ALFA WASSERMANN
Diagnostic Technologies, LLC

SAFETY DATA SHEET

SECTION 1 – PRODUCT AND COMPANY IDENTIFICATION

Product name	Level 1 and Level 2 Chemistry Controls
Catalog number	C1-4 and C1-5
Product use	For monitoring the performance of the diagnostic test accuracy and precision of quantitative determinations made on Alfa Wassermann Clinical Chemistry Systems.
Company name	Alfa Wassermann Diagnostic Technologies, LLC
Company address	4 Henderson Drive West Caldwell, New Jersey 07006
Country	USA
Telephone number	1-800-220-4488
Fax number	1-973-276-0383
Email	info@alfawassermannus.com
Website	www.AWDT.us
Emergency Telephone number	Toll Free: 1-866-419-ALFA (2532)

SECTION 2 – HAZARDS IDENTIFICATION

Hazard classification Biohazard

GHS label elements



Other hazards

Inhalation	May cause systemic effects.
Ingestion	May be harmful if swallowed. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea.

SECTION 3 – COMPOSITION/ INFORMATION ON INGREDIENTS

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.

SECTION 4 – FIRST AID MEASURES

Skin contact	Wash with soap and plenty of water. Remove contaminated clothing and treat with dilute virucidal disinfectant (1%) briefly. Wash skin in detergent and water after swabbing with a virucidal disinfectant (such as Virkon).
Eye contact	Immediately flush with plenty of water or eye wash solution for up to ten minutes. Seek medical attention.
Inhalation	Remove victim to fresh air. Seek medical attention.
Ingestion	Wash out mouth thoroughly with water. Seek medical attention.

SECTION 5 – FIRE-FIGHTING MEASURES	
Flammable	No
Thermal decomposition	Gases which are damaging to health do not form in dangerous quantities.
Extinguishing media	Extinguish with water spray, carbon dioxide, dry chemical or material appropriate for the surrounding fire.
Protection of firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Firefighting instructions	Use standard firefighting procedures and consider the hazards of other involved materials.

SECTION 6 – ACCIDENTAL RELEASE MEASURES	
Personal precautions	Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation and treat material as you would human body fluids.
Methods for containment and cleaning up	Absorb spill with vermiculite or other inert material. Dispose of waste in accordance with all applicable Federal, state, local and provincial environmental regulations.

SECTION 7 – HANDLING AND STORAGE	
Handling	Wear gloves and protective clothing. Wash thoroughly after handling.
Storage	Store at 2-8°C.

SECTION 8 – EXPOSURE CONTROL/ PERSONAL PROTECTION	
Exposure limits	Not available.
Personal protective equipment	☑ Gloves ❒ Respirator ☑ Eye ❒ Footwear ☑ Clothing ❒ Other

SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES	
Physical state	Solid
Color	Pale yellow
Odor	None
pH value	Not determined
Boiling point (°C)	Not applicable
Melting point (°C)	Not determined
Flash point	Not determined
Substance does not have any oxidizing properties	Not determined
Ignition temperature	Not determined
Explosion limits	Not explosive
Vapor pressure	Not determined
Density	Not determined
Solubility in water	Soluble
Viscosity	Not determined

SECTION 10 – STABILITY AND REACTIVITY	
Chemical stability	Stable under normal conditions.
Incompatibility with other substances	Not available
Hazardous decomposition products	Not available

SECTION 11 – TOXICOLOGICAL INFORMATION	
LD50 oral	Not known
LD50 intraperitoneal	Not known
LD50 skin	Not known
LC50 inhalation	Not known
Toxicologic information	Not thoroughly investigated.

SECTION 12 – ECOLOGICAL INFORMATION	
Water hazard class	Data not yet available

SECTION 13 – DISPOSAL CONSIDERATIONS	
Waste disposal	Dispose as infectious waste. Contaminated instruments and surfaces should be disinfected in accordance with your employer's chemical-specific and universal/ standard precautions. Disposal should include autoclaving at 121°C for 20 minutes prior to appropriate disposal with regard to local regulations. Alternatively, decontamination using 0.1% sodium hypochlorite is acceptable. Perform this type of decontamination in a fume hood. Dispose in accordance with all applicable regulations.

SECTION 14 – TRANSPORT INFORMATION	
GGVE/GGVS	Data not yet available.
ICAO/IATA-DGR	Data not yet available.
IMDG-CODE	Data not yet available.
RID/ADR	Data not yet available.
UN-Nr	Data not yet available.
MFAG	Data not yet available.
EMS	Data not yet available.

SECTION 15 – REGULATORY INFORMATION	
US federal regulations	This product contains no hazardous chemicals in reportable quantities according to the Chemicals Hazard Information and Packaging (CHIP 3).
Hazard symbol	Biohazard
Warnings	Material is of human origin; exercise due care.
Precautions	Wear gloves and protective clothing. Wash thoroughly after handling.

SECTION 16 – OTHER INFORMATION	
Supplier's notes	This safety data sheet has been complied, controlled and approved in accordance with the regulations in force. It is the user's responsibility to determine the suitability of this information for the adoption of necessary safety precautions. We reserve the right to revise the Safety Data Sheet periodically as new information becomes available.
Recommended restrictions on use	For in vitro diagnostic use only.
Disclaimer of expressed and implied warranties	Although reasonable care has been taken in the preparation of this document, we extend no warranties and make no representation as to the accuracy or completeness of the information contained herein, and assume no responsibility regarding the suitability of this information for the user's intended purposes or for the consequences of its use. Each individual should make a determination as to the suitability of the information for their particular purposes.
Preparation information	P/N 701197-138 Rev A 7/14

END OF SDS