

Instructions for Use

IBL

LH ELISA

Enzyme immunoassay for the in-vitro-diagnostic quantitative determination of Luteinizing Hormone in human serum.

REF

RE52101



96



2-8°C

EU: **IVD** **CE**

U.S.: *For in-vitro diagnostic use only. 510(k) exempt.*

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1. INTENDED USE

Enzyme immunoassay for the in-vitro-diagnostic quantitative determination of Luteinizing Hormone in human serum.

2. CLINICAL RELEVANCE

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 (1-3). LH, also called interstitial cell-stimulating hormone (ICSH) in men, is a glycoprotein with a molecular weight of approximately 30.000 daltons (4). It is composed of two non covalently associated dissimilar amino acid chains, alpha and beta (5). 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 (6-8).

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 upon a sequence of hormonal events along the gonado-hypothalamic-pituitary axis. The decrease in progesterone and estradiol levels from the preceding ovulation initiates each menstrual cycle (9,10). As a result of the decrease in hormone levels, the hypothalamus increases the secretion of gonadotropin-releasing factors (GnRF), which in turn stimulates the pituitary to increase FSH production and secretion (4). The rising FSH levels stimulate several follicles during the follicular phase, one of these will mature to contain the egg. As the follicle develops, estradiol is secreted, slowly at first, but by day 12 or 13 of a normal cycle increasing rapidly. LH is released as a result of this rapid estradiol rise because of direct stimulation of the pituitary and increasing GnRF and FSH levels. These events constitute the pre-ovulatory phase (11).

Ovulation occurs approximately 12 to 18 hours after the LH reaches a maximum level. After the egg is released, corpus luteum is formed which secretes progesterone and estrogen - two feedback regulators of LH (3,10).

The luteal phase rapidly follows this ovulatory phase, and is characterized by high progesterone levels, a second estradiol increase, and low LH and FSH levels (12). Low LH and FSH levels are the result of the negative feedback effects of estradiol and progesterone on the hypothalamic-pituitary axis.

After conception, the developing embryo produces hCG, which causes the corpus luteum to continue producing progesterone and estradiol. The corpus luteum regresses if pregnancy does not occur, and the corresponding drop in progesterone and estradiol levels results in menstruation. The hypothalamus initiates the menstrual cycle again as a result of these low hormone levels (12).

Patients suffering from hypogonadism show increased concentrations of serum LH. A decrease in steroid hormone production in females is a result of immature ovaries, primary ovarian failure, polycystic ovary disease, or menopause; in these cases, LH secretion is not regulated (10,13). A similar loss of regulatory hormones occurs in males when the testes develop abnormally or anorchia exists. High concentrations of LH may also be found in primary testicular failure and Klinefelter syndrome, although LH levels will not necessarily be elevated if the secretion of androgens continues. Increased concentrations of LH are also present during renal failure, cirrhosis, hyperthyroidism, and severe starvation (10,14).

A lack of secretion by the anterior pituitary may cause lower LH levels. As may be expected, low levels may result in infertility in both males and females. Low levels of LH may also be due to the decreased secretion of GnRH by the hypothalamus, although the same effect may be seen by a failure of the anterior pituitary to respond to GnRH stimulation. Low LH values may therefore indicate some dysfunction of the pituitary or hypothalamus, but the actual source of the problem must be confirmed by other tests (10).

In the differential diagnosis of hypothalamic, pituitary, or gonadal dysfunction, assays of LH concentration are routinely performed in conjunction with FSH assays since their roles are closely interrelated. Furthermore, the hormone levels are used to determine menopause, pinpoint ovulation, and monitor endocrine therapy.

3. PRINCIPLE

The LH ELISA is a solid phase enzyme-linked immunosorbent assay based on the sandwich principle. The microtiter wells are coated with a monoclonal antibody directed towards a unique antigenic site on a β -LH molecule. An aliquot of patient serum containing endogenous LH is incubated in the coated well with enzyme conjugate, which is an anti-LH antiserum conjugated with horseradish peroxidase. After incubation the unbound conjugate is washed off with water. The amount of bound peroxidase is proportional to the concentration of LH in the sample. Having added the substrate solution, the intensity of colour developed is proportional to the concentration of LH in the sample.

4. REAGENTS

1. **MTP** Microtiter wells. Wells coated with anti-LH monoclonal antibody, 96 wells.
2. **ENZCONJ** Enzyme-Conjugate, 11 ml. Anti-LH antiserum conjugated to horseradish peroxidase.
3. **CAL** Reference Standard Set – Serum (lyoph.), 1.0 ml per vial.
0, 10; 20; 40; 100; 200 mIU/ml.
4. **TMB SUBS** Substrate Solution - TMB, 11 ml.
5. **TMB STOP** Stop Solution 0,5M H₂SO₄, 6 ml.

5. MATERIALS REQUIRED BUT NOT SUPPLIED

1. A microtiterplate reader (450±10 nm).
2. Precision micropipettes with disposable tips for 25, 50 and 100 μ l.
3. Dist. water
4. Standard refrigerator.
5. Absorbent paper.

6. PREPARATION OF REAGENTS

Allow all reagents and required number of strips to reach room temperature prior to use.

LH Standards

Reconstitute the lyophilized contents of the standard vial with 1.0 ml Aqua dest.

Note: The reconstituted standards are stable for 2 months at 2-8°C. For longer storage freeze at -20°C.

7. STORAGE CONDITIONS

When stored at 2° to 8°C unbroken reagents will retain reactivity until expiration date. Do not use reagents beyond this date.

Enzyme Conjugate, Substrate Solution, Standards and Zero Standard must be stored at 2° to 8°C.

Microtiter wells must be stored at 2° to 8°C. Once the foil bag has been broken care should be taken to close it tightly again. The immuno-reactivity of the coated microtiter wells is stable for approx. 6 weeks in the broken, but tightly closed bag.

8. WARNINGS AND PRECAUTIONS FOR USERS

1. **CAUTION:** Test methods are not available which can offer complete assurance that Hepatitis B virus, Human Immunodeficiency Virus (HIV/HTLV-III/LAV), or other infectious agents are absent from the reagents in this kit. Therefore, all human blood products, including patient samples, should be considered potentially infectious. Handling and disposal should be in accordance with the procedures defined by an appropriate national biohazard safety guideline or regulation, where it exists (e.g., USA Center for Disease Control/National Institute of Health Manual, "Biosafety in Microbiological and Biomedical Laboratories," 1984).
2. Avoid contact with *Stop Solution* (0.5M H₂SO₄). It may cause skin irritation and burns.
3. Replace caps on reagents immediately. Do not switch caps.
4. Samples containing additives or preservatives, such as sodium azide, should not be used in the enzyme reaction.
5. Do not pipette reagents by mouth.
6. For in vitro diagnostic use only.
7. Do not mix or use components from kits with different lot numbers.

9. SPECIMEN COLLECTION AND PREPARATION

1. Collect blood by venipuncture, allow to clot, and separate serum by centrifugation at room temperature. Avoid hemolysis.
2. Specimens should be capped and may be stored for up to 48 hours at 2-8°C prior to assaying. Specimens held for a longer time should be frozen only once at -20°C prior to assay. Thawed samples should be inverted several times prior to testing.

ATTENTION! This kit is for use with samples without additives only.

10. PERFORMANCE OF THE ASSAY

10.1. GENERAL REMARKS:

1. All reagents and specimens must be allowed to come to room temperature before use. All reagents must be mixed without foaming.
2. Once the test has been started, all steps should be completed without interruption.
3. Use new disposable tips for each specimen.
4. Absorbance is a function of the incubation time and temperature. Before starting the assay, it is recommended that all reagents be ready, caps removed, all needed wells secured in holder, etc. This will ensure equal elapsed time for each pipetting step without interruption.
5. The present LH kit is adjusted to give a maximum absorption of 1.0 to 2.0 within 10 minutes at room temperature (22°C). If that maximum absorption value is above the upper performance limit of your microtiterplate spectrophotometer or lower than 1.000, it is necessary to reduce or extend the incubation time of the final enzymatic formation of color accordingly. As a general rule the enzymatic reaction is linearly proportional to time and temperature. This makes interpolation possible for fixed physico-chemical conditions.

10.2. PROCEDURAL NOTE

1. Manual Pipetting: It is recommended that no more than 32 wells be used for each assay run. Pipetting of all standards, samples, and controls should be completed within 3 minutes.
2. Automated Pipetting: A full plate of 96 wells may be used in each assay run. However, it is recommended that pipetting of all standards, samples, and controls be completed within 3 minutes.
3. All standards, samples, and controls should be run in duplicate concurrently so that all conditions of testing are the same.

10.3. ASSAY PROCEDURE (Quantitative Method)

1. Secure the desired number of coated Microtiter Wells in the holder.
2. Dispense 25 µl LH *Standards* (0; 10; 20; 40; 100; 200 mIU/ml), controls and serum specimen **with new disposable tips** into appropriate wells.
3. Dispense 100 µl Anti-LH *Enzyme-Conjugate* into each well.
4. Thoroughly mix for 10 seconds. It is important to have a complete mixing in this step.
5. Incubate for 30 minutes at room temperature.
6. Briskly shake out the contents of the wells.
7. Rinse the wells 5 times with dist. water.
8. Strike the wells sharply on absorbent paper to remove residual water droplets.
9. Add 100 µl of *Substrate Solution* to each well, at timed intervals.
10. Incubate for 10 minutes at room temperature.
11. Stop the enzymatic reaction by adding 50 µl of *Stop Solution* to each well, at the same timed intervals as in step 9.
12. Read the OD at 450±10 nm with a microtiterplate reader.

Final Reaction Stability

It is recommended that the wells be read within 10 minutes following step 11.

10.4. ASSAY PROCEDURE (Qualitative Method)

This procedure is suitable for the detection of the midcycle LH surge in serum. Patient samples are run with the Reference Standards 20 and 40 mIU/ml. The assay method is exactly the same as for the quantitative method, but step 11 and 12 is omitted.

11. CALCULATION OF RESULTS

1. Calculate the average absorbance values for each set of reference standards, controls and patient samples.
2. Construct a standard curve by plotting the mean absorbance obtained from each reference standard against its concentration in mIU/ml with absorbance value on the vertical(Y) axis and concentration on the horizontal (X) axis.
3. Using the mean absorbance value for each sample determine the corresponding concentration of LH in mIU/ml from the standard curve. Depending on experience and/or the availability of computer capability, other methods of data reduction may be employed.
4. Any diluted samples must be further converted by the appropriate dilution factor.

12. QUALITATIVE RESULTS

For a qualitative analysis of LH level, the specimen is compared with the color of the 0, 20 and 40 mIU/ml Reference Standards.

*< 20 mIU/ml LH: if the blue color is less intense than or equal to the color of the 20 mIU/ml Reference Standard

*>20 and <40 mIU/ml LH: if the blue color is more intense than the color of the 20 mIU/ml Reference Standard, but less intense than the color of the 40 mIU/ml Reference Standard

*>40 mIU/ml LH: if the blue color is equal or more intense than the color of the 40 mIU/ml Reference Standard.

13. EXPECTED VALUES

Each laboratory must establish its own normal ranges based on patient population. The results provided below are based on randomly selected out-patient clinical laboratory samples:

| | Age | Number | LH (mIU/ml) | |
|-------------------------------|-------|--------|-------------|--------------|
| | | | Mean | Range |
| Male (pre-pubescent) | <10 | 10 | 1.1 | 0 to 2.9 |
| Male (normal adult) | 18-65 | 30 | 4.6 | 1.0 to 13.8 |
| Female (pre-pubescent) | <10 | 8 | 0.8 | 0 to 1.5 |
| Female (normal adult) | 20-36 | 47 | 14.8 | 0.6 to 96.2 |
| - follicular and luteal phase | | | | < 20 |
| - LH Surge | | | | 40 - 200 |
| Female (post-menopausal) | 46-60 | 23 | 36.3 | 8.4 to 102.0 |

14. PERFORMANCE CHARACTERISTICS

Sensitivity

The minimal detectable concentration of human luteinizing hormone by this assay is estimated to be 2 mIU/ml.

Precision

a. Intra-Assay Precision

Within-run precision was determined by replicate determinations of three different control sera in one assay. The within-assay variability is shown below:

| Sample | 1 | 2 | 3 |
|------------------------------|------|-------|-------|
| Number of Replicates | 18 | 18 | 18 |
| Mean LH (mIU/ml) | 4.88 | 23.59 | 57.86 |
| Standard Deviation | 0.32 | 1.37 | 3.97 |
| Coefficient of Variation (%) | 0.66 | 5.80 | 6.87 |

b. Inter-Assay Precision

Between-run precision was determined by replicate measurements of three different control sera over several different assays. The between-assay variability is shown below:

| Sample | 1 | 2 | 3 |
|------------------------------|------|-------|-------|
| Number of Replicates | 39 | 24 | 24 |
| Mean LH (mIU/ml) | 5.11 | 23.88 | 57.70 |
| Standard Deviation | 0.48 | 1.71 | 3.30 |
| Coefficient of Variation (%) | 9.39 | 7.16 | 5.71 |

Recovery and Linearity**a. Recovery**

Various patient samples of known LH levels were mixed and assayed in duplicate. The average recovery was 101.6%.

| Expected Concentration (mIU/ml) | Observed Concentration (mIU/ml) | %Recovery |
|---------------------------------|---------------------------------|-----------|
| 5.03 | 5.09 | 101.2 |
| 23.65 | 25.31 | 107.0 |
| 35.64 | 36.43 | 102.2 |
| 46.95 | 51.10 | 108.8 |
| 72.32 | 69.37 | 95.9 |
| 91.78 | 86.61 | 94.4 |

b. Linearity

Two patient samples were serially diluted with Zero Standard in a linearity study. The average recovery was 101.6%.

| Patient Number | | Expected Conc. Dilution(mIU/ml) | Observed Conc. (mIU/ml) | %Recovery |
|----------------|-----------|---------------------------------|-------------------------|-----------|
| 1 | Undiluted | 105.47 | 105.47 | 100.0 |
| | 1:2 | 52.74 | 54.72 | 103.8 |
| | 1:4 | 26.37 | 28.95 | 109.7 |
| | 1:8 | 13.19 | 13.88 | 105.2 |
| | 1:16 | 6.60 | 6.98 | 105.8 |
| 2 | Undiluted | 78.08 | 78.08 | 100.0 |
| | 1:2 | 39.04 | 39.17 | 100.3 |
| | 1:4 | 19.52 | 18.70 | 95.8 |
| | 1:8 | 9.76 | 9.34 | 95.7 |
| | 1:16 | 4.88 | 4.97 | 101.8 |
| | 1:32 | 2.44 | 2.34 | 95.9 |

Specificity

The following hormones were tested for cross-reactivity of the assay:

| Hormone Tested | Concentration | Produced Color Intensity Equivalent to LH in Serum (mIU/ml) |
|--------------------------|----------------|---|
| hCG (WHO 1st IRP75/537) | 200 mIU/ml | 5.2 |
| TSH (WHO 2nd IRP 80/558) | 62 μ IU/ml | 3.0 |
| FSH (WHO 1st IRP 68/40) | 200 mIU/ml | 2.5 |

NOTE: Pregnancy results in elevated levels of hCG, the use of the LH enzyme immunoassay test is not recommended during pregnancy or immediately post-partum.

Hook Effect

In this assay, no hook effect is observed up to 4,000 mIU/ml of LH.

15. QUALITY CONTROL

Good laboratory practice requires that controls are run with each calibration curve. A statistically significant number of controls should be assayed to establish mean values and acceptable ranges to assure proper performance. Controls containing azide should not be used.

16. LIMITATION OF PROCEDURE

1. Reliable and reproducible results will be obtained when the assay procedure is carried out with a complete understanding of the package insert instructions and with adherence to good laboratory practice.
2. The wash procedure is critical. Insufficient washing will result in poor precision and falsely elevated absorbances.

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PROCEDURE FLOW SHEET

| Description | Standard Sample μl | Enzyme- Conjugate μl | | Substrate Solution μl | | Stop Solution μl | | Results mIU/ml |
|-------------|----------------------------------|---------------------------------------|---------------|--|--------------|-----------------------------------|---------------|-------------------|
| Standard 0 | 25 | 100 | Mix for | 100 | Incubate for | 50 | Read the | 0 |
| Standard 1 | 25 | 100 | 10 seconds. | 100 | 10 minutes | 50 | OD at 450 | 10 |
| Standard 2 | 25 | 100 | Incubate for | 100 | at room | 50 | nm | 20 |
| Standard 3 | 25 | 100 | 30 minutes | 100 | temperature | 50 | with a | 40 |
| Standard 4 | 25 | 100 | at room | 100 | | 50 | microtiter- | 100 |
| Standard 5 | 25 | 100 | temperature. | 100 | | 50 | plate reader. | 200 |
| Sample 1 | 25 | 100 | Rinse the | 100 | | 50 | | - |
| Sample 2 | 25 | 100 | wells 5 times | 100 | | 50 | | - |
| Sample 3 | 25 | 100 | with water | 100 | | 50 | | - |
| Sample 4 | 25 | 100 | | 100 | | 50 | | - |
| Sample 5 | 25 | 100 | | 100 | | 50 | | - |

Symbols / Symbole / Symbôles / Símbolos / Símbolos / Σύμβολα

| | |
|--|--|
|  | Cat.-No.: / Kat.-Nr.: / No.- Cat.: / Cat.-No.: / N.º Cat.: / N.-Cat.: / Αριθμός-Κατ.: |
|  | Lot-No.: / Chargen-Bez.: / No. Lot: / Lot-No.: / Lote N.º: / Lotto n.: / Αριθμός -Παραγωγή: |
|  | Use by: / Verwendbar bis: / Utiliser à: / Usado por: / Usar até: / Da utilizzare entro: / Χρησιμοποιείται από: |
|  | No. of Tests: / Kitgröße: / Nb. de Tests: / No. de Determ.: / N.º de Testes: / Quantità dei tests: / Αριθμός εξετάσεων: |
|  | Concentrate / Konzentrat / Concentré / Concentrar / Concentrado / Concentrato / Συμπύκνωμα |
|  | Lyophilized / Lyophilisat / Lyophilisé / Liofilizado / Liofilizado / Liofilizzato / Λυοφιλιασμένο |
|  | In Vitro Diagnostic Medical Device. / In-vitro-Diagnostikum. / Appareil Médical pour Diagnostics In Vitro. / Dispositivo Médico para Diagnóstico In Vitro. / Equipamento Médico de Diagnóstico In Vitro. / Dispositivo Medico Diagnostico In vitro. / Ιατρική συσκευή για In-Vitro Διάγνωση. |
|  | Evaluation kit. / Nur für Leistungsbewertungszwecke. / Kit pour évaluation. / Juego de Reactivos para Evaluació. / Kit de avaliação. / Kit di evaluazione. / Κιτ Αξιολόγησης. |
|  | Read instructions before use. / Arbeitsanleitung lesen. / Lire la fiche technique avant emploi. / Lea las instrucciones antes de usar. / Ler as instruções antes de usar. / Leggere le istruzioni prima dell'uso. / Διαβάστε τις οδηγίες πριν την χρήση. |
|  | Keep away from heat or direct sun light. / Vor Hitze und direkter Sonneneinstrahlung schützen. / Garder à l'abri de la chaleur et de toute exposition lumineuse. / Manténgase alejado del calor o la luz solar directa. / Manter longe do calor ou luz solar directa. / Non esporre ai raggi solari. / Να φυλάσσεται μακριά από θερμότητα και άμεση επαφή με το φως του ηλίου. |
|  | Store at: / Lagern bei: / Stocker à: / Almacene a: / Armazenar a: / Conservare a: / Αποθήκευση στους: |
|  | Manufacturer: / Hersteller: / Fabricant: / Productor: / Fabricante: / Fabricante: / Παραγωγός: |
|  | Caution! / Vorsicht! / Attention! / ¡Precaución! / Cuidado! / Attenzione! / Προσοχή! |
| <p>Symbols of the kit components see MATERIALS SUPPLIED. Die Symbole der Komponenten sind im Kapitel KOMPONENTEN DES KITS beschrieben. Voir MATERIEL FOURNI pour les symbôles des composants du kit. Símbolos de los componentes del juego de reactivos, vea MATERIALES SUMINISTRADOS. Para símbolos dos componentes do kit ver MATERIAIS FORNECIDOS. Per i simboli dei componenti del kit si veda COMPONENTI DEL KIT. Για τα σύμβολα των συστατικών του κιτ συμβουλευτείτε το ΠΑΡΕΧΟΜΕΝΑ ΥΛΙΚΑ.</p> | |

IBL AFFILIATES WORLDWIDE

| | | |
|---|--|--|
|  | IBL-Hamburg GmbH Flughafenstr. 52A, D-22335 Hamburg, Germany | Tel.: + 49 (0) 40 532891 -0 Fax: -11 E-MAIL: ibl@ibl-hamburg.com WEB: http://www.ibl-hamburg.com |
| | IBL-America, Inc. 8201 Central Ave NE Suite P, Minneapolis, MN 55432, USA | Tel.: + 1 763 780 -2955 Fax: -2988 E-MAIL: mkowal@ibl-america.com WEB: http://www.ibl-america.com |
| | IBL-Japan, Ltd. 1091-1 Naka Fujioka-Shi, Gunma 375-0005, Japan | Tel.: + 81 274 22 -2888 Fax: -5746 E-MAIL: do-support@ibl-japan.co.jp WEB: http://www.ibl-japan.co.jp |
| | IBL-Turkey Ltd.Sti. Ivedik Organize San. 21 Cad., 517 Sok. No: 2 Yenimahalle / Ankara, Turkey | Tel.: + 90 (0) 312395 -7007 Fax: -6361 E-MAIL: ibl@ibl-turkey.com WEB: http://www.ibl-turkey.com |

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