

## SAFETY DATA SHEET

### SECTION 1. IDENTIFICATION

Catalog #: 60-9507-0, 60-9522-0 (HIV201), 60-9527-0 (HIV201), 60-9528-0 (HIV202), 60-9529-0 (HIV202)

Product Name: SURE CHECK<sup>®</sup> HIV 1/2 Assay

Synonyms: A qualitative screening test kit for the detection of antibodies to HIV 1/2 in human fingerstick and venous whole blood, serum and plasma



General Use: The Chembio SURE CHECK<sup>®</sup> HIV 1/2 assay is a single-use immunochromatographic, rapid, qualitative in vitro test which uses a combination of antigens for the detection of antibodies to Human Immunodeficiency Virus Types 1 and 2 (HIV 1/2) in fingerstick whole blood, venous whole blood, serum or plasma specimens. The Chembio SURE CHECK<sup>®</sup> HIV 1/2 Assay is intended for use as a point-of-care test to aid in the diagnosis of infection with HIV-1 and HIV-2. This test is suitable for use in multi-test algorithms designed for the statistical validation of rapid HIV test results. When multiple rapid HIV tests are available, this test should be used in appropriate multi-test algorithms.

Manufacturer: Chembio Diagnostic Systems, Inc.  
3661 Horseblock Road, Medford NY 11763  
Phone: 631-924-1135  
[www.chembio.com](http://www.chembio.com)

Emergency Phone: 1-800-327-3635  
1-631-924-1135

### SECTION 2. HAZARDS IDENTIFICATION

The preparation is classified as hazardous under E.C. Directive 1999/45/EC.  
The preparation is classified as Acute Toxicity, Oral Category 4 under E.C. Directive 1272/2008.

| Substance           | % Concentration | CAS        | NFPA Rating   | E.C Directive 1272/2008   |             | E.C. Directive 1999/45/EC |  |
|---------------------|-----------------|------------|---|---|-------------|---------------------------|--|
|                     |                 |            |   | GHS   | Signal Word | EC Hazard Symbol          | R&S Phrases                                  |
| <b>Sodium Azide</b> | 0.2%            | 26628-22-8 |  |  | Warning     | Xn                        | R25<br>R32<br>R52<br>S23<br>S24/25<br>S29/35 |

Hazard Statements: H302: May be harmful if swallowed  
H315: May cause skin irritation  
H317: May cause an allergic skin reaction  
H319: Causes serious eye irritation  
H332: May be harmful if inhaled  
H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled  
H412: Harmful to aquatic life with long lasting effects  
EUH 208: Contains 'gentamicin sulfate'. May produce an allergic reaction  
EUH032: Contact with acids liberates very toxic gas



Precautionary Statements: P261: Avoid breathing dust/fume/gas/mist/vapors/spray  
 P262: Do not get in eyes, on skin, or on clothing  
 P273: Avoid release to the environment  
 P280: Wear protective gloves/protective clothing/eye protection/face protection  
 P332, P313: If skin irritation occurs: Get medical attention  
 P342, P311: If experiencing respiratory symptoms: call a poison center or doctor/physician  
 P391: Collect spillage



This test kit should be used only by qualified personnel trained in laboratory procedures and familiar with their potential hazards. Specific warnings are given in the instructions for use. The absence of a specific warning should not be interpreted as an indication of safety.

**SECTION 3. COMPOSITION / INFORMATION ON INGREDIENTS**

Test Device: A membrane strip containing antigens reactive to HIV-1 and HIV-2 with a colloidal gold detection conjugate housed in a plastic tube.  
 NOTE: This kit does not contain any live or active levels of HIV-1 or HIV-2.

Running Buffer: 350 µL dilute buffer solution in a sealed vial.

| Chemical Ingredient     | Chemical Information   |
|-------------------------|--|
| Gold Conjugate Pad      | <p><b>Contains:</b> Tween 20 (9005-64-5), Protein A (91932-65-9), Sodium Phosphate Monobasic (7558-80-7), Sodium Phosphate Dibasic (7558-79-4), Bovine Serum Albumin (9048-46-8), Sodium Azide (26628-22-8), Triton X (9002-93-1), Hydrogen Tetrachloroaurate(III) Trihydrate (16961-25-4)</p> <p><b>Gold Pad Concentration:</b> Contains 0.01-0.1% concentration or less of the chemicals listed above.</p> <p>The mixture may cause skin and/or eye irritation upon contact in highly sensitive individuals. The material and its container should be disposed of in a safe way and in accordance with Local, State and Federal Regulations. No known or anticipated adverse health hazards are likely for the small amount of chemical mixture provided on this strip. Utilize Good Laboratory Practices.</p> |
| Nitrocellulose Membrane | <p><b>Contains:</b> Synthetic peptides (Biotinylated) to HIV-1 and HV-2, Protein A (91932-65-9), Casein (9000-71-9), Tween 20 (9005-64-5), Sodium Hydroxide (1310-73-2).</p> <p><b>Nitrocellulose Concentration:</b> Contains 0.01-0.1% concentration or less of the chemicals listed above.</p> <p>The mixture may cause skin and/or eye irritation upon contact in highly sensitive individuals. The material and its container should be disposed of in a safe way and in accordance with Local, State and Federal Regulations. No known or anticipated adverse health hazards are likely for the small amount of chemical mixture provided on this strip. Utilize Good Laboratory Practices.</p>   |
| Sample Pad              | <p><b>Contains:</b> NP-40 Tergitol (127087-87-0), Sodium Azide (26628-22-8)</p> <p><b>Sample Pad Concentration:</b> Contains 0.01-0.1% concentration or less of the chemicals listed above.</p> <p>The mixture may cause skin and/or eye irritation upon contact in highly sensitive individuals. The material and its container should be disposed of in a safe way and in accordance with Local, State and Federal Regulations. No known or anticipated adverse health hazards are likely for the small amount of chemical mixture provided on this strip. Utilize Good Laboratory Practices.</p>  |

|                |  |
|----------------|--|
| Running Buffer | <p><b>Contains:</b> Sodium Phosphate Dibasic (7558-79-4), Sodium Phosphate Monobasic (7558-80-7), Sodium Chloride (7647-14-5), Sodium Azide (26628-22-8), Avidin (1405-69-2), Tween 20 (9005-64-5), Sodium Hydroxide (1310-73-2), Gentamicin Sulfate (1405-41-0), animal serum.</p> <p>Appearance: Off-white solution<br/>         Odor: Slight odor<br/>         pH: ~9<br/>         Specific gravity: ~1<br/>         Water solubility: Miscible<br/>         Boiling point: ~100°C</p> <p><b>Running Buffer Concentration:</b> Contains 0.01-0.1% concentration or less of the following chemicals: Avidin, Tween 20, Sodium Hydroxide.</p> <p>  Contains 0.2% Sodium Azide; 0.125% Gentamicin Sulfate, Sodium Phosphate Dibasic, Sodium Phosphate Monobasic and Sodium Chloride; 5-15% animal serum.</p> <p>The mixture may cause skin and/or eye irritation upon contact in highly sensitive individuals. The material and its container should be disposed of in a safe way and in accordance with Local, State and Federal Regulations. No known or anticipated adverse health hazards are likely for the small amount of chemical mixture provided in the buffer. Utilize Good Laboratory Practices.</p> |
|----------------|--|

**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
- 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 dust 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 precautions 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.

**Storage:** Store at 8-30°C. 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**

Available Physical/Chemical Properties and Characteristics are listed in Section 3.

## **SECTION 10. STABILITY AND REACTIVITY**

**Stability:** The product is known to be stable under normal use and storage conditions.

**Conditions to avoid:** Avoid excessive heat, maintain ambient temperatures.  
**Running Buffer:** Avoid strong acids, bases, oxidizers and organic compounds. Avoid water and solid metals (aluminum, mercury, copper, lead, zinc) as contact may generate toxic gas.

**Hazardous Decomposition Products:** May emit toxic fumes under normal fire conditions. Sodium Azide can react with heavy metals to form explosive azides.


**Incompatible Materials:** Sodium Azide has been known to react with lead or copper plumbing. Do not dispose of Sodium Azide or other chemicals down the drain.

**SECTION 11. TOXICOLOGICAL INFORMATION**

Acute: This product is not known to have any specific health or toxicological effects if used as offered for its intended purpose.

Chronic: None known if used as offered for its intended purpose.

Comments: Individual chemical toxicological information has been provided in Section 3. Additional information provided below:

| Component  | Toxicological Information                                 |
|--|---|
| Sodium Azide  | LD50 Oral: 27 mg/kg (rat)<br>LD50 Skin: 20 mg/kg (rabbit) |

**SECTION 12. ECOLOGICAL INFORMATION**

|                            |   |
|----------------------------|---|
| Component:<br>Sodium Azide | Environmental Fate: When released into the soil, this material is not expected to biodegrade. When released into the soil, this material is expected to leach into groundwater. When released into the air, this material may be moderately degraded by photolysis. |
|                            | Environmental Toxicity: This material is expected to be very toxic to aquatic life. The LC50/96-hour values for fish are less than 1 mg/L.  |

**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. Processing, use or contamination of the kit components may change waste management requirements and options. Contact the authority having jurisdiction for your area for specific disposal requirements.

**SECTION 14. TRANSPORTATION INFORMATION**

This product must be shipped in accordance with all applicable Local, State and Federal Regulations. As offered for shipping (based on single kit only):  
DOT: Not a dangerous good.  
IMDG: Not a dangerous good.  
IATA: Not a dangerous good.

Considerations: Processing, use or contamination of the kit components may change shipping requirements and options.

**SECTION 15. REGULATORY INFORMATION**

|   |                      |
|---|----------------------|
| SARA 311/312: Hazard Categories for Reporting                     | Not Hazardous        |
| Canadian WHMIS Classification                                     | Not Applicable       |
| EU Classification (90/492/EEC)                                    | Not Applicable       |
| EU Hazard and Precautionary Statements                            | See Section 2        |
| California Proposition 65   | None                 |
| Minnesota Pollution Control Agency: List of Acute Hazardous Waste | Sodium Azide (≥0.1%) |



**SECTION 16. OTHER INFORMATION**

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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