



ARGUTUS MEDICAL  
**MATERIALS SAFETY DATA SHEET**

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

Product Name: Alpha GST EIA  
Cat Number: BIO91  
Use: An enzyme immunoassay for the quantitative detection of alpha glutathione S-transferase ( $\alpha$ GST) in human urine, serum and plasma.  
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>Calibrator:</u>	0.1mL of purified recombinant $\alpha$ GST. <b>Contains ProClin 950 and Bronidox L.</b>
<u>Positive Control:</u>	1.5mL of purified recombinant $\alpha$ GST. <b>Contains ProClin 950 and Bronidox L.</b>
<u>Sample Diluent:</u>	30mL of ready-to-use diluent. <b>Contains ProClin 950, Bronidox L.</b>
<u>Wash Concentrate:</u>	45mL of concentrated buffer (25X). <b>Contains Trizma Base and ProClin 950.</b>
<u>Conjugate:</u>	11mL of anti- $\alpha$ GST IgG-HRP conjugate. <b>Contains ProClin 950, Bronidox L and Gentamicin.</b>
<u>Substrate:</u>	11mL of <b>Tetramethylbenzidine (TMB)</b> solution.
<u>Stop Solution:</u>	11mL of 0.5M <b>Sulphuric acid</b> (4.9% w/w H <sub>2</sub> SO <sub>4</sub> ).
<u>Urine Stabilisation Buffer:</u>	10mL of urine stabilising buffer. <b>Contains ProClin 950 and Bronidox L.</b>

**3. HAZARDS IDENTIFICATION:**

**Sulphuric acid** is corrosive, causes burns. 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. It is a possible mutagen. Any substrate that comes in contact with the skin should be rinsed off with water.



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**Gentamicin** is toxic. It is harmful by inhalation, in contact with skin and if swallowed. Target organs are kidneys and ears.

**Trizma Base** is an irritant. Irritating to eyes, respiratory system and skin. Remove contaminated clothing and shoes.

**Bronidox L** is harmful if swallowed and irritating to skin.

**ProClin 950** causes burns and sensitisation by skin contact.

**4. FIRST AID MEASURES:** Applicable for all kit components

After inhalation: If inhaled, remove to fresh air. If not breathing give artificial respiration. If breathing is difficult, give oxygen.

After skin contact: Wash skin with copious amounts of water. Remove contaminated clothing and shoes.

After eye contact: 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.

After ingestion: Wash out mouth with copious amounts of water. Give plenty of water to drink. Obtain medical assistance if large quantity is ingested.

**5. FIRE FIGHTING MEASURES:**

Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes. Some components may decompose and emit toxic fumes under fire conditions (Trizma base, TMB, Bronidox L, Proclin 950).

**6. ACCIDENTAL RELEASE MEASURES:**

Methods for cleaning up: Wipe up spills with absorbent paper, then clean area with a concentrated chlorine solution (0.5% hypochlorite) and copious amounts of water. Discard all materials used to wipe up spills using biohazard waste facilities. Residues of chemicals, preparations and kit components are generally considered as hazardous waste. All such materials should be disposed of in accordance with established safety procedures.

**7. HANDLING AND STORAGE:**

Handling All clinical specimens should be handled as though potentially biohazardous.

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

Specific Use: This product is for laboratory use only.

**8. EXPOSURE CONTROLS:**

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.

**9. PHYSICAL AND CHEMICAL PROPERTIES:**

Not Applicable

**ARGUTUS MEDICAL**  
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**Sulphuric acid** is incompatible with water and bases.  
**TMB (3,3',5,5' – tetramethylbenzidine)** is incompatible with strong oxidizing agents.  
**Gentamicin** may form hazardous combustion or decomposition products.  
**Bronidox L** is incompatible with strong oxidising agents.  
**Proclin 950** is incompatible with strong oxidising agents, Amines, Mercaptans and Reducing agents.

**11. TOXICOLOGICAL INFORMATION:**

One reagent contains Gentamicin which is toxic by inhalation, in contact with skin and if swallowed. Proclin 950 may cause allergic skin reaction and is extremely destructive to tissue of the mucous membranes and upper respiratory tract, eyes, and skin. TMB (long term toxicity) has shown a possible mutagenic effect in experimental animals.

**12. 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. Do not allow to enter waters, waste water or soil.

**13. DISPOSAL / CONSIDERATIONS:**

Dispose of all clinical specimens, infected or potentially infected material in accordance with good laboratory practice. All such material should be handled and disposed of as if potentially infectious. Residues of chemicals, preparations and kit components are generally considered as hazardous waste. All such materials should be disposed of in accordance with established safety procedures.

**14. TRANSPORT INFORMATION:**

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

**15. REGULATORY INFORMATION AND CONSIDERATIONS:**

European Union Directive 67/548/EEC  
European Union Directive 1999/45/EC  
EU Regulation 1907/2006  
Local Waste Disposal Regulations  
Directive 98/79/EC on *in vitro* diagnostic medical devices  
Products are manufactured using GMP

**16. OTHER INFORMATION:**

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

Approved: Tony L. Johnson  
Health and Safety Officer

Date: 21/04/2011

Approved: Sharon O'Sullivan  
Senior Management Team Member

Date: 21/04/2011