THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

PUBLIC ASSESSMENT REPORT FOR LH OVULATION RAPID TEST

Version number 2.0, 18.08.2025

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1. Introduction

LH Ovulation Rapid Test is a class B in-vitro diagnostic device belonging to the in vitro diagnostic device specialty category. It is approved in Tanzania as a family of single-use self-testing IVD devices for use by laypersons in home or similar environments to predict the time of ovulation.

1.1. Administrative Information

Registration number	TAN 25 MDR 0181
Brand Name (if relevant)	LH Ovulation Rapid Test
Common name	Ovulation (LH) Test strip
Class of the device and rule applied	Class B; Rule 6 of the IVD classification rules
GMDN code and term	65947 Luteinizing hormone (LH) IVD, kit, rapid ICT, self-testing.
Name and complete address of the Market Authorization Holder	Gene Tech Ents Ltd, 475 Wall Street, #202, Princeton, NJ 08540, USA.
Name and address(es) of local responsible person (LRP).	Pharmarex (T) Limited Mtoni Mtongani, Opp Total Station 15129 Dar es salaam Tanzania

1.2. Assessment Procedure

The application for registration of LH Ovulation Rapid Test was submitted on 17.03.2025. The product underwent full assessment. Assessment was completed in three (3) rounds of evaluation. LH Ovulation Rapid Test was registered on 26.08.2025.

2. Technical information

2.1. Intended use

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

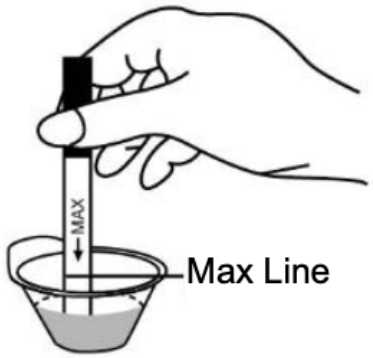
2.2. Device details and features

LH has been registered as a single invitro diagnostic device.

LH is manually operated. It is used to aid prediction of ovulation by detecting LH surge in urine. LH operates by lateral flow immunochromatographic reaction in which labeled antibody-dye conjugate binds to LH in the urine specimen and forms an antibody-antigen complex at the test region. The test output is qualitative.

The type of specimen used is urine. The specimen is collected urinating in a clean, dry plastic or glass container.

The test contains colloidal gold-monoclonal antibody against LH coated on polyester membrane, and monoclonal antibody against LH and goat anti-mouse IgG coated on cellulose nitrate membrane. A positive result is indicated when the test line is equal to or darker than the control line; a negative result is indicated when the test line is lighter than the control line or only the control line appears; and an invalid result is indicated when no control line appears.



2.3. Commercial presentation

There are three (3) approved commercial presentations: One device in a sealed pouch as the primary package. 25 tests in a box as the secondary package.

Additional contents include desiccant in each pouch.

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 24 months.

3.1.2. Storage conditions

The recommended storage condition is 4°C-30°C.

3.1.3. Shipping conditions

The recommended shipping condition is -20 to 50°C.

4. Manufacturing site audit

The manufacturer of the device is Hangzhou Clongene Biotech Co., Ltd., No.1 Yichuang Road, Yuhang Sub-district, Yuhang District, Hangzhou, China.

5. Performance Evaluation

5.1. Analytical Performance

The analytical performance characteristics of the device were established through the following test parameters: analytical sensitivity, analytical specificity, repeatability, cross-reactivity/interference, and usability/layperson study.

5.2. Clinical Performance

Clinical performance was conducted at Zhejiang Provincial People's Hospital and Women's Hospital School of Medicine, Zhejiang University. The following parameters were tested: clinical sensitivity, clinical specificity and total coincidence rate.

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

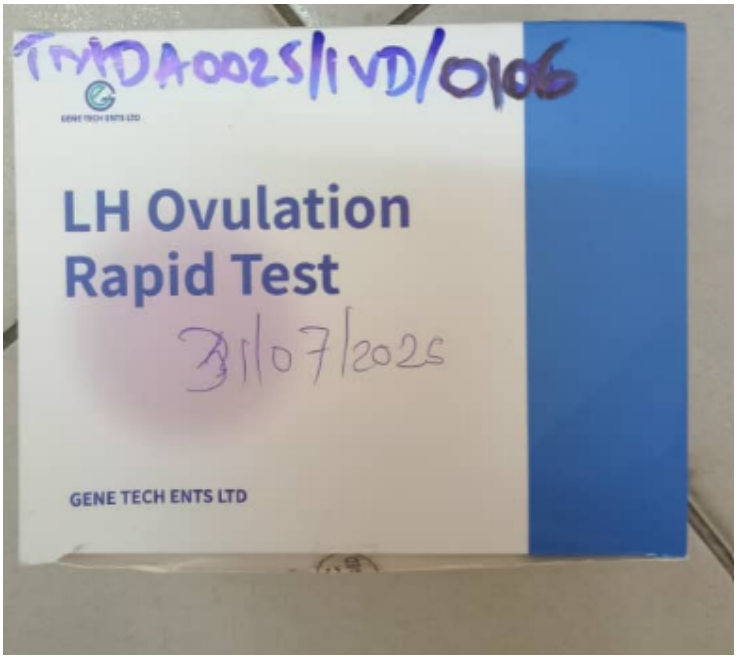
The content of the primary and secondary labels is in line with TMDA labeling requirements in terms of content, layout and design. The final submitted commercial samples demonstrated legible, permanent and prominent labeling information on the primary pack, and the secondary pack included the required manufacturing and expiry information. The label contains sufficient information for proper identification of the device and post-market follow-up of the product in the market.

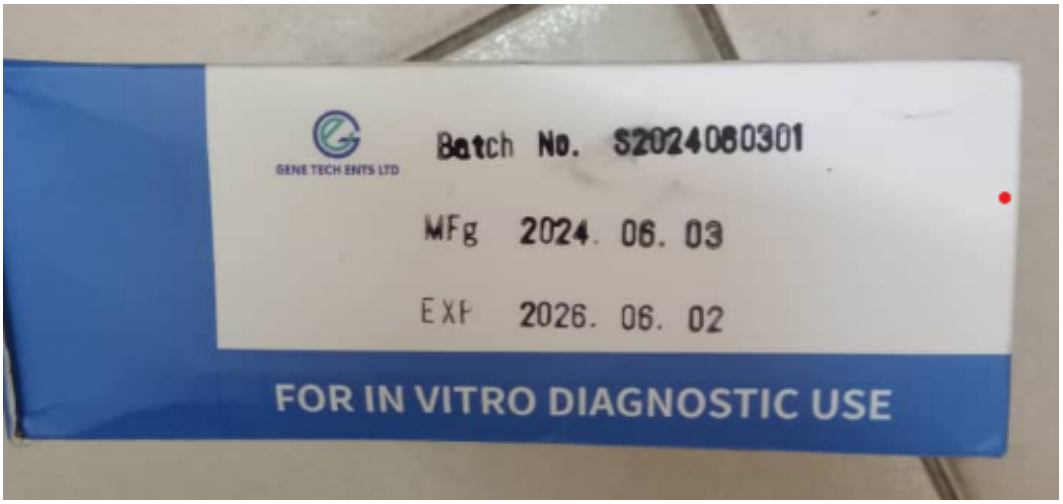
The instructions for use include all the relevant information to ensure correct and safe use of the device by intended user.

6.1. Primary pack



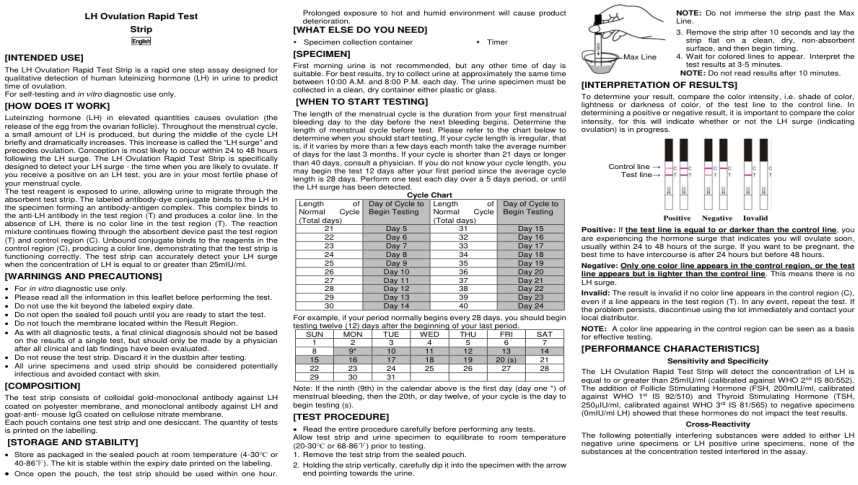
6.2. Secondary pack







6.3 Instructions for use/Package insert



LH Ovulation Rapid Test

Strip

English

[INTENDED USE]

The LH Ovulation Rapid Test Strip is a rapid one step assay designed for qualitative detection of human luteinizing hormone (LH) in urine to predict time of ovulation.
For self-testing and *in vitro* diagnostic use only.

[HOW DOES IT WORK]

Luteinizing hormone (LH) in elevated quantities causes ovulation (the release of the egg from the ovarian follicle). Throughout the menstrual cycle, a small amount of LH is produced, but during the middle of the cycle LH briefly and dramatically increases. This increase is called the "LH surge" and precedes ovulation. Conception is most likely to occur within 24 to 48 hours following the LH surge. The LH Ovulation Rapid Test Strip is specifically designed to detect your LH surge - the time when you are likely to ovulate. If you receive a positive on an LH test, you are in your most fertile phase of your menstrual cycle.
The test reagent is exposed to urine, allowing urine to migrate through the absorbent test strip. The labeled antibody-dye conjugate binds to the LH in the specimen forming an antibody-antigen complex. This complex binds to the anti-LH antibody in the test region (T) and produces a color line. In the absence of LH, there is no color line in the test region (T). The reaction mixture continues flowing through the absorbent device past the test region (T) and control region (C). Unbound conjugate binds to the reagents in the control region (C), producing a color line, demonstrating that the test strip is functioning correctly. The test strip can accurately detect your LH surge when the concentration of LH is equal to or greater than 25mIU/ml.

[WARNINGS AND PRECAUTIONS]

- For *in vitro* diagnostic use only.
- Please read all the information in this leaflet before performing the test.
- Do not use the kit beyond the labeled expiry date.
- Do not open the sealed foil pouch until you are ready to start the test.
- Do not touch the membrane located within the Result Region.
- As with all diagnostic tests, a final clinical diagnosis should not be based on the results of a single test, but should only be made by a physician after all clinical and lab findings have been evaluated.
- Do not reuse the test strip. Discard it in the dustbin after testing.
- All urine specimens and used strip should be considered potentially infectious and avoided contact with skin.

[COMPOSITION]

The test strip consists of colloidal gold-monoclonal antibody against LH coated on polyester membrane, and monoclonal antibody against LH and goat-anti- mouse IgG coated on cellulose nitrate membrane.
Each pouch contains one test strip and one desiccant. The quantity of tests is printed on the labelling.

[STORAGE AND STABILITY]

- Store as packaged in the sealed pouch at room temperature (4-30℃ or 40-86℉). The kit is stable within the expiry date printed on the labeling.
- Once open the pouch, the test strip should be used within one hour. Prolonged exposure to hot and humid environment will cause product deterioration.

[WHAT ELSE DO YOU NEED]

- Specimen collection container
- Timer

[SPECIMEN]

First morning urine is not recommended, but any other time of day is suitable. For best results, try to collect urine at approximately the same time between 10:00 A.M. and 8:00 P.M. each day. The urine specimen must be collected in a clean, dry container either plastic or glass.

[WHEN TO START TESTING]

The length of the menstrual cycle is the duration from your first menstrual bleeding day to the day before the next bleeding begins. Determine the length of menstrual cycle before test. Please refer to the chart below to determine when you should start testing. If your cycle length is irregular, that is, if it varies by more than a few days each month take the average number of days for the last 3 months. If your cycle is shorter than 21 days or longer than 40 days, consult a physician. If you do not know your cycle length, you may begin the test 12 days after your first period since the average cycle length is 28 days. Perform one test each day over a 5 days period, or until the LH surge has been detected.

Cycle Chart

Length of Normal Cycle (Total days)	Day of Cycle to Begin Testing	Length of Normal Cycle (Total days)	Day of Cycle to Begin Testing
21	Day 5	31	Day 15
22	Day 6	32	Day 16
23	Day 7	33	Day 17
24	Day 8	34	Day 18
25	Day 9	35	Day 19
26	Day 10	36	Day 20
27	Day 11	37	Day 21
28	Day 12	38	Day 22
29	Day 13	39	Day 23
30	Day 14	40	Day 24

For example, if your period normally begins every 28 days, you should begin testing twelve (12) days after the beginning of your last period.

SUN	MON	TUE	WED	THU	FRI	SAT
1	2	3	4	5	6	7
8	9*	10	11	12	13	14
15	16	17	18	19	20 (s)	21
22	23	24	25	26	27	28
29	30	31				

Note: If the ninth (9th) in the calendar above is the first day (day one *) of menstrual bleeding, then the 20th, or day twelve, of your cycle is the day to begin testing (s).

[TEST PROCEDURE]

- Read the entire procedure carefully before performing any tests.

Allow test strip and urine specimen to equilibrate to room temperature (20-30℃ or 68-86℉) prior to testing.

1. Remove the test strip from the sealed pouch.
2. Holding the strip vertically, carefully dip it into the specimen with the arrow end pointing towards the urine.

NOTE: Do not immerse the strip past the Max Line.

3. Remove the strip after 10 seconds and lay the strip flat on a clean, dry, non-absorbent surface, and then begin timing.
4. Wait for colored lines to appear. Interpret the test results at 3-5 minutes.

NOTE: Do not read results after 10 minutes.

[INTERPRETATION OF RESULTS]

To determine your result, compare the color intensity, i.e. shade of color, lightness or darkness of color, of the test line to the control line. In determining a positive or negative result, it is important to compare the color intensity, for this will indicate whether or not the LH surge (indicating ovulation) is in progress.

Positive: If **the test line is equal to or darker than the control line**, you are experiencing the hormone surge that indicates you will ovulate soon, usually within 24 to 48 hours of the surge. If you want to be pregnant, the best time to have intercourse is after 24 hours but before 48 hours.

Negative: Only one color line appears in the control region, or the test line appears but is lighter than the control line. This means there is no LH surge.

Invalid: The result is invalid if no color line appears in the control region (C), even if a line appears in the test region (T). In any event, repeat the test. If the problem persists, discontinue using the lot immediately and contact your local distributor.

NOTE: A color line appearing in the control region can be seen as a basis for effective testing.

[PERFORMANCE CHARACTERISTICS]

Sensitivity and Specificity

The LH Ovulation Rapid Test Strip will detect the concentration of LH is equal to or greater than 25mIU/ml (calibrated against WHO 2nd IS 80/552). The addition of Follicle Stimulating Hormone (FSH, 200mIU/ml, calibrated against WHO 1st IS 92/510) and Thyroid Stimulating Hormone (TSH, 250uIU/ml, calibrated against WHO 3rd IS 81/565) to negative specimens (0mIU/ml LH) showed that these hormones do not impact the test results.

Cross-Reactivity

The following potentially interfering substances were added to either LH negative urine specimens or LH positive urine specimens, none of the substances at the concentration tested interfered in the assay.

1/2

7. Risk – Benefit Analysis

On basis of the data submitted, the current state of knowledge and the submitted evidence on performance, labeling and intended use, the benefit of the product outweighs the risks associated with its use when used in accordance with the manufacturer's instructions. LH 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.