INSTRUCTIONS FOR USE CoV2G

VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Controls

REF 619 9921

Rx ONLY

Intended Use

For *in vitro* diagnostic and Laboratory Professional use.

For use in monitoring the performance of the VITROS Immunodiagnostic and Integrated Systems when used for the determination of IgG antibodies to SARS-CoV-2.

Warnings and Precautions

WARNING: *Potentially Infectious Material*

Treat as if capable of transmitting infection.

Use caution when handling material of human origin. Consider all samples potentially infectious. No test method can offer complete assurance that hepatitis B virus, hepatitis C virus (HCV), human immunodeficiency virus (HIV 1+2) or other infectious agents are absent. Handle, use, store and dispose of solid and liquid waste from samples and test components, in accordance with procedures defined by appropriate national biohazard safety guideline or regulation (e.g. CLSI document M29). [1]

VITROS Anti-SARS-CoV-2 IgG Controls 1 and 2 contain: SARS-CoV-2 IgG negative plasma obtained from donors who were tested individually and who were found to be negative for hepatitis B surface antigen, and for antibodies to hepatitis C virus (HCV) and HIV, using approved methods (enzyme immunoassays).

VITROS Anti-SARS-CoV-2 IgG Control 2 in addition contains: SARS-CoV2 IgG. No testing method can rule out the risk of potential infection, handle as if capable of transmitting infection.

WARNING: *Contains ProClin 950 (CAS 2682–20–4)* [2]

The VITROS Anti-SARS-CoV-2 IgG Controls contain 0.5% ProClin 950. H317: May cause an allergic skin reaction. P280: Wear protective gloves. P302 + P352: IF ON SKIN: Wash with plenty of soap and water. P333 + P313: If skin irritation or rash occurs: Get medical advice/attention. P363: Wash contaminated clothing before reuse.

Refer to www.orthoclinicaldiagnostics.com for the Safety Data Sheets and for Ortho contact information.

WARNING

Materials Provided

3 sets of VITROS Anti-SARS-CoV-2 IgG Controls 1 and 2 (human matrix with anti-microbial agent, 2 mL)

Materials Required but Not Provided

Pipette, sample containers.

Control Storage, Preparation and Handling

Control	Storage Condition		Stability
Unopened	Refrigerated	2–8 °C (36–46 °F)	expiration date
Opened	Refrigerated	2–8 °C (36–46 °F)	≤8 weeks
Opened	Frozen	≤-20 °C (≤-4 °F)	≤8 weeks

- VITROS Anti-SARS-CoV-2 IgG Controls are supplied ready to use.
- VITROS Anti-SARS-CoV-2 IgG Controls are suitable for use until the expiration date on the carton when stored and handled as specified. Do not use beyond the expiration date.
- Avoid repeated freeze-thaw cycles.
- Thoroughly mix controls by inversion and bring to 15–30 °C (59–86 °F) before use.
- Handle controls in stoppered containers to avoid contamination and evaporation. To avoid evaporation, limit the amount of time controls are on the system. Refer to the operating instructions for your system.
- Return to 2–8 °C (36–46 °F) as soon as possible after use, or load only sufficient for a single determination.
- The expiration date for the controls must be entered onto the system. For further information, refer to the operating instructions for your system.

Testing Procedure

Load each control onto the system by transferring an aliquot into a sample container (taking account of the volume required by the test and the minimum fill volume of the container). Process in the same manner as samples, according to the instructions in the appropriate VITROS Immunodiagnostic Products Reagent Pack and Calibrator instructions for use.

Note: Do not use visibly damaged product.

For further information on quality control procedures refer to the operating instructions for your system.
Not all products and systems are available in all countries.

Baseline Statistics

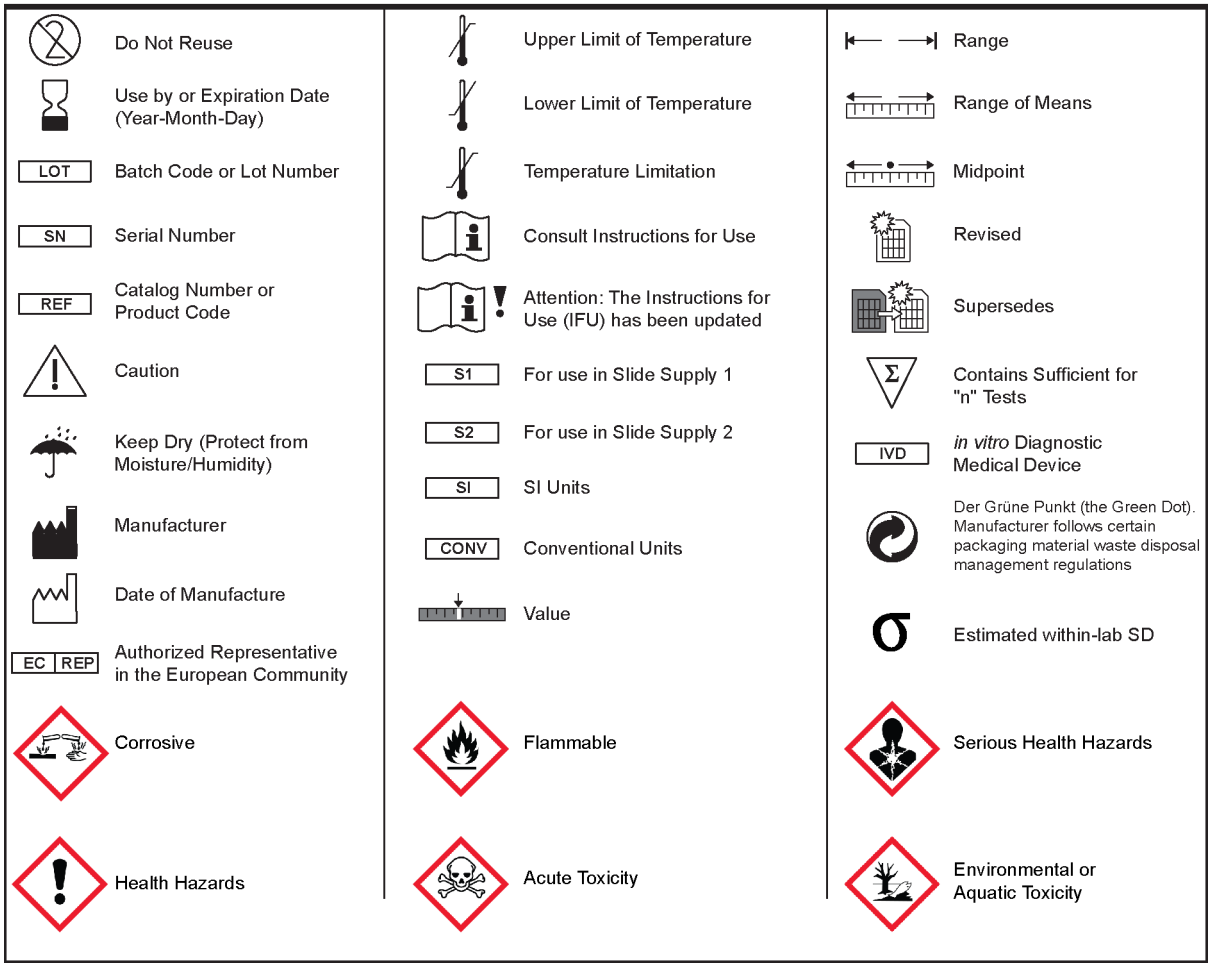
VITROS Anti-SARS-CoV-2 IgG Control 1 should generate Non-reactive (Negative) results.
VITROS Anti-SARS-CoV-2 IgG Control 2 should generate Reactive (Positive) results.

References

1. CLSI. *Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline - Fourth Edition.* CLSI document M29-A4. Wayne, PA: Clinical and Laboratory Standards Institute; 2014.
2. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Glossary of Symbols

The following symbols may have been used in the labeling of this product.



Revision History

Date of Revision	Version	Description of Technical Changes*
2020-05-04	3.0	Materials Provided: changed from 1 mL to 2 mL

The change bars indicate the position of a technical amendment to the text with respect to the previous version of the document.

When this Instructions For Use is replaced, sign and date below and retain as specified by local regulations or laboratory policies, as appropriate.

Signature

Obsolete Date

Conditions of supply: all supplies are made subject to the standard terms and conditions of Ortho Clinical Diagnostics or its distributors. Copies of these are available on request.

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