

## SAFETY DATA SHEET

### SECTION 1. IDENTIFICATION

Catalog #: 60-9557-0

Product Name: DPP® COVID-19 IgM/IgG Control Pack

Synonyms: The Chembio DPP COVID-19 IgM/IgG Control pack is an external quality control kit for use with the DPP COVID-19 IgM/IgG System only.

General Use: The DPP COVID-19 IgM/IgG Reactive/Non-reactive Controls are normal human, serum-based reagents. The controls are specifically formulated and manufactured to ensure performance of the test and are used to verify the user's ability to properly perform the test and interpret the results. Use of the control reagents manufactured by another source may not produce the required results, and therefore, may not meet the requirements for an adequate quality assurance program for the DPP COVID-19 IgM/IgG System. The performance characteristics of the DPP COVID-19 IgM/IgG Control Pack have not been established for any other assay or instrument different from the DPP Micro Reader or DPP Micro Reader II.





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### SECTION 2. HAZARDS IDENTIFICATION

This material has the potential to transmit infectious agents and should be handled according to Biosafety Level 2. Any products potentially containing blood-borne viruses have been heat inactivated. The remaining products have not been inactivated via heat, chemicals or radiation. The use of universal precautions is required by trained personnel.

Substance	% Concentration	CAS #	E.C. Directive 1272/2008
ProClin 950	< 0.1%	2682-20-4	Due to concentration <0.1%, this preparation is not classified as dangerous on the basis of health and/or environmental effects. Signal Word: Warning  
Sodium Azide	< 0.1%	26628-22-8	Due to concentration <0.1%, this preparation is not classified as dangerous on the basis of health and/or environmental effects. Signal Word: Warning  

### **SECTION 3. COMPOSITION / INFORMATION ON INGREDIENTS**

Control Kit: The DPP COVID-19 IgM/IgG Control Pack consists of three vials each containing 0.25mL human serum. One vial contains serum non-reactive for SARS-CoV 2 IgM Antibody and SARS-CoV-2 IgG antibody, a second with serum reactive for SARS-CoV 2 IgM Antibody and SARS-CoV-2 IgG antibody, and the third with serum reactive for SARS-CoV-2 IgG antibody. All contents were subjected to a heat inactivation procedure.

### **SECTION 4. FIRST AID MEASURES**

Inhalation: If inhaled, move to fresh air and keep at rest in a position comfortable for breathing. If breathing is difficult, give oxygen. If not breathing, give artificial respiration and immediately seek medical attention.

Ingestion: Do not induce vomiting. If the patient is conscious, wash out mouth with water. Never give anything by mouth to an unconscious person. Get immediate medical attention.

Skin Contact: Take off all contaminated clothing immediately. Wash thoroughly with antibacterial soap and warm 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

Extinguishing Media: Use extinguishing measures and methods that are appropriate to local circumstances and the surrounding environment.

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 aerosol 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. Avoid contact with skin and eyes. Wash hands thoroughly after handling. Do not eat or drink while handling product.
- Storage:** Store at 2-8°C in. 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

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| <b>Appearance (Physical State, Color, etc.):</b>     | Liquid, Transparent Pale Yellow. |
| <b>Upper/lower flammability or explosive limits:</b> | No data available.               |
| <b>Odor:</b>   | No data available.               |
| <b>Odor Threshold:</b>                               | No data available.               |
| <b>Vapor Pressure:</b>                               | No data available.               |
| <b>Vapor density:</b>                                | No data available.               |
| <b>pH:</b>   | No data available.               |
| <b>Relative density:</b>                             | No data available.               |
| <b>Melting point/freezing point:</b>                 | No data available.               |
| <b>Solubility(ies):</b>                              | No data available.               |
| <b>Initial boiling point and boiling range:</b>      | No data available.               |
| <b>Flash point:</b>                                  | No data available.               |
| <b>Evaporation rate:</b>                             | No data available.               |
| <b>Flammability:</b>                                 | No data available.               |
| <b>Partition coefficient:</b>                        | No data available.               |
| <b>Auto-ignition temperature:</b>                    | No data available.               |
| <b>Decomposition temperature:</b>                    | No data available.               |
| <b>Viscosity:</b>                                    | No data available.               |

**SECTION 10. STABILITY AND REACTIVITY**

Reactivity:	No data available.
Stability:	The product is stable under recommended storage conditions.
Possibility of Hazardous Reactions:	No data available.
Conditions to avoid:	No data available.
Incompatible Material:	No data available.
Hazardous Decomposition Products:	No data available.

**SECTION 11. TOXICOLOGICAL INFORMATION**

Acute Toxicity:	No data available.
Skin Corrosion/ Irritation:	No data available.
Serious Eye Damage/Irritation:	No data available.
Respiratory or Skin Sensitization:	No data available.
Germ Cell Mutagenicity:	No data available.
Carcinogenicity:	No data available.
Reproductive Toxicity:	No data available.
STOT-Single Exposure:	No data available.
Aspiration Hazard:	No data available.

**SECTION 12. ECOLOGICAL INFORMATION**

Toxicity:	No data available.
Persistence and Degradability:	No data available.
Bioaccumulative Potential:	No data available.
Mobility in Soil:	No data available.
Other Adverse Effects:	No data available.

**SECTION 13. DISPOSAL CONSIDERATIONS**

Method:	Material has undergone heat inactivation. All human derived materials should be handled as if the material is infectious. The use of universal precautions is required by trained personnel. Disposal of hazardous wastes, product or packaging must be conducted in accordance with all applicable Local, State and Federal Regulations. Contact the authority having jurisdiction for your area for specific disposal requirements.
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**SECTION 14. TRANSPORTATION INFORMATION**

UN Number: Not applicable.  
Proper Shipping Name: DPP COVID-19 IgM/IgG Control Pack  
Transport Hazard Class(es): Not applicable.  
Packaging Group: Not applicable.  
Environmental Hazards: Not applicable.  
Bulk Transport: Not applicable.  
Labels Required: Human Specimen Label, per Classification Section 3.6.2.2.3.8 of IATA DGR.  
IATA Packaging Requirements: Human Specimen Label, per Classification Section 3.6.2.2.3.8 of IATA DGR.

**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	None
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.

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