TECHNOPATH
CLINICAL DIAGNOSTICS

Multichem® **ID-SeroNeg**

Multichem® **ID-SeroNeg**				
REF	**Level**	**Size**	LOT **Lot Number**	**Expiry Date**
SR100N	Negative	4 x 5mL	SN071020N	2023-10-31
SR100MN	Negative Mini-kit	1 x 5mL	SN071020N	2023-10-31

INSTRUCTIONS FOR USE

IVD

https://eifu.technopathcd.com

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INTENDED USE

Multichem ID-SeroNeg is intended for use as a negative qualitative quality control serum to monitor the precision of laboratory testing procedures for the analytes and associated Immunoassay systems (ABBOTT & DiaSorin) 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.

Users of Multichem ID-series have access to EDCNet, an internet-based infectious disease QC results monitoring system through Technopath IAMQC Peer software at https://www.technopathcd.com.

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 the automation of the control ordering process for the Abbott ARCHITECT and Alinity systems.

Multichem ID-SeroNeg negative control will provide a negative/non-reactive result for the analytes listed below.

Anti-HIV 1 IgG	**Anti-HBc IgG**	**Anti-HTLV I IgG**
Anti-HCV IgG	**HBsAg**	**Anti-Treponema pallidum IgG**

PRECAUTIONS

Warning: Biological source material. Treat as potentially infectious.

1. For *In Vitro* Diagnostic Use.
2. Each donor unit used in the preparation of this material 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. 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] 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. Methylisothiazolones are classified per applicable European Community (EC) Directives as: skin sensitization.
7. This product contains Sodium Azide.

PROCEDURE FOR USE

1. Multichem ID-SeroNeg is ready-to-use.
2. This product should be treated the same as patient specimens and run in accordance with the instructions accompanying the instrument or reagent kit being used.
3. Remove tube from 2-8 °C storage, mix gently.
4. Remove cap and place the tube in a sample rack as per routine samples.
5. After use, replace cap and 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-SeroNeg can be used until the expiration date when stored at 2-8 °C.
2. Multichem ID-SeroNeg is stable for 90 days once opened providing it is closed tightly after use and 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 representative values obtained for a particular lot of product. These values have been generated using the ABBOTT and DiaSorin Immunoassay Systems 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 Microbiological 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.

ADDITIONAL RESOURCES : QConnect

Multichem ID-SeroNeg includes QConnect, an integrated and simplified QC solution https://www.nrlquality.org.au/qconnect

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

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ABBOTT ARCHITECT i				NEGATIVE	
ANALYTES	**ASSAY NAME**	**METHOD**	**UNITS**	**MEAN**	**Representative Reactivity**
Anti-HCV IgG	Architect Anti-HCV	CMIA	S/CO	0.080	Negative
Anti-HIV 1 IgG	Architect HIV Ag/Ab Combo	CMIA	S/CO	0.380	Negative
Anti-HTLV I IgG	Architect rHTLV-I/II	CMIA	S/CO	0.163	Negative
HBsAg	Architect HBsAg Qualitative II	CMIA	S/CO	0.190	Negative
Anti-HBc IgG	Architect-HBc II	CMIA	S/CO	0.127	Negative
Anti-Treponema pallidum IgG	Architect Syphilis TP	CMIA	S/CO	0.110	Negative

ABBOTT ALINITY i				NEGATIVE	
ANALYTES	**ASSAY NAME**	**METHOD**	**UNITS**	**MEAN**	**Representative Reactivity**
Anti-HCV IgG	Alinity Anti-HCV	CMIA	S/CO	0.084	Negative
Anti-HIV 1 IgG	Alinity HIV Ag/Ab Combo	CMIA	S/CO	0.168	Negative
Anti-HTLV I IgG	Alinity rHTLV-I/II	CMIA	S/CO	0.093	Negative
HBsAg	Alinity HBsAg Qualitative II	CMIA	S/CO	0.421	Negative
Anti-HBc IgG	Alinity-HBc II	CMIA	S/CO	0.234	Negative
Anti-Treponema pallidum IgG	Alinity Syphilis TP	CMIA	S/CO	0.106	Negative

ABBOTT ALINITY s				NEGATIVE	
ANALYTES	**ASSAY NAME**	**METHOD**	**UNITS**	**MEAN**	**Representative Reactivity**
Anti-HCV IgG	Alinity Anti-HCV	CMIA	S/CO	0.092	Negative
Anti-HIV 1 IgG	Alinity HIV Ag/Ab Combo	CMIA	S/CO	0.080	Negative
Anti-HTLV I IgG	Alinity HTLV I/II	CMIA	S/CO	0.178	Negative
HBsAg	Alinity HBsAg	CMIA	S/CO	0.176	Negative
Anti-HBc IgG	Alinity-HBc	CMIA	S/CO	0.194	Negative
Anti-Treponema pallidum IgG	Alinity Syphilis	CMIA	S/CO	0.082	Negative

Footnotes:
■ Values are not provided

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INFORMATION FOR USA ONLY: **This product is not intended for use in donor screening tests.**

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FOR AUSTRALIA ONLY

Sponsor Information:
NRL, 4th Floor Healy Building, 41 Victoria Parade.
FITZROY VICTORIA 3065, AUSTRALIA

CONTROL	REF			LOT	IVD			
Control	Catalog Number	Manufacturer	Use By (yyyy-MM-DD)	Lot Number	*In Vitro* Diagnostic Medical Device	Consult Instructions for Use	Biological Risks	Temperature Limitation

	SN	INFORMATION FOR USA ONLY	DISTRIBUTED BY	PRODUCT OF IRELAND	GTIN
Warning: H317 May cause an allergic skin reaction	Serial Number	Information needed for United States of America only	Distributed By	Product of Ireland	Global Trade Item Number

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