

## Intended Use

**Clearview EASY LH** is intended for the qualitative detection of Luteinising Hormone (LH) in the urine of women as an aid to identifying the LH surge. This information can be used to time intercourse to help achieve conception. **Clearview EASY LH** is intended for professional use only. It is intended for in vitro diagnostic use only.

## Summary and Explanation

Luteinising Hormone (LH) is a glycoprotein hormone produced by the pituitary gland<sup>1</sup>. A significant surge in LH occurs approximately 24–36 hours prior to ovulation<sup>2,3</sup>. It is estimated that 10–15% of couples experience infertility problems during their reproductive life<sup>4</sup>. Studies have shown that a woman is most fertile on the day of ovulation and the preceding day<sup>5</sup>. **Clearview EASY LH** is a good indicator for predicting the 2 most fertile days in a woman's cycle, and can therefore be used as an aid to successful conception.

## Test Principle

Urine is added to an Absorbent Sampler, which contains blue beads attached to an anti-LH monoclonal antibody. Urine mobilises the labelled antibodies and moves up the test strip, which contains regions of immobilised antibodies. If LH is present in the urine at 40mIU/ml or above, the Surge Line should be similar to, or darker than the Reference Line. This identifies the LH surge, and the start of the 2 days when the patient is most fertile. Tests are used on sequential days until the LH surge is found.

## Kit Contents and Storage

25 **Clearview EASY LH** Test Sticks each containing murine monoclonal antibodies to LH and goat antibodies. Store at 2–30°C. Do not use after the expiry date. Do not freeze.

## Precautions

- Standard laboratory guidelines should be observed throughout all procedures. Handle all specimens as if they are capable of transmitting disease.
- It is recommended that disposable gloves should be worn whilst handling specimens.
- Dispose of used **Clearview EASY LH** devices in a biohazard container.
- Do not open the foil pouch until ready to test and do not use devices that have become wet or damaged.

## Sample Collection and Storage

Collect samples in clean, dry plastic or glass containers. Samples can be refrigerated at 2–8°C for up to 24 hours. Allow samples to reach 18–30°C before use.

- A urine sample from any time of the day is suitable.
- Test using a sample taken at approximately the same time every day until the LH surge is detected.
- The patient must not have urinated for at least 4 hours prior to providing a urine sample, and must have avoided excessive fluid intake.

## When to Test

The release of an egg from the ovary normally occurs about 14 days before the next period is due (12–16 days is normal)<sup>5</sup>. This information forms the basis of when to start testing to identify the LH surge. First identify when to start testing from the patient's usual cycle length (see the following summary table). If her usual cycle length is 21 days or less, start testing on Day 5; if her usual cycle length is longer than 40 days, start testing 17 days before the next period is expected.

Cycle length	21 or less	22	23	24	25	26	27	28	29	30
Day to start testing	5	5	6	7	8	9	10	11	12	13
Cycle length	31	32	33	34	35	36	37	38	39	40
Day to start testing	14	15	16	17	18	19	20	21	22	23

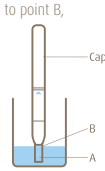
If the patient's usual cycle length is variable, use the shortest cycle in the last 6 months to determine when to start testing.

## Assay Procedure

Ensure all **Clearview EASY LH** tests and samples are at 18–30°C. When ready to test, tear open a foil wrapper and remove the Test Stick. Follow **one** of the following procedures:

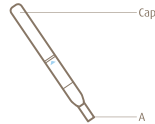
### Method A – Dip

- Dip the Absorbent Sampler (A) into the sample to point B, as indicated in the diagram.
- Hold in place for 15 seconds.
- Remove the Test Stick from the sample.
- Place the Cap over the Absorbent Sampler without inverting the Test Stick.
- Place the Test Stick on a flat surface.
- Read the result between 3 and 10 minutes.

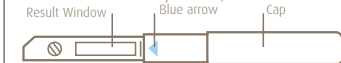


### Method B – Urine Stream

- Ask the patient to hold the Absorbent Sampler (A) pointing downwards in her urine stream for 3 to 7 seconds only.
- After 3 to 7 seconds the patient should remove the Absorbent Sampler from her urine stream and place the Cap over the Absorbent Sampler without inverting the Test Stick.
- Place the Test Stick on a flat surface.
- Read the result between 3 and 10 minutes.



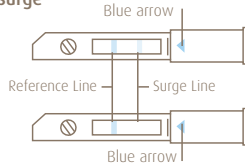
- When the test is ready to read, find the **blue arrow**.



- Hold the Test Stick as shown, with the blue arrow pointing left.

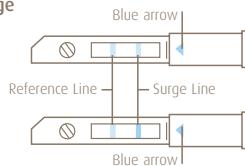
## Interpretation of Results

### No LH surge



- The LH surge has not been detected** if the Surge Line (the line closest to the blue arrow) is **paler** than the Reference Line, or there is **no Surge Line**.
- Test again tomorrow using a urine sample collected at the same time.

### LH surge



- The LH surge has begun** if the Surge Line (the line closest to the blue arrow) is **similar** to, or **darker** than, the Reference Line.
- The two most fertile days begin when the LH surge is detected, and there is no need to continue testing.
- The patient should have intercourse at any time during the next 48 hours to maximise her chances of becoming pregnant.

If no Reference Line appears, the test is invalid. Results must be read between 3 and 10 minutes.

## Limitations of the Test

- Clearview EASY LH** should detect an LH surge in urine at concentrations of  $\geq 40$  mIU/ml. Urine LH concentrations of  $< 22$  mIU/ml should not show a surge.
- If a urine sample is too dilute, then a “no surge” result may be obtained when an LH surge is taking place.
- The presence of LH or hCG (human chorionic gonadotrophin) in the urine sample can cause surge results. Therefore misleading results may be obtained during pregnancy, recent pregnancy, perimenopause, menopause or with fertility drugs containing LH or hCG. Clomiphene citrate does not affect the results of the test but may affect cycle length, so more tests may be needed. High levels of LH may be caused by a variety of conditions, including Polycystic Ovarian Syndrome<sup>6</sup> and the perimenopause<sup>7</sup>.
- Drugs containing tetracycline or oxytetracycline may cause misleading results.
- Identifying the LH surge does not guarantee ovulation will take place. The test is an indicator of when ovulation might be expected to occur.
- Do not open the foil pouch until ready to test.

## Expected Values

Basal levels of LH in the urine of non-pregnant women of childbearing age are generally 3–13 mIU/ml<sup>8</sup>. A surge in LH increases this level to a mean concentration of approximately 50 mIU/ml<sup>9</sup>. **Clearview EASY LH** has been shown to detect an LH surge at LH concentrations of up to and including 1000 mIU/ml, which is higher than the maximum level expected in normally ovulating women.

## Performance Characteristics

### SENSITIVITY

**Clearview EASY LH** can detect LH in urine at concentrations  $\geq 40$  mIU/ml. This test is calibrated against the 3rd International Standard for LH & FSH.

### SPECIFICITY

A variety of substances including other hormones found in urine have been evaluated for potential cross reactivity and interference with **Clearview EASY LH**. No cross reactivity or interference was observed when the following substances were added to urine samples with a confirmed LH surge and urine samples with no LH surge:

- hCG  $\leq 15$  mIU/ml
- FSH  $\leq 200$  mIU/ml
- TSH  $\leq 0.5$  mIU/ml
- Haemoglobin 3.6 mg/ml
- Glucose 100 mg/ml
- Albumin 12 mg/ml
- Urea 100  $\mu$ g/ml
- ibuprofen 400  $\mu$ g/ml
- Uric acid 100  $\mu$ g/ml
- Ascorbic Acid 2 mg/ml
- Paracetamol 200  $\mu$ g/ml
- Nicotine 200 ng/ml
- Salicylic acid 200  $\mu$ g/ml
- Ethanol 1% (v/v)
- EDTA 800  $\mu$ g/ml
- Bilirubin 10  $\mu$ g/ml
- Caffeine 200  $\mu$ g/ml

### ACCURACY

A study was conducted using urine samples collected from 140 cycles. Of these cycles, 117 were shown to have an identifiable LH surge, as determined by a commercially available qualitative test for LH. The urine samples from these 117 cycles were also tested using **Clearview EASY LH**. The overall accuracy of **Clearview EASY LH** compared to the commercially available test was 99%.

### Advice Line

Further information can be obtained at [www.clearview.com](http://www.clearview.com), your distributor or UK customers can call Unipath Customer Services on **08705 134952**.

## References/Referencias/

## Riferimenti/Referenzen/

## Références

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IVD

Lot Number/  
Número de lote/  
Numero di lotto/  
Chargennummer/  
Numéro de lot

LOT

Use By/Expiry Date/  
Utilizar antes de/Fecha de caducidad/  
Da utilizarsai entro/Data di scadenza/  
Zur Verwendung durch/Verfallsdatum/  
Date limite d'utilisation



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