


**SAFETY DATA SHEET**

**SECTION 1 – PRODUCT AND COMPANY IDENTIFICATION**

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

**SECTION 2 – HAZARDS IDENTIFICATION**

<b>Hazard classification</b>	Biohazard
<b>GHS label elements</b>	
<b>Other hazards</b>	
<b>Inhalation</b>	May cause systemic effects.
<b>Ingestion</b>	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**

<b>Skin contact</b>	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).
<b>Eye contact</b>	Immediately flush with plenty of water or eye wash solution for up to ten minutes. Seek medical attention.
<b>Inhalation</b>	Remove victim to fresh air. Seek medical attention.
<b>Ingestion</b>	Wash out mouth thoroughly with water. Seek medical attention.

**SECTION 5 – FIRE-FIGHTING MEASURES**

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

**SECTION 6 – ACCIDENTAL RELEASE MEASURES**

<b>Personal precautions</b>	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.
<b>Methods for containment and cleaning up</b>	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**

<b>Handling</b>	Wear gloves and protective clothing. Wash thoroughly after handling.
<b>Storage</b>	Store at 2-8°C.

**SECTION 8 – EXPOSURE CONTROL/ PERSONAL PROTECTION**

<b>Exposure limits</b>	Not available.
<b>Personal protective equipment</b>	<input checked="" type="checkbox"/> Gloves <input type="checkbox"/> Respirator <input checked="" type="checkbox"/> Eye <input type="checkbox"/> Footwear <input checked="" type="checkbox"/> Clothing <input type="checkbox"/> Other

**SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES**

<b>Physical state</b>	Solid
<b>Color</b>	Pale yellow
<b>Odor</b>	None
<b>pH value</b>	Not determined
<b>Boiling point (°C)</b>	Not applicable
<b>Melting point (°C)</b>	Not determined
<b>Flash point</b>	Not determined
<b>Substance does not have any oxidizing properties</b>	Not determined
<b>Ignition temperature</b>	Not determined
<b>Explosion limits</b>	Not explosive
<b>Vapor pressure</b>	Not determined
<b>Density</b>	Not determined
<b>Solubility in water</b>	Soluble
<b>Viscosity</b>	Not determined

**SECTION 10 – STABILITY AND REACTIVITY**

<b>Chemical stability</b>	Stable under normal conditions.
<b>Incompatibility with other substances</b>	Not available
<b>Hazardous decomposition products</b>	Not available

**SECTION 11 – TOXICOLOGICAL INFORMATION**

<b>LD50 oral</b>	Not known
<b>LD50 intraperitoneal</b>	Not known
<b>LD50 skin</b>	Not known
<b>LC50 inhalation</b>	Not known
<b>Toxicologic information</b>	Not thoroughly investigated.

**SECTION 12 – ECOLOGICAL INFORMATION**

<b>Water hazard class</b>	Data not yet available
---------------------------	------------------------

**SECTION 13 – DISPOSAL CONSIDERATIONS**

<b>Waste disposal</b>	<p>Dispose as infectious waste. Contaminated instruments and surfaces should be disinfected in accordance with your employer's chemical-specific and universal/standard precautions.</p> <p>Dispose 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.</p> <p>Dispose in accordance with all applicable regulations.</p>
-----------------------	--

**SECTION 14 – TRANSPORT INFORMATION**

<b>GGVE/GGVS</b>	Data not yet available.
<b>ICAO/IATA-DGR</b>	Data not yet available.
<b>IMDG-CODE</b>	Data not yet available.
<b>RID/ADR</b>	Data not yet available.
<b>UN-Nr</b>	Data not yet available.
<b>MFAG</b>	Data not yet available.
<b>EMS</b>	Data not yet available.

**SECTION 15 – REGULATORY INFORMATION**

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

**SECTION 16 – OTHER INFORMATION**

<b>Supplier's notes</b>	This safety data sheet has been compiled, 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.
<b>Recommended restrictions on use</b>	For in vitro diagnostic use only.
<b>Disclaimer of expressed and implied warranties</b>	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.
<b>Preparation information</b>	P/N 701197-138 Rev A 7/14

**END OF SDS**