

## Biocan COVID-19 IgG/IgM Antibody Controls

Instructions for Use Catalog Number: B251PNC  
For use under an Emergency Use Authorization (EUA) Only  
For In Vitro Diagnostic Use

### INTENDED USE

Biocan COVID-19 IgG/IgM Antibody Controls is intended for use as an external positive and negative qualitative quality control to monitor the precision of laboratory testing procedures for the determination of Immunoglobulin G (IgG) and Immunoglobulin M (IgM) antibodies to SARS-CoV-2 on Biocan Tell Me Fast Novel Coronavirus (COVID-19) IgG/IgM Antibody Test. For professional use only.

### SUMMARY AND PRINCIPLE

The use of external quality control material is indicated as an objective assessment of the precision of methods and techniques and is an integral part of good laboratory practices. A positive and negative control is provided to allow performance monitoring of the test system.

### COMPOSITION AND CONTENTS

This positive controls comprises of Anti-SARS-CoV-2 antibodies (IgM and IgG) in horse serum with proclin and negative control comprises of horse serum with proclin. One positive control vial and one negative control vial each of 0.1 mL is provided.

### DIRECTIONS FOR USE

These controls should be treated the same as patient serum/plasma specimens and run in accordance with the instructions for use accompanying the Biocan Tell Me Fast Novel Coronavirus (COVID-19) IgG/IgM Antibody Test.

### STORAGE AND STABILITY

Biocan COVID-19 IgG/IgM Antibody Controls can be used until the expiration date when stored at 2-8 °C and is stable for 10 days once opened providing it is closed tightly after use and promptly returned to storage at 2-8 °C. The controls should always be stored upright and not be used beyond the expiration date.

### LIMITATIONS

1. Do not use the product past the expiration date.
2. If there is evidence of microbial contamination or excessive turbidity in the product, discard the vial.


3. This product is not intended for use as a standard or calibrator.
4. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions.

### PRECAUTIONS

Warning: Biological source material. Treat as potentially infectious.

1. For use under Emergency Use Authorization only. For IN VITRO Diagnostic use only.
2. For professional use only.
3. This test has not been FDA cleared or approved; the test has been authorized by FDA under an Emergency Use Authorization (EUA) for use by laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform moderate or high complexity tests.
4. This test has been authorized only for the presence of IgM and IgG antibodies against SARS-CoV2, not for any other viruses or pathogens.
5. This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb3(b)(1), unless the authorization is terminated or revoked sooner.
5. Do not use the product beyond the expiration date.
6. Adhere to Biosafety Level 2 or other appropriate biosafety practices.
7. Dispose of any discarded materials in accordance with the requirements of your local waste management authorities.
8. For use only with Biocan Tell Me Fast Novel Coronavirus (COVID-19) IgG/IgM Antibody Test.
9. Follow Good Laboratory Practices, wear protective clothing, use disposable gloves and do not eat or drink in the area.
10. All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.

Product Information, Literature and/or SDS please email: [sales@rapidtest.ca](mailto:sales@rapidtest.ca)

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