



ARGUTUS MEDICAL  
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MATERIALS SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE / PREPARATION AND OF THE COMPANY / UNDERTAKING:

**Product Name:** Nephkit-Alpha EIA

**Cat No.** BIO66NEPHA

**Use:** An enzyme immunoassay for the quantitative determination of human alpha glutathione S-transferase ( $\alpha$ GST) in urine.

**Company/Undertaking Identification:** Argutus Medical LTD,  
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2. COMPOSITION / INFORMATION ON INGREDIENTS:

<u>Reagent</u>	<u>Content</u>
<u>Coated Strips:</u>	12 x 8 well strips coated with IgG directed against $\alpha$ GST.
<u>Conjugate Concentrate:</u>	300 $\mu$ L (50X) of anti $\alpha$ GST MRP-IgG conjugate. <b>Contains Thiomersal.</b>
<u>GST Calibrator **:</u>	200 $\mu$ l purified $\alpha$ GST. <b>Contains Thiomersal and Sodium Azide.</b>
<u>Positive Control**</u>	4.5 mL of protein containint solution with added stabilisers. <b>Contains Thiomersal and Sodium Azide.</b>
<u>Wash Concentrate:</u>	55mL of a concentrated buffer (20x) <b>Contains Thiomersal.</b>
<u>Substrate:</u>	11mL of <b>Tetramethylbenzidine (TMB)</b> solution.
<u>Sample Diluent:</u>	50 ml of ready to use diluents. <b>Contains 1% Triton X100 and Sodium Azide.</b>
<u>Urine Stabilising Buffer:</u> <b>Sodium</b>	10 mL of stabilising buffer. <b>Contains Thiomersal and Azide.</b>
<u>Stop Solution</u>	11mL of 0.5M <b>Sulphuric Acid</b> (4.9% w/w) H <sub>2</sub> SO <sub>4</sub>

**\*\* Potentially Biohazardous Material**



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**Reagents marked with \*\* are considered POTENTIALLY BIOHAZARDOUS MATERIAL.** The calibrator and positive control contains material of human origin, which has been tested and found to be negative for Hepatitis B DNA, HCV RNA and HIV RNA. However, no test method can offer complete assurance that infectious agents are absent.

**Thiomersal** is toxic by inhalation, in contact with skin and if swallowed. It is irritating to eyes, respiratory system and skin. It is a possible mutagen, which may affect kidneys and nerves.

**Sodium Azide** is an irritant. Avoid contact with components containing azide. Do not ingest or inhale. Harmful if swallowed. Contact with acids liberates very toxic gas.

**Sulphuric acid** is corrosive. Avoid contact with the skin and eyes. If contact occurs rinse immediately with water and seek medical advice.

**TMB (3,3',5,5' – tetramethylbenzidine)** may irritate the skin and mucous membranes. Any substrate that comes in contact with the skin should be rinsed off with water.

**Triton X100** is harmful. Risk of serious damage to eyes. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

### 3. FIRST AID MEASURES: Applicable for all kit components

**Inhalation:** If exposure is severe remove to fresh air

**Skin:** Wash skin with copious amounts of water.

**Eye:** Flush eyes with copious amounts of water for at least 15 minutes. Assure adequate flushing of the eyes by separating the eyelids. If any irritation persists, obtain medical assistance.

**Ingestion:** Wash out mouth with copious amounts of water. Give plenty of water to drink. Obtain medical attention if large quantity is ingested.

### 4. FIRE FIGHTING MEASURES:

**Precautions during fire:** Avoid inhalation of fumes

**Suitable extinguishing media:** Dry chemical powder. Do not use water on sodium azide containing components.

**Special exposure hazards:** Some components may decompose and emit toxic fumes under fire conditions (Sodium Azide, TMB, Thiomersal).



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**Special fire-fighting procedures:** Self-contained breathing apparatus may be required if heavy fumes are emitted. It is advisable for protective clothing to be worn to prevent contact with skin and eyes.

#### 5. ACCIDENTAL RELEASE MEASURES:

**Personal Precautions:** Wear protective clothing for the prevention of skin and eye contact.

**Environmental precautions:** The Positive Control, GST calibrator and Sample Diluent contains sodium azide which may form potentially explosive metal azides with lead and copper plumbing. For disposal, reagent should be flushed with large volumes of water to prevent azide build up.

**Methods for cleaning up:** Wipe up spills with absorbent paper, then clean area with a concentrated chlorine solution, 0.5% available chlorine (0.5% hypochlorite). Discard all materials used to wipe up spills using biohazard waste facilities.

#### 6. HANDLING AND STORAGE:

**Handling:** All clinical specimens, calibrator and positive control and any infected or potentially infected material should be handled as though potentially infectious.

**Storage:** Store all reagents and ELISA plate at 2-8°C

**Specific Use:** Laboratory use only.

#### 7. EXPOSURE CONTROLS:

The calibrator, positive control and all patient specimens are considered potentially biohazardous materials. They should be handled at the Biosafety Level 2 as recommended for any potentially infectious human serum or blood specimen in the CDC/NIH manual "Biosafety in Microbiological and Biomedical Laboratories", 1998.

Some of the reagents in this kit contain toxic or irritant components (Refer to section 3). Wear protective clothing, disposable latex gloves and eye protection while handling specimens and performing the assay. Wash hands thoroughly when finished.

#### 8. PHYSICAL AND CHEMICAL PROPERTIES:

Not Applicable



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### 9. STABILITY AND REACTIVITY:

The stop solution (0.5M H<sub>2</sub>SO<sub>4</sub>) is incompatible with water and bases.

Some components contain sodium azide, which may form potentially explosive metal azides with lead and copper plumbing. Sodium azide explodes when heated and may form hazardous combustion or decomposition products.

Substrate (TMB solution) is incompatible with strong oxidizing agents.

Thiomersal is incompatible with strong oxidising agents, strong acids and strong bases.

### 10. TOXICOLOGICAL INFORMATION:

Some reagents contain thiomersal and/or sodium azide both of which are toxic by inhalation, in contact with skin and if swallowed.

### 11. ECOLOGICAL INFORMATION:

TMB is toxic to aquatic organisms, miscible with water, may cause long term adverse effects in the aquatic environment. Avoid emptying into waters or drains. H<sub>2</sub>SO<sub>4</sub> is harmful to aquatic life in very low concentrations. It may be dangerous if it enters water intakes. Thiomersal is highly toxic to aquatic organisms and may cause long term adverse effects in the aquatic environment. Do not allow to enter waters, waste water or soil.

### 12. DISPOSAL / CONSIDERATIONS

Dispose of all clinical specimens, infected or potentially infected material in accordance with good laboratory practice. All such materials should be handled and disposed of as if potentially infectious.

Chemical residues are generally classified as special waste, and such are covered by regulations, which vary according to location. Contact your local waste authority for advice, or pass to a registered chemical disposal company. Observe all local, state and federal regulations.

### 13. TRANSPORT INFORMATION:

This manufactured product is not subject to International Air Transport Association Dangerous Goods Regulations.

### 14. REGULATORY INFORMATION AND CONSIDERATIONS:

Directive 98/79/EC (In Vitro Diagnostics Medical Devices);  
European Union Directive 67/548/EEC;



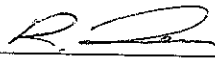
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EU Regulation 1907/2006  
Products are manufactured using GMP

**15. OTHER INFORMATION:**

**Training:** This product should be handled only by technically qualified individuals in handling potentially biohazardous material.  
The contents of this MSDS should be known before use.

**Restrictions on Use:** The product is for laboratory use only.

Approved:  Date: 31/03/09  
Health and Safety Officer

Approved:  Date: 31/03/09  
Senior Management Team Member