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Amendment Record

Issue Level	Date Issued	Summary of Amendment	Reviewed by
1.1	29.08.2017	General Review	Sondos Shalabi

2. General Information.

Trade Names & Synonyms: LH Elisa Kit, 96T/Kit.

Chemical Family: In Vitro Diagnostic Test kit (ELISA KITS).

Formula: Not Applicable.

Manufacturer: Atlas Medical.

Manufacturer's address: William James House
Cowley Road
Cambridge, CB4 0WX, UK.

Manufacturer's phone: +44 (0) 1223 858 910

Manufacturer's Fax: +44 (0) 1223 858 524

Email: info@atlas-site.co.uk

3. Composition, Information on Active Ingredients.

ACTIVE INGREDIENTS:

The LH quantitative test kit is based on the principle of a solid phase enzyme linked immunosorbent assay. The assay system utilizes one anti-LH antibody for solid phase (Microtiter wells) immobilization and another mouse monoclonal anti-LH antibody is in the antibody-enzyme (horseradish peroxidase) conjugate solution.

4. Hazard Information.

Hazard description:

The reagents contain 0.1% Sodium Azide which is toxic and can be absorbed through the skin. When drained, the drains should be thoroughly flushed with water.
Sodium azide may react with lead or copper plumbing to form highly explosive metal azides. Flush sink and plumbing well with plenty of running water to prevent build-up. Sodium azide is classified as harmful (Xn)

Information concerning particular hazards for human and environment:

Under the recommended conditions of use, there is no risk of exposure to any of the materials contained in the reagent.

4. Health Hazard Data.

Sodium Azide:
Spill: Not applicable.
Exposure Controls: Not applicable.

Personal Protection: Not applicable.
Physical Properties: Not applicable.
Stability/Reactivity: Stable. Non-reactive in this test.
Toxicological Information: Exposure above acceptable limits may be harmful

6. Fire & Explosion Hazard Data.

Non-flammable
Using the reagents according to protocol should not incur a fire or explosion hazard.
In case of fire, use water, foam, carbon dioxide, or dry chemical, as suitable for the surrounding fire and materials.

7. Accidental release measures.

Health Hazards: Poison, Do Not Inhale or Swallow.
First Aid Measures: Inhale: Remove to fresh air.
Contact: Flush with water for 15 minutes.
Swallow: If conscious, wash mouth out with water
Call Physician.

8. Handling and Storage.

Information for safe handling:
Keep out of reach of children.
Storage:
Store in the original container at 2-30°C.
Requirements to be met by storerooms and receptacles:
No special requirements.

9. Exposure control and personal gear.

Ingredients with limit values that require monitoring in the workplace:
The product does not contain any relevant quantities of materials with critical values that have to be monitored in the workplace.
Personal protective equipment:
General protective and hygienic measures: Adhere to good laboratory practices (GLP). Wash hands before breaks and at the end of work.
Respiratory protection: Not required
Protection of hands: Disposable gloves.
Material of gloves: Latex/natural rubber.
Penetration time of glove material: Glove resistance is not critical as the gloves are intended to provide protection against the sample material.
Eye protection: Not required
Body protection: Lab coat

10. Physical and chemical properties.

General Information

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. LH, also called interstitial cell-stimulating hormone (ICSH) in men, is a glycoprotein with a molecular weight of approximately 30,000 Daltons. It is composed of two non-covalently associated dissimilar amino acid chains, alpha and beta. The alpha chain is similar to that found in human thyroid stimulating hormone (TSH), follicle stimulating hormone (FSH) and human chorionic gonadotropin (hCG). The differences between these hormones lie in the amino acid composition of their beta subunits, which accounts 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 of 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. The decrease in progesterone and estradiol levels from the preceding ovulation initiates each menstrual cycle. 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. 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 it increases 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.

Ovulation occurs approximately 12 to 18 hours after the LH reaches a maximal level. After the egg is released, the corpus luteum is formed which secretes progesterone and estrogen feedback regulators of LH.

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. 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 result in menstruation. The hypothalamus initiates the menstrual cycle again as a result of these low hormone levels.

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. 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.

A lack of secretion by the anterior pituitary may cause lower LH levels. As may be expected, 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. In the differential diagnosis of hypothalamic, pituitary, or 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.

Odor: Odorless.
Flash point: Not applicable.
Self-igniting: Product is not self-igniting.
Danger of explosion: Product does not present an explosion hazard.

11. Stability and Reactivity Data.

Stability: The product is stable in accordance with the recommended storage conditions.
Materials to be avoided: None.
Hazardous reactions: No dangerous reactions known.
Hazardous decomposition products: No dangerous decomposition products known.
These products should not be used if turbid, and should **not** be diluted. Stable until expiry date stated on the vial if stored according to manufacturers recommendation

12. Toxicological information.

Acute toxicity: Quantitative data on the toxic effects of this product is not available.
Primary effects:
After skin contact: No irritating effects known.
After eye contact: No irritating effects known.
Sensitization: No sensitizing effects known.

13. Ecological information.

Environmental Toxicity:
Quantitative data on the toxic effects of this product is not available.

Incorrect sample and used kit disposable:

Bio-hazards may exert cumulative environmental effects due to chemicals and biological materials present in the test kit.

14. Waste disposal information.

Product:

When disposing of reagents that contain Sodium azide, flush down the drain with copious amounts of tap water to prevent the build-up of explosive residues in the plumbing. As this reagent is of animal origin care must be taken during disposal, as there is a potential infection risk. Follow local and national guidelines

Packaging:

Disposal must be made in accordance with local waste management regulations.
Non-contaminated packaging materials may be recycled. Contact your local service providers for further information.

15. Transport information.

The product is not subject to transport regulations.
Product should be shipped with ice pack. A label should be affixed to the outside of the package - "Refrigerate Upon Arrival".

16. Regulatory information.

NA.

17. Other information.

The product is for in-vitro use only.

18. Disclaimer.

The information above is believed to be accurate represents the best information currently available to us.
However we make no warranty of merchantability or any other warranty expressed or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purpose. In no way shall the company be liable for any claims, losses or damages of any third party or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if the company has been advised of the possibility of such damages.