
 <b>Atlas Medical</b>	<b>File Title:</b> Product File.	<b>Document Title:</b> Material Safety Data Sheet.	<b>Date Issued</b> 12.07.2018
	<b>Item Title:</b> Hcg ELISA Kit	<b>Item Code:</b> 8.10.01.x.xxxx	<b>Issue Level:</b> 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: Hcg 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](mailto:info@atlas-site.co.uk)

## 3. Composition of kit.

- Murine Monoclonal Anti  $\beta$  -hCG-coated microtiter wells.
- Set of Reference Standards: 0, 2.5, 5, 10, 25, and 50 ng/ml, lyophilized.
- Zero Buffer (Sample diluent), 13 ml.
- Enzyme Conjugate Reagent, 18 ml.
- TMB Reagent (One-Step), 11 ml.
- Stop Solution (1N HCl), 11 ml.


## 4. Hazard Information.

### *Hazard description:*

- **Potential biohazard:**

The Calibrator and Controls are formulated with a buffer base, animal serum, and human serum. The human serums are tested by a United States Food and Drug Administration (USFDA) licensed method and found to be non-reactive for HIV-1, HIV-2, Hepatitis B surface antigen and HCV. Because no test method can offer absolute assurance that these agents are absent, reagents should be handled at the Biosafety Level 2, as recommended for any potentially infectious human blood product, in the United States Center for Disease Control (USCDC) and National Institute of Health (USNIH) manual "Biosafety in Microbiological Laboratories", 1988. All bovine products and goat sera have been derived from animals of US origin and processed in USDA licensed facilities.

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- **CHEMICAL HAZARD:**

The TMB Chromogenic Substrate containing TMB, is formulated with DMSO, an irritant and mucous membranes. In case of contact with any of these reagents, wash thoroughly with water. TMB is a suspected carcinogen. Stop Solution is an acidic and corrosive agent. Avoid contact with skin.

### 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

Human Chorionic Gonadotropin (hCG) is a glycoprotein hormone normally produced by placenta during pregnancy. The hormone is present in blood and urine around seven to thirteen days following implantation of the fertilized ovum. Structurally intact hCG molecules consist of two non-covalently linked polypeptide subunits, the alpha and beta chain subunits. Measurement of intact hCG and of the alpha subunit of hCG appears to give similar results in blood and urine but not the levels of beta subunit. In the normal second-trimester maternal sera, the level of intact hCG range from 20,000 mIU/ml to 50,000 mIU/ml (1 ng = 15 mIU). In contrast, the levels of either free  $\alpha$ - or free  $\beta$ -hCG are on average one half of 1% of hCG levels. hCG and the free subunits appear not to be useful as serological markers for nontrophoblastic tumors; however, the absolute increase of  $\beta$ -hCG level in choriocarcinoma patients clearly differentiates it from normal pregnancy.

**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 manufacturer's recommendation.

## 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.

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***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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