



Clearview® COMPLETE HIV 1/2 SAFETY DATA SHEET

SECTION 1.

IDENTIFICATION

Catalog #: 92111

Product Name: **Clearview® COMPLETE HIV 1/2**

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

General Use: The **Clearview® COMPLETE HIV 1/2** assay is a single use, immunochromatographic, rapid, in vitro, qualitative test which uses a combination of antigens to detect antibodies to Human Immunodeficiency Virus Type 1 (HIV-1) and Type 2 (HIV-2) in serum, plasma or whole blood. The **Clearview® COMPLETE 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	Distributed by:	Alere Scarborough, Inc. 10 Southgate Road Scarborough, Maine 04074 - United States T +1 (207) 730-5750 ts.scr@alere.com
Emergency Phone:	1-800-327-3635, 1-631-924-1135		+1 (207) 730-5750

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.

Preparation/Substance: Components contributing to the Hazard: Sodium Azide					
% Concentration	CAS	E.C Directive 1272/2008		E.C. Directive 1999/45/EC	
		GHS	Signal Word	EC Hazard Symbol	R&S Phrases
0.2%	26628-22-8		Warning	Xn	R25 R32 R52 S23 S24/25 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



Clearview® COMPLETE HIV 1/2 SAFETY DATA SHEET

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	Contains: 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) Gold Pad Concentration: Contains 0.01-0.1% concentration or less of the chemicals listed above. 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.
Nitrocellulose Membrane	Contains: Synthetic peptides (Biotinylated) to HIV-1 and HIV-2, Protein A (91932-65-9), Casein (9000-71-9), Tween 20 (9005-64-5), Sodium Hydroxide (1310-73-2). Nitrocellulose Concentration: Contains 0.01-0.1% concentration or less of the chemicals listed above. 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.
Sample Pad	Contains: NP-40 Tergitol (127087-87-0), Sodium Azide (26628-22-8) Sample Pad Concentration: Contains 0.01-0.1% concentration or less of the chemicals listed above. 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.



**Clearview® COMPLETE HIV 1/2
SAFETY DATA SHEET**

Running Buffer	<p>Contains: 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 Odor: Slight odor pH: ~9 Specific gravity: ~1 Water solubility: Miscible Boiling point: ~100°C</p> <p>Running Buffer Concentration: Contains 0.01-0.1% concentration or less of the following chemicals: Avidin, Tween 20, sodium hydroxide.</p> <p> Contains 0.2% sodium azide; 0.1-5% gentamicin sulfate, sodium phosphate dibasic, sodium phosphate monobasic and sodium chloride; 5-15% animal serum. 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.
-------------	---



Clearview® COMPLETE HIV 1/2 SAFETY DATA SHEET

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.

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.



**Clearview® COMPLETE HIV 1/2
SAFETY DATA SHEET**

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.

SECTION 12.

ECOLOGICAL INFORMATION

Component	Ecological Information
Sodium Azide 	LD50 Oral: 27 mg/kg (rat) LD50 Skin: 20 mg/kg (rabbit)

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/EE)	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.

© 2015 Alere. All rights reserved.

The Alere Logo, Alere and Clearview are trademarks of the Alere group of companies.

All other trademarks referenced are trademarks of their respective owners.