SAFETY DATA SHEET

SECTION 1. IDENTIFICATION

Catalog #: 65-9503-0

Product Name: DPP® EDN System

Synonyms: Rapid quantitative immune-chromatographic test and reader system intended to measure Eosinophil-Derived Neurotoxin (EDN, ng/mL) in human fingerstick and venous whole blood, and plasma.

General Use: The Chembio 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 System, 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 System, it is the user's obligation to assure safe use of the product. The quantitative DPP EDN System has been developed by Chembio using its proprietary immune-chromatographic Dual Path platform, DPP (US/7189522 and WO/2006/099191) and dedicated Microreader. The Chembio DPP® EDN System is intended for use by trained laboratory personnel who are proficient in performing and interpreting immunoassays.

Manufacturer: Chembio Diagnostic Systems, Inc.

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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 'gentamicin sulfate'. May produce an allergic reaction

Statements:	EUH032: Contact with acids liberates very toxic gas Precautionary 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

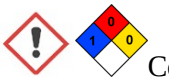
laboratory procedures and familiar with their potential hazards. Specific warnings are given in the instructions for use. The absence of a specific warning should not be interpreted as an indication of safety.

SECTION 3. COMPOSITION / INFORMATION ON INGREDIENTS

Test Device: A membrane strip containing antibody reactive to EDN antigen with a colloidal gold detection conjugate housed in a plastic cassette.
NOTE: This kit does not contain any live or active levels of infectious agents.

Running Buffer: 10 mL dilute buffer solution in a bottle.

Chemical Ingredient	Chemical Information
Gold Conjugate Pad	**Contains:** Tween 20 (9005-64-5), 141), Sodium Phosphate Dibasic (7558-79-4), Bovine Serum Albumin (9048-46-8), Sodium Azide (26628-22-8), Gold Chloride (27988-77-8), Trisoudium Citrate (6132-04-3), Sodium Ascorbate (134-03-2). **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:** Anti EDN Monoclonal and Goat anti Rabbit Polyclonal antibodies. **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.

DPP EDN Buffer	**Contains:** Sodium Phosphate Dibasic (7558-79-4), Sodium Phosphate Monobasic (7558-80-7), Sodium Chloride (7647-14-5), Sodium Azide (26628-22-8), Tween 20 (9005-64-5), Gentamicin Sulfate (1405-41-0),Streptomicin Sulfate (3810-74-0), EDTA Tetrasodium (10378-23-1), EDTA Disodium (6381-92-6),animal serum (CAS # not available) , NP 40(Tergitol) (127087-87-0) Appearance: Off-white solution Odor: Slight odor pH: ~9.5 Specific gravity: ~1 Water solubility: Miscible Boiling point: ~100°C **DPP EDN Buffer Concentration:** Contains 0.01-0.1% concentration or less of Tween 20.  Contains 0.9% Sodium Azide; 0.125% Gentamicin Sulfate, 0.125% Streptomycin Sulfate, Sodium Phosphate Dibasic, Sodium Phosphate Monobasic and Sodium Chloride; 0.186% EDTA Disodium,0.2% EDTA Tetrasodium,10% 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.

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 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

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 toxological effects if used as offered for its intended purpose.

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

Comments: Individual chemical toxological 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/EEC)	Not Applicable
EU Hazard and Precautionary Statements	See Section 2
California Proposition 65	Stroptomycin Sulfate (≥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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