MATERIAL SAFETY DATA SHEET

SECTION 1. IDENTIFICATION

Catalog #: 60-9552-0

Product Name: DPP® HIV 1/2 Rapid Test Control Pack

Synonyms: The Chembio DPP HIV Reactive/Nonreactive Controls are quality control reagents for use with the Chembio DPP HIV 1/2 Assay only.

General Use: The Chembio DPP HIV Reactive/Nonreactive Controls are human, plasma-based reagents. The Controls are specifically formulated and manufactured to ensure performance of the test, and are used to verify the user's ability to properly perform the test and interpret the results. The HIV 1 and HIV 2 Reactive Controls will produce a REACTIVE Test Result and have been manufactured to produce a faint Test "T" line. The Nonreactive Control will produce a NONREACTIVE Test Result.

Manufacturer:
ZeptoMetrix Corporation
25 Kenwood Circle, Suite 6
Franklin, MA 02038, USA
Phone: 1-508-553-5800

Distributed by:
Chembio Diagnostic Systems, Inc.
3661 Horseblock Rd.
Medford, NY 11763, USA
Phone: 1-631-924-1135
www.chembio.com

Emergency Phone: 1-800-327-3635

SECTION 2. HAZARDS IDENTIFICATION

Substance	% Concentration	CAS #	E.C. Directive 1999/45/EC
Sodium Azide	0.09%	26628-22-8	Due to concentration <0.1%, this preparation is not classified as dangerous on the basis of health and/or environmental effects.

Note: This product does contain material derived from human sources and may be considered a biohazard and/or Regulated Medical Waste in your state. Check your local environmental regulations.

A heat inactivation procedure was carried out on each member of the Chembio DPP HIV 1/2 Rapid Test Control Pack. This method is validated to be effective for the inactivation of HIV. However, no method can be guaranteed 100% effective. This material should be handled appropriately with the requisite Good Laboratory Practices and Universal Precautions.

SECTION 3. COMPOSITION / INFORMATION ON INGREDIENTS

Control Kit: The Chembio DPP HIV 1/2 Rapid Test Control Pack consists of three vials each containing 0.5 mL human plasma. One vial contains plasma non-reactive for HIV, a second with plasma reactive for HIV-1 and the third reactive for HIV-2. All contents were subjected to a heat inactivation procedure.

SECTION 4. FIRST AID MEASURES

Inhalation: If inhaled, move to fresh air. If breathing is difficult, give oxygen. If not breathing, give artificial respiration and immediately seek medical attention.

Ingestion: If the patient is conscious, wash out mouth with water, give one or two glasses of water or milk to dilute immediately. Get immediate medical attention.

Skin Contact: Take off all contaminated clothing immediately. Wash off with soap and plenty of water. Wash contaminated clothing before re-use.

Eye Contact: Check for, and if possible, remove contact lenses. Rinse immediately with generous amounts of water, adequately flushing by separating the eyelids with fingers, for at least 15 minutes. If exposure symptoms develop, seek medical attention.

SECTION 5. FIRE FIGHTING MEASURES

Flash Point: No method used

Flammable Limits: LEL: Not Applicable, UEL: Not Applicable

Extinguishing Media: Use whatever is appropriate for the surrounding area.

Special Fire Fighting Procedures: It is always best to wear a self-contained breathing apparatus. Use whatever is required in the surrounding area for extinguishing fires.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Spill/Leak: Avoid creating aerosol or direct contact with skin, eyes, mucous membranes and clothing by wearing appropriate lab Personnel Protective Equipment (PPE), including gloves, lab coat or apron and eye/face protection (goggles). In the event of a hazardous material spill, contain the spill if it is safe to do so and immediately move to a safe area. Isolate the hazard area and ventilate if appropriate. Ensure that appropriate spill cleanup materials and PPE are available. Wear chemical resistant rubber gloves and a laboratory apron. Exercise appropriate precaution to avoid direct contact with skin or eyes. Take up with absorbent material. Wipe up area with a damp paper towel and place in a biohazard container. Disinfect spill area with a 10% bleach solution. Dispose as biohazardous waste.

SECTION 7. HANDLING AND STORAGE

Handling: Wear appropriate Personnel Protective Equipment (PPE), including gloves, lab coat or equivalent and eye/face protection. Avoid splashing, spills and the generation of aerosols.

Storage: Store at 8-30°C. No special storage precautions required.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ventilation: Use general room ventilation.

Respiratory Equipment: None required.

Protective Gloves: Wear standard laboratory protective gloves. Replace torn or punctured gloves promptly.

Eye Protection: Wear standard laboratory safety glasses. Contact lenses should not be worn in the laboratory.

Skin and Body:	Wear appropriate body protection, including but not limited to closed toe shoes, laboratory coat or equivalent.
Comments:	Standard biohazard precautions should be employed when using serum, plasma or blood samples.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance and Odor:	Clear, pale amber solution with no odor
pH:	7.5 ± 0.5
Specific Gravity:	N/D
Boiling Point (^{o}F):	N/D
Melting Point (^{o}F):	N/A
Vapor Pressure:	N/D
Evaporation Rate:	N/D
Solubility in Water:	Soluble
N/A – Not Applicable	N/D = Not Determined

SECTION 10. STABILITY AND REACTIVITY

Stability:	The product is stable under normal use and storage conditions
Conditions to Avoid:	None determined
Substances to Avoid:	Avoid contact with metals (aluminum, mercury, copper, lead, zinc) and acids. Do not dispose of Sodium Azide or other chemicals down the drain.
Hazardous Decomposition Products:	May emit toxic fumes under normal fire conditions. Sodium azide can react with heavy metals to form explosive azides.
Hazardous Polymerization:	Will not occur

SECTION 11. TOXICOLOGICAL INFORMATION

Acute:	This product is not known to have any specific health or toxological effects if used as offered for its intended purpose.
Carcinogen or Suspected Carcinogen:	None of the components are listed as a carcinogen or suspected carcinogen.
Medical Conditions Aggravated by Exposure:	May contain active human disease causing material. None currently known.
Chronic:	None known if used as offered for its intended purpose.
Inhalation:	Inhalation of mists may cause respiratory irritation and possible systemic effects similar to ingestion.

Ingestion:	Contains human serum or other human source material. Ingestion of sodium azide has been reported to cause shortness of breath, nausea, vomiting, restlessness, diarrhea, lowering of blood pressure (hypotension) and collapse. Rated highly toxic in animals.
Skin Contact:	May cause mild irritation. May contain active human disease causing material. Prolonged and extensive skin contact may result in absorption with systemic symptoms similar to ingestion.
Eye Contact:	May cause irritation.
Acute Toxicity Values:	Sodium Azide: LD50 Oral: 27 mg/kg (rat); LD50 Skin: 20 mg/kg (rabbit)

SECTION 12. ECOLOGICAL INFORMATION

Ecological effects of this material have not been determined. The LD50 for sodium azide in Daphnia pulex is reported to be 4.2 mg/L/96 hr. @ 15°C and in Rainbow Trout is reported to be 0.8-1.6 mg/L/96 hr. @ 13°C, Wt 1.4 G.

SECTION 13. DISPOSAL CONSIDERATION

Method: Disposal of hazardous wastes, product or packaging must be conducted in accordance with all applicable Local, State and Federal Regulations. Contact the authority having jurisdiction for your area for specific disposal requirements.

SECTION 14. TRANSPORTATION INFORMATION

Proper Shipping Name:	Chembio DPP HIV 1/2 Rapid Test Control Pack
Technical Name:	Heat Inactivated Defibrinated Human Plasma with 0.09% Sodium Azide
UN Number:	Not Applicable
Hazard Class and Packaging Group:	Not Applicable
Labels:	Not Applicable
Packing Instruction (Passenger Aircraft):	Not Applicable
Packing Instruction (Cargo Aircraft):	Not Applicable
Unit Volume:	3 x 0.5 mL
Primary Container Type:	Polypropylene

SECTION 15. OTHER REGULATORY INFORMATION

SARA 311/312: Hazard Categories for Reporting	Not Hazardous
Canadian WHMIS Classification	Not Applicable
EU Classification (90/492/EE)	Not Applicable
EU Hazard and Precautionary Statements	None
California Proposition 65	None
Minnesota Pollution Control Agency: List of Acute Hazardous Waste	Sodium Azide (<0.1%)

SECTION 16. OTHER INFORMATION

WARNING – POSSIBLE HAZARDOUS MATERIAL

Any product prepared from human blood, plasma or serum should be handled cautiously as a hazardous material according to good manufacturing practices.

If substantial amounts of reagents containing sodium azide are disposed of in plumbing systems, sodium azide may build up and form metal azides with copper or lead. This may produce a potential explosion hazard. See product insert or "Safety Management CDC-22 (United States Center for Disease Control) Decontamination of Laboratory Sink Drains to Remove Azide Salts".

The Chemical Safety Assessment has been carried out for the mixture by the manufacturer. The information contained herein is accurate to the best knowledge of Chembio Diagnostic Systems, Inc. Chembio makes no warranty of any kind, expressed or implied, concerning the safe use of this material in the process or in combination with any other substances. Since the use of this information and the conditions of use of the product are not within the control of Chembio Diagnostic Systems, it is the users' obligation to assure safe use of the product.

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