TECHNOPATH
CLINICAL DIAGNOSTICS

Multichem® **ID-COVID19Neg**

Multichem® **ID-COVID19Neg**				
REF	**Level**	**Size**	**LOT** **Lot Number**	**Expiry Date**
CVN100N	N	4 x 2mL	CVN010520N	2023-05-06

INSTRUCTIONS FOR USE

IVD

https://eifu.technopathcd.com

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INTENDED USE

Multichem ID-COVID19Neg is intended for use as a negative qualitative quality control serum to monitor the precision of laboratory testing procedures for the determination of Immunoglobulin G (IgG) antibodies to SARS-CoV-2 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 negative 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 and for convenience, the tube label has a barcode for automation of control ordering process for Abbott ARCHITECT and Abbott Alinity systems.
Multichem ID-COVID19Neg control will provide a negative / none reactive result for the analyte listed below.

ANALYTE	SARS-CoV-2 IgG

PRECAUTIONS

Warning: Biological source material. Treat as potentially infectious.

1. For *In Vitro* Diagnostic Use.
2. 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 sensitization.
7. This product contains: Sodium Azide.

PROCEDURE FOR USE

1. Multichem ID-COVID19Neg 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-COVID19Neg control from 2-8 °C storage, mix gently.
3. The control can be used in one of two ways :
   a) Directly from Control tube
   b) Sample cup
4. Remove cap and place the tube in a sample / control rack or pipette control material into a sample cup and place onto the instrument / analyzer.
5. After use, replace cap and promptly return tubes to 2-8 °C storage.
6. Prior to subsequent use, remove from 2-8°C storage, mix gently and remove cap before sampling.
7. In the event of damage to packaging, contact qcsupport@technopathcd.com

STORAGE AND STABILITY

1. Multichem ID-COVID19Neg can be used until the expiration date when stored at 2-8 °C.
2. Multichem ID-COVID19Neg is stable for 30 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 REACTIVITY

The 'representative reactivity' provided in the package insert were derived from replicate analyses and are specific for a particular lot of product. This 'representative reactivity' has been generated using Immunoassays Systems listed in the package insert and is specific to one measurement procedure. Tests were performed by the Control manufacture and / or by independent laboratories.

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.

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Abbott Architect i		
ANALYTE	**ASSAY NAME**	**Representative Reactivity**
SARS-CoV-2 IgG	SARS-CoV-2 IgG	Negative

Roche Cobas		
ANALYTE	**ASSAY NAME**	**Representative Reactivity**
SARS-CoV-2 IgG	Elecsys Anti-SARS-CoV-2	Negative

Ortho Vitros		
ANALYTE	**ASSAY NAME**	**Representative Reactivity**
SARS-CoV-2 IgG	Anti-SARS-CoV-2 Total	Negative

Techno-path Manufacturing Ltd, Fort Henry Business Park, Ballina, Co. Tipperary, Ireland.
Ph: +353 (0) 61 525700 Web: www.technopathcd.com

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

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