THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

PUBLIC ASSESSMENT REPORT FOR CorDx HCG PREGNANCY TEST MIDSTREAM URINE

Version number 2.0, 26.05.2026

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1. Introduction

CorDx 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 and laypersons.

1.1. Administrative Information

Registration number	TAN 24 MDR 0064
Brand Name (if relevant)	CorDx
Common name	HCG pregnancy test midstream urine
Class of the device and rule applied	Class B, Rule 4 of in vitro diagnostics classification
GMDN code and term	66852, Total human chorionic gonadotropin IVD, kit, rapid ICT, self-testing.
Name and complete address of the Market Authorization Holder	CorDx, Inc., 9540 Waples St C, San Diego 92121, USA
Name and address(es) of local responsible person (LRP).	Generics and Specialities Limited. Plot. 478/479, 2nd floor, Zahra Arcade, Mindu Street, P. O. Box 1469, Dar es Salaam, Tanzania

1.2. Assessment Procedure

The application for registration of CorDx was submitted on 23.01.2024. The product underwent full assessment. Assessment was completed in two rounds of evaluation. CorDx was registered on 09.05.2025

2. Technical information

2.1. Intended use

The intended use of CorDx as declared by the manufacturer and approved by TMDA is a self-testing immunoassay made for the rapid, visual and qualitative determination of human chorionic gonadotropin (HCG) in urine specimen to aid in the early detection of pregnancy. CorDx is approved for both self-testing and professional use.

2.2. Device details and features

CorDx has been registered as a single invitro diagnostic device.

CorDx is a rapid test device. It is used to aid in early detection of pregnancy. CorDx operates by double antibody sandwich method technology and uses colloidal gold as indicator to detect the concentration of HCG in urine. The detection area of the kit is coated with α-HCG monoclonal antibody, and the quality control area is coated with goat anti- mouse polyclonal antibody, colloidal gold labeled anti-β-HCG monoclonal antibody. This kit is made using the principle of double antibody sandwich method. Using the α-subunit and β-subunit of HCG as antigens, respectively, an anti-HCG α-subunit antibody and an anti-HCG β-subunit antibody were prepared. The anti-HCG β-subunit antibody is coupled with colloidal gold particles to prepare a colloidal gold-antibody complex. The non-woven fabric is selected as the carrier of the colloidal gold-antibody complex to prepare the carrier of the colloidal gold-antibody complex. Then the antibody against the α-subunit of HCG is made into an antibody solution of a certain concentration, and the nitrocellulose membrane is used as a carrier, and the prepared antibody solution is coated on the nitrocellulose. membrane to obtain a coated membrane. Using double-antibody sandwich reaction, combined with immune colloidal gold and membrane chromatography technology, the prepared glass fiber membrane and coating membrane, as well as some other auxiliary materials, are assembled into test strips that can be used for detection. When the tested human urine contains HCG antigen, it will first form an immune complex with colloidal gold anti-HCG antibody (colloidal gold-anti-HCG antibody-HCG). Due to the chromatographic effect, the immune complex moves along the membrane to the detection. The anti-HCG antibody coated on the area is captured to form a color band T line, and when it moves to the control area, it forms an antigen-antibody conjugate with the goat anti-mouse IgG antibody to form a control color band (line C), which is positive The

sample has two color bands (T, C), while the negative sample has only one color band C. If the Cline and T line are not colored, it means that the paper strip is invalid or the quality is defective. The test out-put is qualitative.

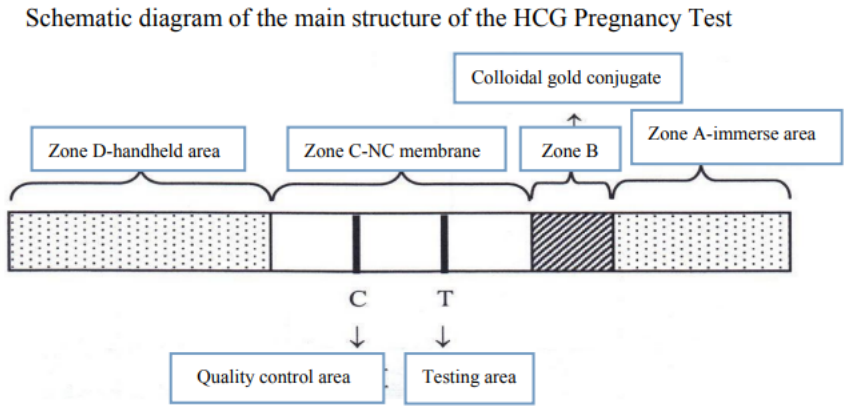
The type of specimen used is midstream urine and is collected by direct urination on the absorbent tip of the test cassette.

It consists of s test strip and its support. The main components on the test strip are

a) α-HCG monoclonal antibody (detection area fixed on nitrocellulose membrane);

b) Goat anti-mouse IgG polyclonal antibody (quality control area fixed on nitrocellulosemembrane);

c) β-HCG monoclonal antibody-colloidal gold (fixed on the binding pad); d) Other test strip supports.



2.3. Commercial presentation

There are three approved commercial presentations as follows: one test strip in an aluminum foil pouch as the primary package. 1 test, 2 tests, and 25 tests are placed in box as the secondary package.

Additional contents include 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 condition 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 Core Technology Co., Ltd Room 100, C Building, No. 29 Life Park Rd,Changping District, Beijing, 102206, China.

5. Performance Evaluation

5.1. Analytical Performance

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

5.2. Clinical Performance

Clinical performance was conducted at Core Technology Co., Ltd Room 100, C Building, No. 29 Life Park Rd,Changping District, Beijing, 102206, China. The following parameters were tested sensitivity and specificity.

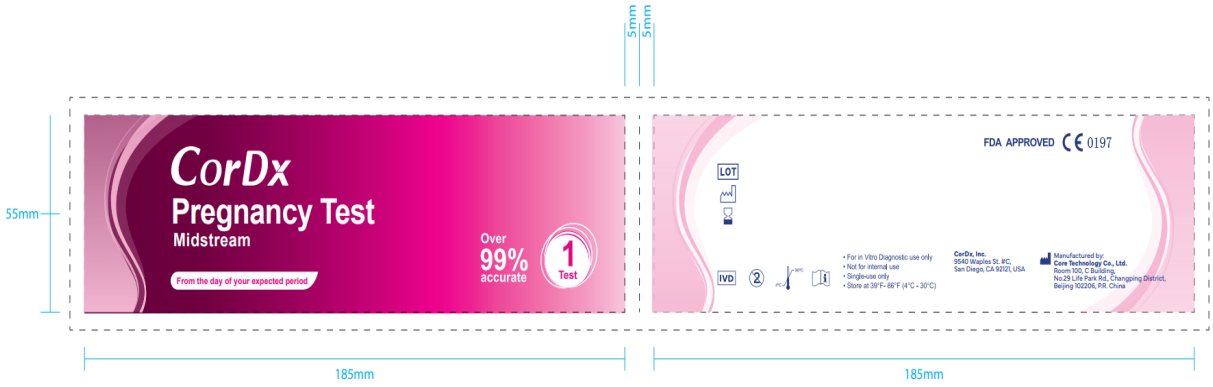
Based on results of the performance studies, it was concluded that the test clinical sensitivity and clinical specificity is 100% and 100% respectively. The studies further concluded that CorDx is capable of consistently producing accurate and reliable test output.

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 include 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. CorDx 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

CorDx

Pregnancy Test Midstream



PLEASE READ ALL THE INFORMATION IN THIS INSERT BEFORE PERFORMING THE TEST.

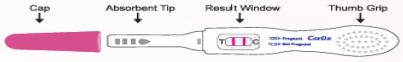
INTENDED USE

Pregnancy Test Midstream is a rapid pregnancy test. It detects the presence of the pregnancy hormone hCG (human chorionic gonadotropin) in urine. It is intended for home users and for prescription use.

CONTENT OF THE TEST KIT

- One pouch containing a test kit and desiccant.
- An instruction sheet.

HOW TO USE TEST



1. Remove the test kit from the sealed pouch and use it as soon as possible.
2. Remove the Cap to expose the Urine Absorbent Tip.
3. Hold the kit by the Thumb Grip.With the Absorbent Tip pointing downward, place the Absorbent Tip in urine stream for at least 5 seconds till it is thoroughly wet.
4. Re-cap the test kit and lay it on a flat surface with Result Window facing up.
5. Read the test result in 5 minutes. Results read after 6 minutes may be inaccurate.

NOTE: Do not hold the kit with the Absorbent Tip pointing upwards throughout testing.

HOW TO READ THE RESULT



Pregnant
One line appears at the "C" region and one line appears at the "T" region.



Not Pregnant
One line appears at the "C" region and NO visible line appears at the "T" region.



Invalid
NO line appears at the "C" region with or without a line appearing at the "T" region.

STORAGE

Store at 39°F-86°F (4°C-30°C) in the sealed pouch up to the expiration date. Open the pouch only shortly before the test.

PRECAUTIONS

- Do not use the test kit if the pouch is damaged.
- Do no use after the expiration date.
- For in-vitro diagnostic use only. Not to be taken internally.
- The procedures should be followed precisely for accurate results.
- Single-use device. Do not reuse.
- Do not freeze.

LIMITATIONS

- Medical treatment containing hCG can affect the test result.
- Certain health conditions may cause elevated hCG concentration. Always confirm your pregnancy with a physician.
- This device cannot be used to diagnose abnormal pregnancy.

QUESTIONS AND ANSWERS

Q: How does the Pregnancy Test Midstream work?
A: The test is designed to detect hCG in urine. hCG is produced by the human body during pregnancy.

Q: When should I use the Pregnancy Test Midstream ?
A: You can use the test as soon as the first day of the missed period.

Q:How accurate is the test?
A: The test can detect hCG in urine. However, some pregnant women may not have detectable amounts of the hCG pregnancy hormone in their urine on the first day of the expected period or may have miscalculated the first day of their period.

Q: What do I do if the result is positive (Pregnant)?
A: You should go to your doctor to confirm that you are pregnant and get your doctor's professional advice on what to do next.

Q: What do I do if the result is negative (Not Pregnant)?
A: You may not pregnant. However, a false negative result (negative when pregnancy exists) may occur if the urine is too dilute or with a very early stage of pregnancy. If pregnancy is still suspected and you already missed your period, another urine specimen should be collected 2-3 days later and tested.

Q: Do I have to use first-morning urine for testing?
A: You can use the test at any time of day. However, in general, your first-morning urine contains the highest concentration of the pregnancy hormone hCG.

Q: What do I do if the result is invalid?
A: If you have waited for 5 minutes and the result is invalid (no line appears at the "C" region), you should retest using a new test kit. Invalid result could be due to insufficient urine on the Absorbent Tip.

CorDx, Inc.
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