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	Item Title: hCG Latex Test.	Item Code: 8.00.07.x.xxxx	Issue Level: 1.2

2. General Information.

Trade Names & Synonyms:	hCG Latex Test, All sizes.
Chemical Family:	In Vitro Diagnostic Test kit (Latex Kits).
Formula:	not applicable.
Manufacturer:	Atlas Medical.
Manufacturer's address:	Atlas Medical UG , Ludwig-Erhaed-Ring 3 15827 Blankenefelde-Mahlow Germany
Manufacturer's phone:	+49(0)33708355030
Email:	info@atlas-medical.com

3. Composition, Information on Active Ingredients.

Latex reagent: White latex suspension coated with anti-hCG monoclonal antibodies.
 Positive control: buffered hCG positive solution.
 Negative control: buffered hCG negative solution.
 * All reagents contain 0.1% (w/v) sodium azide as a preservative.

4. Hazard Information.

Hazard description:


Components contain less than 0.1% wt of Sodium Azide (NaN₃) as preservative.

The control component(s) in each of the above products contain(s) materials derived from human or animal sources. The source material used to prepare these controls are tested by an approved method for the presence of human immunodeficiency virus (HIV) as well as for Hepatitis B surface antigen; and only those materials found to be negative (not repeatedly reactive) are used to prepare products for sale.

When used in accordance with the Principles of Good Laboratory Practice, Good Standards of Occupational Hygiene and the instructions stated in the product insert, these products are not considered to present a hazard to health.

Information concerning particular hazards for human and environment:

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

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. 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:

- The reagents in this kit contain sodium azide as a preservative. Sodium azide has been reported to form lead or copper azide in laboratory plumbing which may explode on percussion. Flush drains with water thoroughly after disposing of fluids containing sodium azide.
- It should be noted, however, that there is no guarantee for products derived from human and animal sources not to transmit infectious diseases and thus should be handled with care.
- Keep out of reach of children.

Storage:

- Store in the original container at 2-8°C.

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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 (for sample handling) .

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: Safety glasses are recommended.

Body protection: Lab coat.

10. Physical and chemical properties.

General Information

Atlas hCG Monoclonal Direct Latex test is a rapid latex particle agglutination test for determination of human chorionic gonadotropin in urine for early detection of pregnancy.

Colour: white latex and Straw controls.

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.

12. Toxicological information.

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

Primary effects:

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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.

Persistence and Degradability:

The test kit contains plastic and other components that are not readily degradable.

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:

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent.

or

Remains of samples, reagents and controls should be collected in a recipient for this purpose and autoclaved 1 hour at 121°C.

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.

16. Regulatory information.

Labeling according to directive 98/79/EC.

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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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