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	Item Title: TSH Elisa kit, 96T/Kit	Item Code: 8.12.02.0.0096	Issue Level: 1.1


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1. Amendment Record

Issue Level	Date Issued	Summary of Amendment	Reviewed by
1.1	02.04.2017	General Review	Amani

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2. General Information.

Trade Names & Synonyms:	TSH 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.


REAGENTS	INITIAL CONCENTRATION	CLASSIFICATION
STD 1 TSH 1.0 mL		NOT
TSH	0 µIU/mL	
Proclin30	0.25%	
0	N/A	
Tris-NaCl	0.25%	
ADP	0.10%	
STD 2 TSH 1.0 mL		NOT DANGEROUS
TSH	0.5 µIU/mL	
Proclin300	0.25%	
Tris-NaCl	N/A	
Sodium azide	0.25%	

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ADP	0.10%	
STD 3 TSH 1.0 mL		NOT
TSH	2 µIU/mL	
Proclin30	0.25%	
0	N/A	
Tris-NaCl	0.25%	
ADP	0.10%	
STD 4 TSH 1.0 mL		NOT DANGEROUS
TSH	5.0 µIU/mL	
Proclin300	0.25%	
Tris-NaCl	N/A	
Sodium azide	0.25%	
ADP	0.10%	
STD 5 TSH 1.0 mL		NOT DANGEROUS
TSH	10 µIU/mL	
Proclin300	0.25%	
Tris-NaCl	N/A	
Sodium azide	0.25%	
ADP	0.10%	
STD 6 TSH 1.0 mL		NOT DANGEROUS
TSH	20 µIU/mL	
Proclin300	0.25%	
Tris-NaCl	N/A	
Sodium azide	0.25%	
ADP	0.10%	
ENZYME CONJUGATE		NOT DANGEROUS
Tris	0.05mol/L	
BSA	3%	
Proclin 300	0.2%	
Anti-TSH-HRP	1:3000	

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COATED MICROPLATE Coated with Anti-TSH (MAb)		NOT DANGEROUS
TMB SUBSTRATE 3,3',5,5'- tetramethylbenzidine Hydrogen peroxide Other ingredients	0.03% 0.015%	NOT DANGEROUS
WASH SOLUTION PBS TWEEN 20	0.01M 0.05%	NOT DANGEROUS
STOP SOLUTION Sulphuric Acid	1M	NOT DANGEROUS

4. Hazard Information.

Classification of the substance or mixture

The product is a kit consisting of individual ingredients. The classification of the ingredients can be obtained from section 3.

Label elements

Not a hazardous substance or mixture.

5. 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.

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In case of fire, use water, foam, carbon dioxide, or dry chemical, as suitable for the surrounding fire and materials.

7. Accidental release measures.

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Refer to protective measures listed in sections 7 and 8.

Environmental precautions

Environmental precautions: Local authorities should be advised if significant spillages cannot be contained.

Methods and material for containment and cleaning up

Methods for cleaning up: Wipe up with absorbent material (e.g. cloth, fleece).

Keep in suitable, closed containers for disposal

8. Handling and Storage.

Handling

Handling No special requirements.

Conditions for safe storage

Storage Store in tightly closed containers under cool conditions.

9. Exposure control and personal gear.

Exposure controls

Eye protection: Safety glasses.


Hand protection: Protective gloves.

Wash hands before breaks and at the end of work. Skin and body protection

Protective Sui

Respiratory protection: No personal respiratory protective equipment normally required.

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10. Physical and chemical properties.

General Information

Thyroid-stimulating hormone (TSH, thyrotropin) is a glycoprotein having a molecular weight of approx.30000 daltons and consisting of two subunits. Measurement of the serum concentration oftentimes thyrotropin (TSH), a glycoprotein with amolecular weight of 28,000 daltons and secreted from the anterior pituitary, is generally regarded as the most sensitive indicator available for the diagnosis of primary and secondary(pituitary) hypothyroidism.

TSH measurements are equally useful in differentiating secondary and tertiary (hypothalamic) hypothyroidism from the primary thyroid disease. TSH release from the pituitary is regulated by thyrotropin releasing factor (TRH), which is secreted by the hypothalamus, and by direct action of T4 and triiodothyronine (T3), the thyroid hormones, at the pituitary.Increase levels of T3 and T4 reduces the response of the pituitary to the stimulatory effects of TRH. In secondary and tertiary hypothyroidism, concentrations of T4 are usually low and TSH levels are generally low or normal. Either pituitary TSH deficiency (secondary hypothyroidism) or insufficiency of stimulation of the pituitary by TRH (tertiary hypothyroidism)causes this. The TRH stimulation test differentiates the seconditions. In secondary hypothyroidism, TSH response to TRH is blunted while a normal or delayed response is obtained intertiary hypothyroidism.Further, the advent of immunoenzymometric assays has provided the laboratory with sufficient sensitivity to enable the differentiating of hyperthyroidism from euthyroid population and extending the usefulness of TSH measurements. This method is a second-generation assay, which provide the means for discrimination in the hyperthyroid-euthyroid range.

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.

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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,

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incidental, consequential or exemplary damages, howsoever arising, even if the company has been advised of the possibility of such damages.

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