sensitivity and analytical specificity.

5.2. Clinical Performance

Clinical performance was conducted at DGChem Labs Pvt. Ltd, 231, U.S Complex, Adjoining Jasola Metro Station, Opp, Apollo Hospital, Mathura Road, New Delhi- 110076. The following parameters were tested sensitivity and specificity.

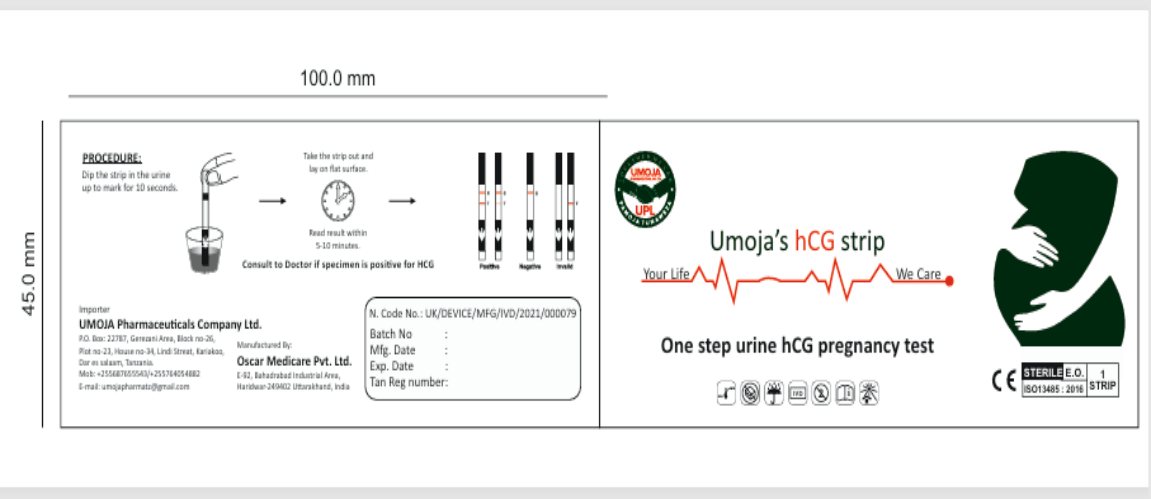
Based on results of the performance studies, it was concluded that the test sensitivity and specificity is 100% and 100% respectively. The studies further concluded that Umoja's hCG strip is capable of consistently producing accurate and reliable test output.

6. Product label and instructions for use

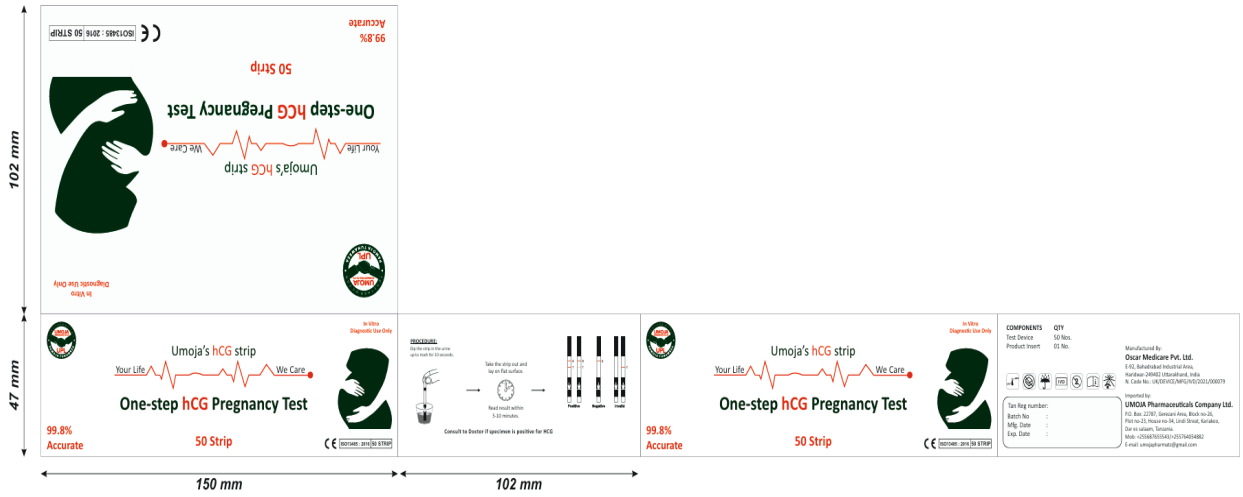
The content of the primary and secondary labels is in line with TMDA labeling requirements in terms of content, layout and design. The label contains sufficient information for proper identification of the device and post marketing follow up of the product in the market.

The *instructions 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

See on the last page.

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. Umoja's hCG strip is recommended for registration.

8. Post-approval updates

8.1 Variation applications

Reference number	Date submitted	Change requested	Recommendation	Granting date
None	None	None	None	None

8.2 Feedback from pharmacovigilance, post marketing surveillance and enforcement activities

Type of feedback	Impact	Response
None reported	None reported	None reported

8.3 Re-registration applications

Not applicable

Umoja's hCG strip

One-step hCG Pregnancy Test

Rapid test Strip for qualitative detection of
HCG (Human chorionic gonadotropin) in human urine

CE

INTENDED USE

One-step hCG Pregnancy Test is a one step rapid chromatographic immuno-assay for the qualitative detection of hCG (human chorionic gonadotropin) in urine to aid in the early diagnosis of pregnancy. For professional use only.

SUMMARY

Human chorionic gonadotropin (hCG) is glycoprotein hormone produced by the developing placenta shortly after fertilization. In normal pregnancy, hCG can be detected in both urine and serum as early as 7 to 10 days after conceptions. hCG levels continue to rise very rapidly frequently exceeding100 mIU/ml by the first missed menstrual period and peaking in the range of 100,000-200,000 mIU/ml around10-12 weeks of pregnancy. The appearance of hCG in both the urine and serum soon after conception, and its subsequent rapid rise during early gestational growth, makes it an excellent marker for the early diagnosis of pregnancy.

TEST PRINCIPLE

One-step hCG Pregnancy Test contains test strip coated with anti hCG at test line (T), goat anti rabbit IgG at control line (C) region. The gold conjugate pad contains colloidal gold particles coated with anti hCG and rabbit IgG. The assay is conducted by applying / placing of test strip into urine specimen and observed for the formation of pink / purple line (s) in result area of NCM .

Positive specimens containing hCG reacts with gold conjugate containing anti HCG antibodies and forms an immune complex. This complex travels through the membrane by chromatographic principle and reacts with the anti hCG antibody immobilized at the test line "T" on the nitrocellulose membrane. Positive reaction is made visible by a pink / purple line at "T" position in addition to 'C' line on NC membrane towards holding end . Absence of this colored line suggests a negative result. As a procedural in-built control, a colored line should always appear in the control line region "C". This indicates that proper test reaction has occurred.

REAGENTS & MATERIALS PROVIDED

1. **Test strips :** Packed in poly laminated pouch along with a desiccant pouch. Each test strip contains anti-hCG antibodies, Goat anti rabbit IgG and dried pad of colloidal gold particles coated with anti hCG antibodies & rabbit IgG.
2. *Product insert*

MATERIALS REQUIRED BUT NOT PROVIDED

- Specimen Collection Container & Timer

PRECAUTIONS

- For *in-vitro* diagnostic use only.
- Do not use after the expiration date.
- The test should remain in the sealed pouch until use.
  All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test should be discarded according to local regulations.

STORAGE AND STABILITY

One-step hCG Pregnancy Test kit is stable up to the expiry date mentioned on the packing box / pouches if stored at 2-30°C in sealed condition. **DO NOT FREEZE.**

SPECIMEN COLLECTION AND STORAGE

A urine specimen must be collected in a clean and dry container. A first morning urine specimen is preferred since it generally contains the highest concentration of hCG; however, urine specimens collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing. If immediate testing is not possible, specimen can be stored up to 48 hours at 2-8°C. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

LIMITATIONS

1. The **One-step hCG Pregnancy Test** is a preliminary qualitative test therefore, neither the quantitative value nor the rate of increase in hCG can be determined by this test.
2. Low concentrations of hCG in urine specimen from very early pregnancy shortly after implantation may not be detected in this test. If pregnancy is still suspected, repeat the test with first morning urine collected 48-72 hours after the initial test.
3. A number of conditions other than pregnancy, including trophoblastic disease and certain non-trophoblastic neoplasms including testicular tumors, prostate cancer, breast cancer, and lung cancer, cause elevated levels of hCG. Therefore, the presence of hCG should not be used to diagnose pregnancy unless these conditions have been ruled out. These condition may produce false positive results.
4. When the level of hCG is below the sensitivity level of the test, false negative results may occur . If pregnancy is still suspected, repeat the test with first morning urine collected 48-72 hours after initial testing. In case pregnancy is still suspected and the test continues to produce negative results, see a physician for further diagnosis.
5. This test provides a presumptive diagnosis for pregnancy. A confirmed pregnancy diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
6. As with any assay employing antibodies, presence of cross reacting heterophilic antibodies may yield discrepant results.

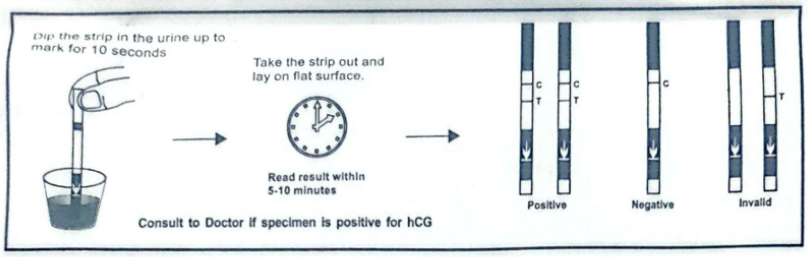
7. Although the **One-step hCG Pregnancy Test** is very accurate for detecting hCG hormone, a low titer of hormone in urine below detection limit can lead to false results. Other clinical tests are required if questionable results are obtained. As other diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test. It is recommended the diagnosis decision is made by the physician after all clinical and laboratory findings have been evaluated.
8. Specimen found to be reactive by the above screening test must be confirmed by standard supplemental assay, like ELISA / CLIA / PCR.

DIRECTIONS FOR USE

Allow the test strip, specimen and/or controls to reach room temperature (15-30°C) prior to testing.

1. Remove the test strip from the sealed pouch by tearing from the notch provided and use it as soon as possible.
2. Hold the strip from the holding end (coloured end) and dip in to the urine specimen up to the arrow mark (↓), at least for 10 seconds.
3. Remove the test strip from the urine specimen and place it on flat surface away from high blow of air / fan.
4. Wait for the appearance of pink / purple line(s) in result area of the membrane. The result should be read between 5-10 minutes. **Do not interpret the result after 10 minutes.**

NOTE: A low hCG concentration will show a weak line in the test line region (T).



QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume and correct procedural technique. It is recommended that a positive hCG control (containing 25-250 mIU/ml hCG) and a negative hCG control (containing "0" mIU/ml hCG) be evaluated to verify proper test performance when a new shipment of tests are received.

PERFORMANCE CHARACTERISTICS

The results of **One-step hCG Pregnancy Test** was compared with other commercially available hCG test (urine). The study included 100 urine specimens, and both assays identified 25 negative and 75 positive results. The results demonstrated 100% overall accuracy of the **One-step hCG Pregnancy Test** as compared to the other commercially available hCG test

SENSITIVITY AND SPECIFICITY

One-step hCG Pregnancy Test detects hCG at a concentration of 25 mIU/ml or greater. The test has been standardized to the W.H.O. International Standard. The addition of LH (300 mIU/ml), FSH (1,000 mIU/ml), and TSH (1,000 IU/ml) to negative (0 mIU/ml hCG) and positive (25 mIU/ml hCG) specimens showed no cross-reactivity.

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