

SAFETY DATA SHEET

SECTION 1. IDENTIFICATION

Catalog #: 65-9560-0

Product Name: Chembio DPP® Zika IgM Assay System

Synonyms: A qualitative screening test kit for the detection of antibodies to Zika virus in human fingerstick and venous whole blood, serum and plasma

General Use: The Chembio DPP® Zika IgM Assay System is intended for the presumptive detection of Zika virus IgM antibodies in human serum (plain or separation gel) and fingerstick whole blood, EDTA venous whole blood, or EDTA plasma (each collected alongside a patient-matched serum specimen) specimens collected from individuals meeting the CDC Zika virus clinical criteria (e.g., a history of clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active Zika transmission at the time of travel, or other epidemiological criteria for which Zika virus testing may be indicated). *Specimens from symptomatic patients or returning travelers from endemic areas should not be collected prior to 8 days after onset of symptoms or risk of exposure, respectively.* The assay is intended for use in laboratories in the United States that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high or moderate complexity tests, or by similarly qualified non-U.S. laboratories, consistent with the latest CDC guidance for the diagnosis of Zika virus infection.



The Chembio DPP® Zika IgM Assay System is intended for use by trained laboratory personnel who are proficient in performing and interpreting immunoassays. The assay is only for use under the Food and Drug Administration’s Emergency Use Authorization.

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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 1272/2008		E.C. Directive 1999/45/EC	
				GHS	Signal Word	EC Hazard Symbol	R&S Phrases
Sodium Azide	< 0.1%	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 'gentamycin sulfate'. May produce an allergic reaction
 EUH 032: 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 advice/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: Two independent membrane strips housed in a plastic cassette. One membrane containing antigen to detect IgM antibodies with a colloidal gold detection conjugate, Protein A control line and a sample delivery membrane strip housed in a plastic cassette.

Buffer: 7.5 mL (7500 uL) dilute buffer solution in a sealed vial.

Chemical Ingredient	Chemical Information
Gold Conjugate Pad (S2)	<p>Contains: Polyvinyl Alcohol (9002-89-5), Tris (77-86-1), Tween 20 (9005-64-5), Sodium Phosphate Monobasic (7558-80-7), Sodium Phosphate Dibasic (7558-79-4), Bovine Serum Albumin (9048-46-8), Sodium Azide (26628-22-8), Sodium Ascorbate (134-03-2), Sucrose (57-50-1), Trisodium Citrate (68-04-2), 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>

Chemical Ingredient	Chemical Information
Nitrocellulose Membrane (S2)	<p>Contains: Sodium Azide (26628-22-8), Zika Virus NS1 Recombinant antigen, Protein A (91932-65-9), Sodium Phosphate Monobasic (7558-80-7), Sodium Phosphate Dibasic (7558-79-4), Sodium Chloride (7647-14-5), Potassium Chloride (7447-40-7).</p> <p>Nitrocellulose Membrane 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>
EDTA Disodium	<p>CAS# 6381-92-6 LD50 Oral: 2000 mg/kg (rat)</p> <p>May be harmful if inhaled. May cause respiratory irritation. 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.</p> <p>Concentration: This product contains <0.2% 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>
EDTA Tetrasodium	<p>CAS# 10378-23-1 LD50 Oral: 630-1260 mg/kg (rat)</p> <p>May be harmful if inhaled. May cause respiratory irritation. May cause skin irritation. The material and its container should be disposed of in a safe way and in accordance with Local, State and Federal Regulations.</p> <p>Concentration: This product contains < 0.2% 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 Phosphate Dibasic	<p>CAS# 7558-79-4</p> <p>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.</p> <p>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 Phosphate Monobasic	<p>CAS# 7558-80-7</p> <p>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.</p> <p>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>

Chemical Ingredient	Chemical Information
Sodium Chloride	CAS# 7647-14-5 LD50 Oral: 3000 mg/kg (rat) LC50 Inhalation: 42000 mg/m³ May cause eye and skin irritation. May cause damage to organs, skin, eyes, and/or 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.
Sodium Azide	CAS# 26628-22-8 LD50 Oral: 27 mg/kg (rat) LD50 Skin: 20 mg/kg (rabbit)  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 < 0.1% 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.
Tru Block™3	CAS# Not Applicable No information available Concentration: This product contains 0.1-5% concentration or less 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.
Tergitol	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% concentration or less 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.
Tween 20	CAS# 9005-64-5 LD50 Oral: 36,700mg/kg (rat) May cause respiratory irritation. 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% concentration or less 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.

Chemical Ingredient	Chemical Information
Animal Serum	<p>CAS# Not Applicable 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 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>
Urea	<p>CAS# 57-13-6 LD50 Oral: 8471 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>
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 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>
Anti-Human IgG	<p>CAS# Not Applicable No information available 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>

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 2-8°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 Zika IgM Buffer

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

Also see Available Physical/Chemical Properties and Characteristics 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) 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 CONSIDERATIONS

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: Developmental Toxicity	Streptomycin Sulfate ($\geq 0.1\%$)
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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