 Atlas Medical	File Title: Product File.	Document Title: Material Safety Data Sheet.	Date Issued 20.10.2013
	Item Title: FSH Elisa Kit, 96T/Kit.	Item Code: 8.10.03.0.0096	Issue Level: 1.0

2. General Information.

Trade Names & Synonyms:	FSH 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 FSH EIA test is based on the principle of a solid phase enzyme linked immunosorbent assay. The assay system utilizes a mouse monoclonal anti- α -FSH antibody for solid phase (Microtiter wells) immobilization and another mouse monoclonal anti- β -FSH antibody 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.

PMX8.10.03.0.0096D.10	Issued for	Prepared by. QA	Reviewed by. R&D	Approved by. QA	Page 2 of 6
	Date:	Date: 20.10.2008	Date: 20.10.2008	Date: 20.10.2008	

 Atlas Medical	File Title: Product File.	Document Title: Material Safety Data Sheet.	Date Issued 20.10.2013
	Item Title: FSH Elisa Kit, 96T/Kit.	Item Code: 8.10.03.0.0096	Issue Level: 1.0

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

PMX8.10.03.0.0096D.10	Issued for	Prepared by. QA	Reviewed by. R&D	Approved by. QA	Page 3 of 6
	Date:	Date: 20.10.2008	Date: 20.10.2008	Date: 20.10.2008	

 Atlas Medical	File Title: Product File.	Document Title: Material Safety Data Sheet.	Date Issued 20.10.2013
	Item Title: FSH Elisa Kit, 96T/Kit.	Item Code: 8.10.03.0.0096	Issue Level: 1.0

10. Physical and chemical properties.

General Information

Follicle stimulating hormone (FSH) and Luteinizing hormone (LH) are intimately involved in the growth and reproductive activities of the gonadal tissues, which synthesize and secrete male and female sex hormones. The levels of circulating FSH and LH are controlled by these sex hormones through a negative feedback relationship.

FSH is a glycoprotein secreted by the basophilic cells of the anterior pituitary. Gonadotropin-release hormone (GnRH), produced in the hypothalamus, controls the release of FSH from anterior pituitary. Like other glycoproteins, such as LH, TSH, and hCG, FSH consists of two subunits designated as alpha and beta. Hormones of this type have alpha subunits that are very similar structurally; therefore the biological and immunological properties of each are dependent on the unique beta subunits.

In the female, FSH stimulates the growth and maturation of ovarian follicles by acting directly on the receptors located on the granulosa cells; follicular steroid genesis is promoted and LH production is stimulated. The LH produced then binds to the theca cells and stimulates steroid genesis. Increased intraovarian estradiol production occurs as follicular maturation advances, thereupon stimulating increased FSH receptor activity and FSH follicular binding. FSH, LH, and estradiol are therefore intimately related in supporting ovarian recruitment and maturation in women.

FSH levels are elevated after menopause, castration, and in premature ovarian failure. The levels of FSH may be normalized through the administration of estrogen, which demonstrate a negative feedback mechanism. Abnormal relationships between FSH and LH, and between FSH and estrogen have been linked to anorexia nervosa and polycystic ovarian disease. Although there are significant exceptions, ovarian failure is indicated when random FSH concentrations exceed 40mIU/ml.

The growth of the seminiferous tubules and maintenance of spermatogenesis in men are regulated by FSH. However, androgens, unlike estrogen, do not lower FSH levels, therefore demonstrating a feedback relationship only with serum LH. For reasons not fully understood, azospermic and oligospermic males usually have elevated FSH levels. Tumors of the testes generally depress serum FSH concentrations. High levels of FSH in men may be found in primary testicular failure and Klinefelter syndrome. Elevated concentrations are also present in cases of starvation, renal failure, hypothyroidism and cirrhosis.

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.

PMX8.10.03.0.0096D.10	Issued for	Prepared by. QA	Reviewed by. R&D	Approved by. QA	Page 4 of 6
	Date:	Date: 20.10.2008	Date: 20.10.2008	Date: 20.10.2008	

	File Title: Product File.	Document Title: Material Safety Data Sheet.	Date Issued 20.10.2013
	Item Title: FSH Elisa Kit, 96T/Kit.	Item Code: 8.10.03.0.0096	Issue Level: 1.0

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.

PMX8.10.03.0.0096D.10	Issued for	Prepared by. QA	Reviewed by. R&D	Approved by. QA	Page 5 of 6
	Date:	Date: 20.10.2008	Date: 20.10.2008	Date: 20.10.2008	

 Atlas Medical	File Title: Product File.	Document Title: Material Safety Data Sheet.	Date Issued 20.10.2013
	Item Title: FSH Elisa Kit, 96T/Kit.	Item Code: 8.10.03.0.0096	Issue Level: 1.0

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.

PMX8.10.03.0.0096D.10	Issued for Date:	Prepared by. QA Date: 20.10.2008	Reviewed by. R&D Date: 20.10.2008	Approved by. QA Date: 20.10.2008	Page 6 of 6
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