

# **FIAcheck™**

## **LH**

**Fluorescence Immunoassay for Quantitative determination of Luteinizing Hormone (LH) in Human Serum**

**DEVICE**

FOR IN VITRO DIAGNOSTIC USE ONLY  
Store at 4°C to 30°C

### INTENDED USE

**FIAcheck™ LH** Fluorescence Immunoassay is intended for the in-vitro quantitative measurement of Luteinizing hormone (LH) in human serum.

### INTRODUCTION

Luteinizing hormone (LH) is produced in both men and women from the anterior pituitary gland in response to luteinizing hormone releasing-hormone (LH-RH or Gn-RH), which is released by the hypothalamus. The alpha chain is similar to that found in human thyroid-stimulating hormone (TSH), follicle-stimulating hormone (FSH) and human chorionic gonadotropin (hCG). The difference between these hormones lie in the amino acid composition of their beta subunits, which account for their immunological differentiation.

The basal secretion of LH in men is episodic and has the primary function of stimulating the interstitial cells (Leydig cells) to produce testosterone. The variation in LH concentrations in women is subject to the complex ovulatory cycle of healthy menstruating women and depends on a sequence of hormonal events along the gonado-hypothalamic-pituitary axis. In the differential diagnosis of hypothalamic, pituitary, gonadal dysfunction, assays of LH concentration are routinely performed in conjugation with FSH assays since their roles are closely interrelated. Furthermore, the hormone levels are used to determine menopause, pinpoint ovulation and monitor endocrine therapy.

### PRINCIPLE OF THE TEST

**FIAcheck™ LH** is based on principle of agglutination of antibodies/anti-sera with respective antigen in immunochromatographic format using fluorophores as signal generators. The **FIAcheck™ LH** test device is coated with immobilized LH mouse monoclonal antibody 1 on the test line, goat anti chicken IgY in control line and a mixture of LH mouse monoclonal antibody 2 and Chicken IgY labeled with fluorescent microspheres on the binding pad.

LH in sample binds to the LH mouse monoclonal antibody 2 labeled with fluorescent microspheres in the binding pad. The fluorescent labeled Ag-Ab complex moves forward due to capillary action and is captured by the immobilized LH monoclonal antibody 1 forming a double antibody sandwich and produces the test line. Chicken IgY labelled with fluorescent microspheres binds with goat anti chicken IgY to produce the control line. When the **FIAcheck™** test device is inserted in the **FIAcheck™** analyzer, it scans both the test line and control line. The ratio of the two fluorescence values is used to calculate the concentration of the analyte present in the sample.

### MATERIALS AND COMPONENTS

#### Materials provided with the test kits:

- **FIAcheck™ LH** test device in a sealed pouch with desiccant.
- QR Code card for calibration.

#### Materials required but not provided

- Precision pipettes: 100µl
- Disposable pipette tips
- Disposable Gloves
- **FIAcheck™** Analyzer (Time Resolved Fluorescence Immunoassay Analyzer)
- Digital Thermometer
- Stopwatch













### STORAGE AND STABILITY

1. **FIAcheck™ LH** kit is stable at 4°C to 30°C upto expiry date printed on the label. DO NOT FREEZE
2. **FIAcheck™** Test device should be used within 30 minutes once the foil pouch is opened.
3. If the colour of the desiccant has changed from blue to pink or colourless at the time of opening the pouch, kindly discard the device and use another device.

### SAMPLE COLLECTION

1. Only Human Serum sample should be used. Other bodily fluids and samples may not give accurate result.

### SYMBOL KEYS

 Temperature Limitation	 Consult Instructions for use	 Date of Manufacture	 Do not reuse
 Manufacturer	 IVD In vitro Diagnostic Medical Device	 This side up	 Use by
 Contains sufficient for <n> tests	 REF Catalogue Number	 LOT Batch Number / Lot Number	 DEVICE Device



Manufactured by:

**Zephyr Biomedicals**

A Division of Tulip Diagnostics (P) Ltd.

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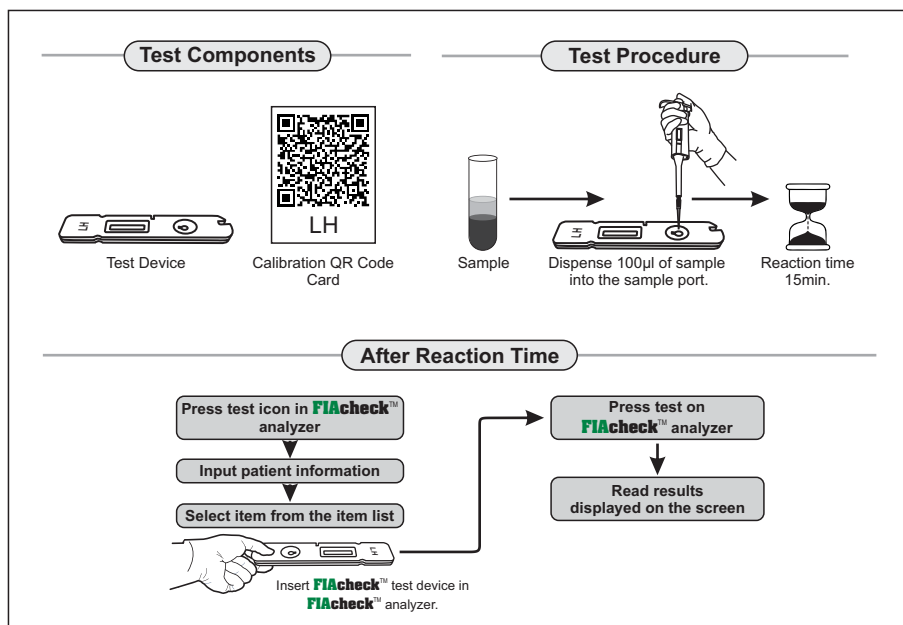
- The test should be performed within 4 hours after the sample collection at room temperature.
- Avoid grossly hemolytic, lipemic or turbid samples.
- Preferably use fresh samples. However, samples can be stored for 3 days at 2°C to 8°C, and if more than 3 days, they should be stored at -20°C.
- The sample should be recovered to room temperature (18°C to 30°C) before testing. Avoid repeated freezing and thawing of samples as it can affect test values.
- Samples containing precipitate or particulate matter should be clarified by centrifugation prior to use.
- Samples should be free from particulate matter and microbial contamination.

#### PRECAUTIONS

- Only for In vitro diagnostic use.
- After the test device is removed from the sealed pouch, it should be used immediately or within 30 minutes of opening the pouch.
- Do not reuse the tested **FIACheck™** device.
- Do not use damaged **FIACheck™** test device or pouch.
- All samples should be considered potentially infectious and discarded appropriately as per Standard Bio-Safety guidelines.
- Do not use kit after the expiry date.
- Do not mix components of one kit with another.
- Always use new tip for each sample.
- Scan QR code card specific to the lot you are using.
- Ambient temperature of testing environment directly impacts the accuracy of results. Ideal working temperature is 18°C to 30°C.
- The **FIACheck™** test device should be read immediately after the specified reaction time. Delay in reading might affect the accuracy of results.
- The **FIACheck™** test device should be used only in conjunction with **FIACheck™** analyzer for accurate and reliable results.

#### TEST PROCEDURE

- To calibrate the **FIACheck™ LH** kit, scan the QR code card provided with the kit.
- Remove **FIACheck™ LH** test device from sealed pouch and place it horizontally on a clean table, label the device with sample identity.
- Dispense 100 µl of sample onto the sample port in the **FIACheck™ LH** test device.
- Incubate at room temperature (18°C to 30°C) for 15 minutes.
- After 15 minutes, insert the test device immediately into the **FIACheck™** analyzer and read results.



#### Expected Range

The following reference interval was obtained after statistical analysis of the confidence interval for the tests of the content of LH in serum samples of healthy people:

Gender	Stage	Range (mIU/mL)
Mature male	-	1.50-9.25
Mature female	Follicular phase	1.25-11.80
	Ovulation	13.15-94.75
	Luteal phase	1.05-14.50
	Menopause	7.70-64.20

It is recommended that each laboratory establish its own reference range for the population it serves.

#### PERFORMANCE CHARACTERISTICS

- Measuring Range: 1.02-200mIU/mL.
- Lower Detection Limit: ≤1 mIU/mL.
- Upper Detection Limit: ≥200mIU/mL.
- Accuracy: Based on comparison experiments, the relative standard deviation of ≤15%, the correlation coefficient of r≥0.990 was observed.
- Within-Run Precision: ≤15%.
- Between-Run Precision: ≤15%.
- Hook Test: No hook effect with high concentration sample. Hook test was conducted with reference material exceeding the upper limit of measuring range, and the detection result was greater than the upper limit of detection.
- In an internal Study, **FIACheck™ LH** was evaluated against commercially available licensed kit with 100 random clinical samples and **FIACheck™ LH** has demonstrated 100% clinical correlation with the commercially available licensed kit.

LH Levels	No. of samples	<b>FIACheck™ LH</b>	EIA LH
Normal	80	80	80
Low	8	8	8
High	12	12	12

- In an external Study, **FIACheck™ LH** has been evaluated by a NABL accredited lab against their reference method. In this evaluation **FIACheck™ LH** has demonstrated 100% correlation with the reference method.

\*Data file: Zephyr Biomedicals (A Division of Tulip Diagnostics (P) Ltd).

#### LIMITATIONS OF THE ASSAY

- As with all diagnostic tests, a definite clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.
- This kit is only for human serum.

#### WARRANTY

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose. In the event of performance changes or product malfunction, please contact manufacturer.

#### BIBLIOGRAPHY

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- Huerta R, Malacara JM, Fajardo ME, Nava LE, Bocanegra A, Sanchez J. High-Frequency FSH and LH Pulses in Obese Menopausal Women. Endocrine, 1997, 7(3): 281-286