

SAFETY DATA SHEET

SECTION 1.

IDENTIFICATION

Catalog #: 65-9520-0, 65-9520-1, 65-9521-0

Name: DPP® Syphilis Screen and Confirm

Synonyms: A qualitative screening device for simultaneous and separate detection of treponemal and non-treponemal markers of syphilis at the point of care in human serum, plasma or whole blood.

General Use: The Chembio DPP® Syphilis Screen & Confirm Assay is a single-use immunochromatographic rapid screening test for the simultaneous detection of antibodies against non-treponemal and *Treponema pallidum* antigens in fingerstick whole blood, venous whole blood, serum, and plasma. The Chembio DPP Syphilis Screen & Confirm Assay is intended for use as a point-of-care (POC) test to aid in the screening and confirmation of infection with Syphilis.

Manufacturer: Chembio Diagnostic Systems, Inc.
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Emergency Phone: 1-800-327-3635
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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 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.

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
- H361: Suspected of damaging fertility or the unborn child.
- 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

DPP® Syphilis Screen and Confirm consists of two parts - the test device and liquid running buffer.
 Test Device: A membrane containing Syphilis antigens to *T. pallidum* and antigens for non-Treponema, Protein A and anti-human IgM antibody control line conjugated to colloidal gold particles, and a sample delivery membrane strip housed in a plastic cassette.
 Running Buffer: 6mL dilute buffer solution in a sealed vial.

Chemical Ingredient	Chemical Information
Gold Conjugate Pad	<p>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), Monoclonal Mouse Anti-human IgM antibody.</p> <p>Gold Pad Concentration: 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>Contains: Syphilis antigens, Protein A (91932-65-9), Sodium Phosphate Monobasic (7558-80-7), Sodium Phosphate Dibasic (7558-79-4), Sodium Azide (26628-22-8), Sodium Chloride (7647-14-5), EDTA Disodium Salt (6381-92-6), Choline Chloride (67-48-1), Phosphate Buffered Saline.</p> <p>Nitrocellulose Concentration: 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>Contains: NP-40 Tergitol (127087-87-0), Sodium Azide (26628-22-8)</p> <p>Sample Pad Concentration: 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>

Chemical Ingredient	Chemical Information
Tris	<p>CAS# 77-86-1 LD50 Oral: 5900 mg/kg (rat) May cause eye and skin irritation. May cause drowsiness or dizziness. May cause respiratory irritation. The material and its container should be disposed of in a safe way and in accordance with Local, State and Federal Regulations. Concentration: This product contains 0.1-5% of this chemical. No known or anticipated adverse health hazards are likely for the small amount of chemical mixture provided in the product. Utilize Good Laboratory Practices.</p>
Sea Block	<p>CAS# Not Applicable May be harmful if inhaled. May be harmful if swallowed. May cause skin irritation. May cause eye irritation. The material and its container should be disposed of in a safe way and in accordance with Local, State and Federal Regulations. Concentration: This product contains 5-15% of this chemical. No known or anticipated adverse health hazards are likely for the small amount of chemical mixture provided in the product. Utilize Good Laboratory Practices.</p>
NP-40 Tergitol	<p>CAS# 127087-87-0 May be harmful if inhaled. May be harmful if swallowed. May cause skin irritation. May cause eye irritation. The material and its container should be disposed of in a safe way and in accordance with Local, State and Federal Regulations. Concentration: This product contains 0.1-5% of this chemical. No known or anticipated adverse health hazards are likely for the small amount of chemical mixture provided in the product. Utilize Good Laboratory Practices.</p>
Sodium Chloride	<p>CAS# 7647-14-5 LD50 Oral: 3000 mg/kg (rat) LC50 Inhalation: 42000 mg/m³ LD50 Skin: >10,000 mg/kg (rabbit) May cause eye and skin irritation. May cause damage to organs, skin, eyes, stomach. When ingested in large quantities may cause gastrointestinal upset. The material and its container should be disposed of in a safe way and in accordance with Local, State and Federal Regulations. Concentration: This product contains 0.1-5% of this chemical. No known or anticipated adverse health hazards are likely for the small amount of chemical mixture provided in the product. Utilize Good Laboratory Practices.</p>
Sodium Azide	<p>CAS# 26628-22-8 LD50 Oral: 27 mg/kg (rat) LD50 Skin: 20 mg/kg (rabbit)</p> <div style="display: flex; align-items: center;">   <div style="margin-left: 10px;"> <p>Very toxic by inhalation, in contact with skin and ingestion. Wear suitable protective clothing, gloves and eye/face protection. Avoid contact with metals. The material and its container should be disposed of in a safe way and in accordance with Local, State and Federal Regulations. Concentration: This product contains 0.09% sodium azide. No known or anticipated adverse health hazards are likely for the small amount of chemical mixture provided in the product. Utilize Good Laboratory Practices.</p> </div> </div>

Chemical Ingredient	Chemical Information
Microcide III	<p>CAS# 96118-96-6 LD50 Oral: 5440 mg/kg (rat) LC50 Inhalation: 1.23 mg/L (rat) May cause an allergic skin reaction and skin irritation. May cause eye irritation. The material and its container should be disposed of in a safe way and in accordance with Local, State and Federal Regulations. Concentration: This product contains <0.01% of this chemical. No known or anticipated adverse health hazards are likely for the small amount of chemical mixture provided in the product. Utilize Good Laboratory Practices.</p>
Gentamicin Sulfate	<p>CAS# 1405-41-0 LD50 Oral: >5000 mg/kg (rat) Caution, may be harmful if inhaled. May cause respiratory tract infection. May be harmful if swallowed. May be harmful if absorbed through skin. May cause skin irritation. May cause eye irritation. The material and its container should be disposed of in a safe way and in accordance with Local, State and Federal Regulations. Concentration: This product contains 0.1-5% of this chemical. No known or anticipated adverse health hazards are likely for the small amount of chemical mixture provided in the product. Utilize Good Laboratory Practices.</p>
Streptomycin Sulfate	<p>CAS# 3810-74-0 LD50 Oral: 430 mg/kg (rat) Caution, may be harmful if inhaled. May be harmful if swallowed. May be harmful if absorbed through skin. May cause skin irritation. May cause eye irritation. The material and its container should be disposed of in a safe way and in accordance with Local, State and Federal Regulations. Concentration: This product contains 0.1-5% of this chemical. No known or anticipated adverse health hazards are likely for the small amount of chemical mixture provided in the product. 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 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 2-30 °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

DPP Syphilis Running Buffer:

Appearance: Off-white solution
 Odor: Slight odor
 pH: ~9
 Specific gravity: ~1
 Water solubility: Miscible
 Boiling point: ~100 °C

See Section 3 for additional information.

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 and Sample 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: May emit toxic fumes under normal fire conditions. Sodium azide can react with heavy metals to form explosive azides.

Products:


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) LD50 Skin: 20 mg/kg (rabbit)

SECTION 12. ECOLOGICAL INFORMATION

Component: 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/EE)	Not Applicable
EU Risk and Safety Phrases	None
California Proposition 65	Streptomycin Sulfate ($\geq 0.1\%$)
Minnesota Pollution Control Agency: List of Acute Hazardous Waste	Sodium Azide ($\geq 0.1\%$)

SECTION 16. OTHER INFORMATION

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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