TECHNOPATH
CLINICAL DIAGNOSTICS

Multichem® **ID-COVID19 G**

Multichem® **ID-COVID19 G**				
REF	**Level**	**Size**	**LOT** **Lot Number**	**Expiry Date**
CVG300P	P	4 x 4mL	CVG030520P	2021-05-31

INSTRUCTIONS FOR USE

IVD

https://eifu.technopathcd.com

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INTENDED USE

Multichem ID-COVID19 G is intended for use as a qualitative quality control serum to monitor the precision of laboratory testing procedures for the determination of antibodies to SARS-CoV-2 (including IgG) on Immunoassay systems listed in the package insert.

SUMMARY AND PRINCIPLE

The use of 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 / reactive control is provided to allow performance monitoring of the test system.

COMPOSITION

This product is prepared from human plasma to which preservatives and stabilizers have been added. This product contains extracts of human origin. The control is used in liquid form for convenience. Multichem ID-COVID19 G control will provide a positive / reactive result for the analytes listed below.

ANALYTES	Antibodies to SARS-CoV-2 (including IgG)

PRECAUTIONS

Warning: Biological source material. Treat as potentially infectious.

1. For *In Vitro* Diagnostic Use.
2. Multichem ID-COVID19 G was prepared using heat inactivated[4] disease state human plasma prepared in non-disease human plasma where each donor unit used in its preparation was tested by United States Food and Drug Administration (FDA) approved methods and found to be negative for antibodies to HIV and HCV, and nonreactive for HBsAg. Because no test method can offer complete assurance that HIV, hepatitis B virus and hepatitis C virus or other infectious agents are absent, this material should be handled as though capable of transmitting infectious diseases.
3. USE UNIVERSAL PRECAUTIONS - This product may also contain other human source material for which there is no approved test. It is recommended that this material be handled in accordance with the OSHA Standard on bloodborne pathogens[1], Biosafety Level 2[2] or other appropriate biosafety practices[3].
4. Dispose of any discarded materials in accordance with the requirements of your local waste management authorities.
5. Material Safety Data Sheet (MSDS) is available for professional user upon request.
6. This product also contains methylisothiazolones, which are compounds of ProClin 950. Methylisothiazolones are classified per applicable European Community (EC) Directives as: skin sensitzation.
7. This product contains: Sodium Azide.

PROCEDURE FOR USE

1. Multichem ID-COVID19 G should be treated the same as patient specimens and run in accordance with the instructions accompanying the instrument, kit or reagent being used.
2. Remove Multichem ID-COVID19 G control from 2-8 °C storage, mix gently.
3. Remove cap and stopper before use.
4. After use, replace cap and promptly return to 2-8 °C storage.
5. Prior to subsequent use, remove from 2-8°C storage, mix gently before sampling.
6. In the event of damage to packaging, contact qcsupport@technopathcd.com

STORAGE AND STABILITY

1. Multichem ID-COVID19 G can be used until the expiration date when stored at 2-8 °C.
2. SARS-CoV-2 IgG is stable for **21 days** once opened providing it is closed tightly after use and promptly returned to storage at 2-8 °C.
3. Should always be stored upright.
4. Must 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 tube.
3. This product is not intended for use as a standard or calibrator.
4. This control must not be used as a substitute for mandatory manufacturers kit control provided with the reagent assay.

REPRESENTATIVE VALUES

The values provided in the data sheet were derived from replicate analyses and are specific for a particular lot of product. These values have been generated using the Immunoassay Systems listed in the package insert and are specific to one measurement procedure.
Technopath make no accuracy claims regarding these values. Tests were performed by the control manufacturer and/ or by independent laboratories.
Laboratory means may vary from the values listed, particularly between different reagent lots, different calibrator lots and during the life of the control. Values are provided only as guidelines, each laboratory should establish its own statistical limits.

BIBLIOGRAPHY

1. US Department of Labor, Occupational Safety and Health Administration, 29 CFR Part 1910.1030, Bloodborne pathogens.
2. US Department of Health and Human Services. Biosafety in Micro- biological and Biomedical Laboratories. 5th ed. Washington, DC: US Government Printing Office; December 2009.
3. World Health Organisation. Laboratory Biosafety Manual. 3rd ed. Geneva: World Health Organisation; 2004.
4. Harada, S., Yoshiyama, H., & Yamamoto, N. (1985). Effect of heat and fresh human serum on the infectivity of human T-cell lymphotropic virus type III evaluated with new bioassay systems. Journal of clinical microbiology, 22(6), 908–911.

Customer Service: Contact Technopath Customer Services or your local representative.

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Roche Cobas				Positive	
ANALYTES	**ASSAY NAME**	**METHOD**	**UNIT**	**MEAN**	**REPRESENTATIVE REACTIVITY**
Antibodies to SARS-CoV-2 (including IgG)	Elecsys Anti-SARS-CoV-2	CMIA	COI	3.76	Reactive

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CONTROL Control

REF Catalog Number

Manufacturer

Use By (yyyy-MM-DD)

LOT Lot Number

IVD *In Vitro* Diagnostic Medical Device

Consult Instructions for Use

Biological Risks

Warning: H317
May cause an allergic skin reaction

Temperature Limitation

INFORMATION FOR USA ONLY
Information needed for United States of America only

PRODUCT OF IRELAND
Product of Ireland

GTIN
Global Trade Item Number

CE