SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING	
1.1 Product Identifiers	
Product Name	IMMUNOASSAY SPECIALITY II - LEVEL 3 (IA SPECIALITY II LEV 3)
Cat. No.	IAS3119
1.2 Relevant identified uses of the substance or mixture and uses advised against.	For *in vitro* diagnostic use. Do not pipette by mouth. Handle laboratory reagents in accordance with Good Laboratory Practice.
1.3 Details of the supplier of the safety data sheet	
Company	Randox Laboratories Ltd., 55 Diamond Road, Crumlin, Co. Antrim, United Kingdom, BT29 4QY
Telephone	+44 (0) 28 9442 2413
Fax	+44 (0) 28 9445 2912
E-mail Address	**sds@randox.com**
Website	www.randox.com
1.4 **Emergency Telephone Number**	
Emergency Phone No.	+44 (0) 28 9442 2413 (GMT, English spoken, Mon - Fri. 08.40-17.20)

2. HAZARDS IDENTIFICATION	
2.1 Classification of the substance or mixture	
2.1.1 Regulation (EC) No. 1272/2008 (CLP)	This product contains no hazardous chemicals in reportable quantities according to Regulation (EC) No 1272/2008 (CLP)
2.1.2 Directive 67/548/EEC & Directive 1999/45/EC	This product contains no hazardous chemicals in reportable quantities according to EU Directives 67/548/EEC or 1999/45/EC
2.2 Label Elements	
Labelling according to Regulation (EC) No. 1272/2008 (CLP)	
Product Name	IMMUNOASSAY SPECIALITY II - LEVEL 3 (IA SPECIALITY II LEV 3)
Hazard Pictogram (s)	None assigned
Signal Word (s)	None assigned
Hazard Statement (s)	None assigned
Precautionary Statement (s)	None assigned
2.3 Other Hazards	 Biohazard - The serum in this kit is of human origin. This serum has been tested for the HIV (Human Immunodeficiency Virus) Antibody, HBs Ag and HCV and found to be non-reactive. However, as no method can offer complete assurance as to the absence of infectious agents this material and all patient samples should be handled as though capable of transmitting infectious disease and disposed of accordingly.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances – Not applicable

3.2 Mixtures

EC Classification No. 1272/2008

Component Name	Chemical Identity of the Substance	Concentration (% w/v)	CAS No.	Hazard Statement(s)
Immunoassay Speciality II - Level 3	None	Not Applicable	Not Applicable	Not Applicable

EC Classification No. 67/548/EEC

Component Name	Chemical Identity of the Substance	Concentration (% w/v)	CAS No.	EC Classification and Risk phrases
Immunoassay Speciality II - Level 3	None	Not Applicable	Not Applicable	Not Applicable

4. FIRST AID MEASURES

4.1 Description of first aid measures	
Inhalation	If inhaled, remove to fresh air. If breathing becomes difficult, call a physician.
Skin Contact	In case of skin contact, wash immediately with soap and copious quantities of water.
Eye Contact	Flush with copious amounts of water for at least 15 minutes. Assure adequate flushing by separating eyelids with fingers. Call a physician.
Ingestion	If swallowed wash out mouth with water, provided person is conscious. Call a physician.
4.2 Most important symptoms and effects, both acute and delayed	May cause irritation to skin and eyes, may be irritating to mucous membranes and upper respiratory tract. Avoid contact with skin, inhalation and ingestion.
4.3 Indication of any immediate medical attention and special treatment needed	Call an internal person trained in First Aid if available, or contact a physician.

5. FIREFIGHTING MEASURES

5.1 Extinguishing media	As appropriate for surrounding fire
5.2 Special hazards arising from the substance or mixture	May emit toxic fumes under fire conditions.
5.3 Advice for firefighters	Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

6. ACCIDENTAL RELEASE MEASURES	
6.1 Personal precautions, protective equipment and emergency procedures	**Precaution** Treat material as you would human body fluids. Wear appropriate personal protective equipment (see section 8.2.2)
6.2 Environmental Precautions	None determined
6.3 Methods and materials for containment and cleaning up	Treat material as you would human body fluids. Disposal should, therefore include autoclaving at 121°C for 20 minutes prior to appropriate disposal with regard to local regulations. Alternatively, decontamination using a 0.1% sodium hypochlorite is acceptable. Perform this type of decontamination in a fume hood.
6.4 Reference to other sections	Refer to Section 8 & 13

7. HANDLING AND STORAGE	
7.1 Precautions for safe handling	Wear personal protective equipment (see section 8.2.2). Wash thoroughly after handling. Do not use if skin is cut or scratched. Avoid contact with eyes, skin and clothing. Do not eat, drink or smoke when using this product.
7.2 Conditions for safe storage, including any incompatibilities	Store at temperatures and conditions as indicated on the product label.
7.3 Specific end use (s)	*In vitro* diagnostic use

8. EXPOSURE CONTROLS/PERSONAL PROTECTION	
8.1 Control Parameters	Not determined
8.2 Exposure Controls	
8.2.1 Appropriate engineering controls	Ensure adequate ventilation.
8.2.2 Personal protective equipment	
Eye/Face Protection	Protective glasses
Hand Protection	Standard laboratory rubber or latex gloves
Skin Protection	Laboratory coat
Respiratory Protection	Not applicable
8.2.3 Environmental Exposure Controls	Not determined

9. PHYSICAL AND CHEMICAL PROPERTIES	
9.1 Information on basic physical and chemical properties	
Appearance	Lyophilised
Colour	Pale yellow liquid when reconstituted
Odour	Not determined
Odour threshold (ppm)	Not determined
pH	Not determined
Melting point / Freezing point	Not determined
Initial boiling point and boiling range	Not determined
Flash point (^{o}C)	Not determined
Evaporation rate	Not determined
Flammability (solid, gas)	Not determined
Upper/lower flammability or explosive limits	Not determined
Vapour pressure	Not determined
Vapour Density	Not determined
Relative Density	Not determined
Solubility(ies)	Not determined
Partition coefficient: (n-octanol/water)	Not determined
Auto ignition temperature (°C)	Not determined
Decomposition temperature (^{o}C)	Not determined
Viscosity (mPa.s)	Not determined
Explosive properties	Not determined
Oxidising properties	Not determined
9.2 Other information	No data available

10. STABILITY AND REACTIVITY	
10.1 Reactivity	Not determined
10.2 Chemical Stability	Stable
10.3 Possibility of hazardous reactions	Not determined
10.4 Conditions to avoid	Not determined
10.5 Incompatible materials	Strong oxidizing agents and acids
10.6 Hazardous decomposition products	Not determined

11. TOXICOLOGICAL INFORMATION	
11.1 Information on toxicological effects	
Acute toxicity Ingestion Inhalation Skin Contact Eye Contact	Not determined Not determined Not determined Not determined Not determined
Skin corrosion/irritation	Not determined
Serious eye damage/eye irritation	Not determined
Respiratory or skin sensitization	Not determined
Germ cell mutagenicity	Not determined
Carcinogenicity	Not determined
Reproductive toxicity	Not determined
STOT – Single exposure	Not determined
STOT- Repeated exposure	Not determined
Aspiration hazard	Not determined
11.2 Other information	The serum in this kit is of human origin. See section 2.3.

12. ECOLOGICAL INFORMATION	
12.1 Toxicity	Not determined
12.2 Persistence and degradability	Not determined
12.3 Bioaccumulative potential	Not determined
12.4 Mobility in soil	Not determined
12.5 Results of PBT and vPvB assessment	Not determined
12.6 Other adverse effects	Not determined

13. DISPOSAL CONSIDERATIONS	
13.1 Waste Treatment Methods	Treat material as you would human body fluids. Disposal should, therefore include autoclaving at 121°C for 20 minutes prior to appropriate disposal with regard to local regulations. Alternatively, decontamination using a 0.1% sodium hypochlorite is acceptable. Perform this type of decontamination in a fume hood.
13.2 Additional Information	Not determined

14. TRANSPORT INFORMATION	
14.1 UN Number	Not classified as hazardous for transport
14.2 UN Proper Shipping Name	Not determined
14.3 Transport hazard class (es)	Not applicable
14.4 Packing Group	Not applicable
14.5 Environmental Hazards	Not determined
14.6 Special Precautions for User	Refer to section 7
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable

15. REGULATORY INFORMATION This safety data sheet complies with the requirements of EU Regulations 1907/2006 (REACH), 1272/2008 (CLP) & 453/2010.	
15.1 Safety, health and environmental Regulations/legislation specific for the substance or mixture	Not determined
15.2 Chemical Safety Assessments	A CSA has not been carried out

16. OTHER INFORMATION
The information provided herein is believed to be correct as of the date hereof but does not purport to be all-inclusive and shall be used only as a guide. The information present in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. The recipient of our products is responsible for observing any National Laws and guidelines applicable.