

SECTION 3. COMPOSITION / INFORMATION ON INGREDIENTS

Control Kit: The Chembio DPP HIV-Syphilis Rapid Test Control Pack consists of three vials each containing human plasma. One vial contains plasma negative for both HIV-1/2 and *T. pallidum* antibodies, a second with plasma reactive for HIV-1 and *T. pallidum* antibodies and a third vial with plasma reactive for HIV-2 antibodies only. All contents were subjected to a heat inactivation procedure.

SECTION 4. FIRST AID MEASURES

Inhalation: If inhaled, move to fresh air and keep at rest in a position comfortable for breathing. If breathing is difficult, give oxygen. If not breathing, give artificial respiration and immediately seek medical attention.

Ingestion: Do not induce vomiting. If the patient is conscious, wash out mouth with water. Never give anything by mouth to an unconscious person. Get immediate medical attention.

Skin Contact: Take off all contaminated clothing immediately. Wash thoroughly with antibacterial soap and warm 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 extinguishing measures and methods that are appropriate to local circumstances and the surrounding environment.

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: The individual kit components within the test kit should be handled only by qualified personnel. Utilize Good Laboratory Practices and safety guidelines for handling chemicals

and other hazards. Wear appropriate Personnel Protective Equipment (PPE), including gloves, lab coat or equivalent and eye/face protection. Avoid splashing, spills and the generation of aerosols. Avoid contact with skin and eye. Wash hands thoroughly after handling. Do not eat or drink while handling product.

Storage: Store at 2-8°C in. No special storage precautions required.
NOTE: the handling and storing of the packaged kit should not pose any threat to the shipper. If the product integrity is in question due to excessive damage, utilize proper safety procedures and handle using appropriate PPE.

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: Clear, pale amber solution.

Upper/lower flammability or explosive limits: No data available.

Odor: No odor.

Odor Threshold: No data available.

Vapor Pressure: Not determined.

Vapor density: No data available.

pH: 7.5 ± 0.5

Relative density: No data available.

Melting Point/freezing point: Not applicable.

Solubility (ies): Soluble.

Initial boiling point and boiling range: Not determined.

Flash point: No data available.

Evaporation Rate: Not determined.

Flammability: No data available.

Partition coefficient: No data available.

Auto-ignition temperature: No data available.

Decomposition temperature: No data available.



Viscosity: No data available.

SECTION 10. STABILITY AND REACTIVITY

Reactivity: No data available.
Stability: The product is stable under recommended storage conditions.
Possibility of Hazardous Reactions: No data available.
Conditions to Avoid: None determined.
Incompatible Material: 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 Product: May emit toxic fumes under normal fire conditions. Sodium azide can react with heavy metals to form explosive azides.

SECTION 11. TOXICOLOGICAL INFORMATION

Acute Toxicity: This product is not known to have any specific health or toxicological effects if used as offered for its intended purpose.
Skin Corrosion/Irritation: 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.
Serious Eye Damage/Irritation: May cause irritation.
Respiratory or Skin Sensitization: Inhalation of mists may cause respiratory irritation and possible systemic effects similar to ingestion.
Germ Cell Mutagenicity: No data available
Carcinogenicity: None of the components are listed as a carcinogen or suspected carcinogen.
Reproductive Toxicity: No data available.
STOT-Single Exposure: No data available.
Aspiration Hazard: No data available.

SECTION 12. ECOLOGICAL INFORMATION

Toxicity: No data available.
Persistence and Degradability: No data available.
Bioaccumulative Potential: No data available.
Mobility in Soil: No data available.
Other Adverse Effects: No data available.

SECTION 13. DISPOSAL CONSIDERATION

Method: Material has undergone heat inactivation. All human derived materials should be handled as if the material is infectious. The use of universal precautions is required by trained



personnel. 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

UN Number: Not Applicable.
 Proper Shipping Name: Chembio DPP HIV-Syphilis Rapid Test Control Pack
 Transport Hazard Class(es): Not applicable.
 Packaging Group: Not applicable.
 Environmental Hazard: Not applicable.
 Bulk Transport: Not applicable.
 Labels Required: Human Specimen Label, per Classification Section 3.6.2.2.3.8 of IATA DGR.
 IATA Packaging Requirements: Human Specimen Label, per Classification Section 3.6.2.2.3.8 of IATA DGR.

SECTION 15. 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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