 Atlas Medical	File Title: Product File.	Document Title: Material Safety Data Sheet.	Date Issued 11.07.2018
	Item Title: T4 ELISA Kit	Item Code: 8.12.01.x.xxxx	Issue Level: 1.0


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1. Amendment Record

Issue Level	Date Issued	Summary of Amendment	Reviewed by

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2. General Information.

Trade Names & Synonyms:	T4 ELISA 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.

Components	Main Ingredients	Classification
Coated Microplate	8 x 12 strips, 96 wells, pre-coated with T4 derivant.	Not Dangerous
Calibrators	6 white cap vials, 1 ml each, ready to use; Concentrations: 0(A), 2.5(B), 5(C), 10(D), 15(E) and 30(F) µg/dL.	Not Dangerous
Enzyme Conjugate	1 red cap vial, 6.0 ml of HRP (horseradish peroxidase) labeled mouse monoclonal T4 in Tris-NaCl buffer containing BSA (bovine serum albumin). Contains 0.2% ProClin300® preservative. ANS 1.5 mg/mL.	Not Dangerous
Substrate	1 brown cap vial, 11ml, ready to use, (tetra methyl benzidine) TMB	Not Dangerous
Stop Solution	1 yellow cap vial, 6.0 ml of 1 mol/l sulfuric acid.	Not Dangerous
Wash Solution Concentrate (40X)	transparent cap bottle, 25 ml ,PBS-Tween wash solution. Note: it could be cristalized leave it at room temperature until dissolve .For dilution add 1ml of concentrated buffer to 39 ml distilled water	Not Dangerous

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4. Hazard Information.

Hazard description:

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

5. Health Hazard Data.

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 2-8°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.

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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:

The hormone thyroxine (T4) is the main product secreted by the thyroid gland and is an integral component of the hypothalamus anterior pituitary-thyroid regulating system. It has the function of anabolically influencing metabolism. Thyroxine is formed in a coupling reaction from two DIT molecules (3,5-diiodotyrosine) in the thyroid gland. It is stored bound to thyroglobulin in the Lumina of the thyroid follicles and is secreted as required under the influence of TSH.

The major part (> 99 %) of total thyroxine (T4) in serum is present in protein-bound form. As the concentrations of the transport proteins in serum are subject to exogenous and endogenous effects, the status of the binding proteins must also be taken into account in the assessment of the thyroid hormone concentration in serum. If this is ignored, changes in the binding proteins (e.g. due to estrogen-containing preparations, during pregnancy or in the presence of a nephritic syndrome etc.) can lead to erroneous assessments of the thyroid metabolic state.

The determination of T4 can be utilized for the following indications: the detection of hyperthyroidism, the detection of primary and secondary hypothyroidism, and the monitoring of TSH-suppression therapy.

The ATLAS ENZYCODE T4 assay employs a competitive test principle with an antibody specifically directed against T4. Endogenous T4, released by the action of 8-anilino-1-naphthalene sulfonic acid (ANS).

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.

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12. Toxicological information.

Acute toxicity: Quantitative data on the toxic effects of this product is not available.

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, 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.

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