



SAFETY DATA SHEET

SECTION 1. IDENTIFICATION

Catalog #: 65-9569-0, 65-9572-0 (CE Mark)
 Product Name: Chembio DPP® COVID-19 IgM/IgG System
 Synonyms: A qualitative screening test kit for the detection of Immunoglobulin M (IgM) and Immunoglobulin G (IgG) antibodies to SARS-CoV-2 in fingerstick whole blood, venous whole blood, serum, or plasma (lithium heparin or EDTA)
 General Use: The Chembio DPP COVID-19 IgM/IgG System is a single-use rapid immunochromatographic test for the detection and differentiation of Immunoglobulin M (IgM) and Immunoglobulin G (IgG) antibodies to SARS-CoV-2 in fingerstick whole blood, EDTA venous whole blood, serum, or EDTA plasma samples. The Chembio DPP COVID-19 IgM/IgG System is intended for use in clinical and point-of-care (POC) settings to aid in the diagnosis of SARS-CoV-2 infection only in patients who meet COVID-19 clinical and/or epidemiological criteria. This test is intended to provide a preliminary result. Results of this test cannot be used as the sole basis of patient management decisions and must be combined with patient history and other diagnostic information to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.
 Manufacturer: Chembio Diagnostic Systems, Inc.
 3661 Horseblock Road, Medford, NY 11763
 Phone: 631-924-1135
www.chembio.com
 Emergency Phone: +001 631 924 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
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 containing antigens specific to COVID-19 housed in a plastic case. One strip contains anti-human IgM antibodies conjugated to colloidal gold and the other strip contains anti-human IgG antibodies conjugated to colloidal gold. The plastic case also contains a sample delivery strip as well as another strip for buffer delivery to the membrane strips.

Running Buffer: 9.5 mL (9500 µL) 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
Gold Conjugate Pad (S3)	<p>Contains: Polyvinyl Alcohol (9002-89-5), Tris (77-86-1), 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), 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).</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 Membranes (S2 and S3)	<p>Contains: Sodium Azide (26628-22-8), COVID-19 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>
Sample Pad (S1)	<p>Contains: TRU Block 3, Bovine Serum Albumin (9048-46-8), Tween 20 (9005-64-5), Tris (77-86-1), Sodium Chloride (7647-14-5), Sucrose (57-50-1).</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>
EDTA Disodium	<p>CAS# 6381-92-6 LD50 Oral: 2000 mg/kg (rat) 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 $\leq 0.2\%$ 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>

Chemical Ingredient	Chemical Information
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% 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.</p>
Tween 20	<p>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.</p>
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>

Chemical Ingredient	Chemical Information
Streptomycin Sulfate	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.

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

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) 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	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.

Contact Info:
Chembio Diagnostic Systems, Inc.
3661 Horseblock Road
Medford, New York 11763 USA
Telephone: 631-924-1135