THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

PUBLIC ASSESSMENT REPORT FOR CorDx LH OVULATION TEST MIDSTREAM

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 in-vitro diagnostic device for use in women in reproductive age.

1.1. Administrative Information

Registration number	TAN 25 MDR 0094
Brand Name (if relevant)	CorDx
Common name	LH Ovulation test midstream
Class of the device and rule applied	Class B, Rule 4 of in- vitro diagnostics classification
GMDN code and term	65947 Luteinizing hormone (LH) IVD, kit, rapid ICT, self-testing
Name and complete address of the Market Authorization Holder	CorDx, Inc., 9540 Waples St C, San Diego. Post code : 92121, USA
Name and address(es) of local responsible person (LRP).	Generics and Specialities Limited. Plot. 478/479, 2nd floor, Zahra Arcade, Mindu Street,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 four rounds of evaluation. CorDx was registered on 25042025.

2. Technical information

2.1. Intended use

The intended use of CorDx as declared by the manufacturer and approved by TMDA is a rapid chromatographic immunoassay for the qualitative detection self-testing of luteinizing hormone (LH) in urine to predict the time of ovulation. CorDx is approved for self-testing by women in reproductive age.

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 for detection of luteinizing hormone (LH) in urine to predict the time of ovulation. CorDx operates by chromatographic immunoassay (CIA). the colored conjugate (mouse anti-β LH monoclonal antibody-colloidal gold conjugate) which has been pre-dried on the test strip. The mixture then moves upward on the membrane chromatographically by capillary action. For a positive result, a pink-colored band with the specific antibody-LH-colored conjugate complex will form in the test band region of the membrane, and the color intensity of the test line is as the same as, or stronger than that of the control line. This means the positive results. For a negative result, the color intensity of the test line is weaker than that of the control line. The test result means that the concentration of LH in the urine sample is in the normal level. Regardless of the presence of LH, as the mixture continues to move across the membrane to the immobilized goat anti-mouse, a pink-colored band at the control band region will always appear. The presence of this pink-colored band serves as: 1) verification that sufficient volume is added. 2) That proper flow is obtained, and 3) as a control for the reagents. The test out-put is qualitative.

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

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

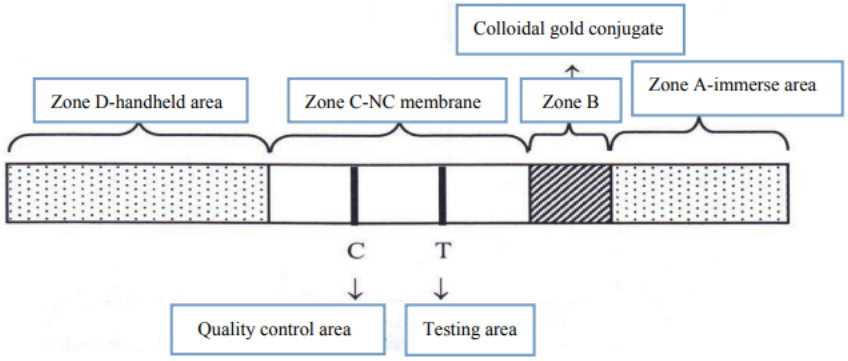
a) α-HCG monoclonal antibody (detection area fixed on nitrocellulose membrane);

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

c) β-LH monoclonal antibody-colloidal gold (fixed on the binding pad);

d) Other test strip supports.

Schematic diagram of the main structure of the LH Ovulation Test



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 in a box, 2 tests in a box and 25 tests in a 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

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 sensitivity and 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

LH Ovulation Test Midstream

FDA APPROVED

CE 0197

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

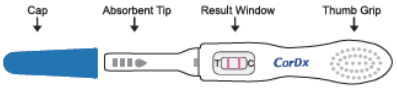
INTENDED USE

LH Ovulation Test Midstream is a rapid test for the qualitative detection of luteinizing hormone (LH) in urine to predict the time of ovulation. It is intended for home users.

CONTENT OF THE TEST KIT

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

HOW TO USE TEST



1: Remove the test midstream from the sealed pouch and use it as soon as possible.
2: Remove the Cap to expose the absorbent tip.
3: Hold the midstream by the Thumb Grip with the exposed absorbent tip pointing downward. Urinate on the absorbent tip directly till it is thoroughly wet (at least 5 seconds). NOTE: Be careful not to urinate in the Result Window.
4: Re-cap the test midstream and lay it on a flat surface with Result Window facing up.
5: Wait for pink-colored lines to appear. Read the result between 3 to 8 minutes.

WHEN TO START TESTING

Circle Your Usual Cycle Length WHEN TO START CHART

YOUR CYCLE LENGTH	START TO TEST TIME	YOUR CYCLE LENGTH	START TO TEST TIME
21 days	day 6	32 days	day 15
22 days	day 6	33 days	day 16
23 days	day 7	34 days	day 17
24 days	day 7	35 days	day 18
25 days	day 8	36 days	day 19
26 days	day 9	37 days	day 20
27 days	day 10	38 days	day 21
28 days	day 11	39 days	day 22
29 days	day 12	more than 40 days	Consult doctor
30 days	day 13		
31 days	day 14		

1: Determine the Length of Your Menstrual Cycle.
2: Your Menstrual Cycle Length is the number of days from the first day of your period (menstrual bleeding) to last day before your next period starts. Think back over the last few months to decide what your usual cycle length has been.
3: Circle your usual cycle length on the WHEN TO START CHART. Select the corresponding number directly.
4: Starting the first day of your last period, count ahead the selected number of days on your calendar. This is the day you should begin testing.

Count ahead this many days STARTING WITH THE FIRST DAY of your last period.

Example: If your usual cycle length is 28 days according to the "WHEN TO START CHART" begin, testing on day 11 of your cycle. If your last period started on the 5th day of the month, count ahead 11 days from the 5th as day one, and you should begin testing on the 15th day of the month.

Key: ◯ First day of the last period
☐ Begin testing with the Ovulation Test

Sample Calendar

S	M	T	W	T	F	S
	1	2	3	4	(5)	6
7	8	9	10	11	12	13
14	[15]	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30	31			



HOW TO READ THE RESULT



LH Surge | No LH Surge | Invalid

LH Surge: If two pink-colored lines are visible and the test line (T) is equal to or darker than the control line (C), you will probably ovulate in the next 24-48 hours. If you want to be pregnant, the best time to have intercourse is after 24 hours but before 48 hours.

No LH Surge: Only control line (C) appears or the test line (T) is present but lighter in color intensity than the control line. This indicates that no LH surge has been detected and you should continue daily testing.

Invalid: No line appears in the control 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 not 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.

LIMITATIONS

1: Reagents used in the test midstream are cross- reactive with HCG. The midstream is intended only for the analysis of LH in HCG-free specimens.
2: Women suffering from polycystic ovary syndrome may have elevated LH concentration.
3: The test midstream will not work properly if you are pregnant, menopausal, or taking birth control pills.
4: The test results should not be affected by pain relievers. Medications containing HCG or LH may affect the test and should not be taken while using the LH Ovulation Test Midstream.
5: The test provides a presumptive diagnosis for the time of ovulation. The user should not take any decision of medical relevance without first consulting his or her medical practitioner.

QUESTIONS AND ANSWERS

Q: If the LH Ovulation Test Midstream can determine my most fertile time, why can't I use it for contraception (birth control)?
A: Sperm can survive up to 72 hours (3 days), and this test predicts your LH surge only up to 24-36 hours in advance. Therefore, if you have intercourse before you discover your surge, the egg can still be fertilized.

Q: Do alcohol or common medications affect the test?
A: No, but you should consult your physician if you are taking any hormonal medication. Also, recent oral contraceptive use, breast feeding, or pregnancy could affect the test results.

Q: How does the test work?
A: Luteinizing Hormone (LH) is always present in your urine and will increase just before ovulation. This increase or "surge" in LH triggers ovulation, which is the release of an egg from your ovaries and the most fertile time of your cycle. The LH Ovulation Test Midstream detects the LH surge, which precedes ovulation by 24-36 hours. Your two most fertile days begin with the LH surge.
If you have intercourse within the next 24-36 hours of your surge. You will maximize your chances of becoming pregnant.

Q: Will the amount of liquid I drink affect the result?
A: Heavy intake of fluids prior to testing will dilute the hormone in your urine. We suggest that you limit your fluid intake for about two hours before you perform the test.

Q: Once I see a positive result, when is the best time to have intercourse if I want to get pregnant?
A: Once you see a positive result, your ovulation is likely to occur within 24-48 hours. This is your most fertile time. Sexual intercourse after 24 hours but before 48 hours is advised.

CorDx, Inc.
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CA 92121, USA

X-CorDx-LH-03-01, Rev. 10/2022
Questions? Call: 1-858-333-1122