INSTRUCTIONS FOR USE

CV2Ag

VITROS Immunodiagnostic Products SARS-CoV-2 Antigen Controls

REF 619 9943

Rx ONLY

Intended Use

For *in vitro* diagnostic and laboratory professional use.

For use in monitoring the performance of the VITROS 3600 Immunodiagnostic System and the VITROS 5600/XT 7600 Integrated Systems for the qualitative detection of the SARS-CoV-2 nucleocapsid antigen.

Warnings and Precautions

WARNING:	*Potentially Infectious Material* *Treat as if capable of transmitting infection.* *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]
WARNING:	*Contains 2-methyl-3(2H) isothiazolone (MIT) (CAS 2682-20-4)*[2] *The VITROS SARS-CoV-2 Antigen Controls contain 0.0475% 2-methyl-3(2H) isothiazolone (MIT). H317: May cause an allergic skin reaction. P261: Avoid breathing dust/fume/gas/mist/vapors/spray. P280: Wear protective gloves. P333 + P313: If skin irritation or rash occurs: Get medical advice/attention. P362 + P364: Take off contaminated clothing and wash it before reuse. P501: Dispose of contents/container to an approved waste disposal plant.* *Refer to www.orthoclinicaldiagnostics.com for the Safety Data Sheets and for Ortho contact information.*

WARNING

Materials Provided

3 sets of VITROS SARS-CoV-2 Antigen Controls 1 and 2 (recombinant SARS-CoV-2 nucleocapsid antigen in buffer with bovine serum albumin and antimicrobial agent, 3 mL)

Materials Required but Not Provided

- Pipette, sample containers
- VITROS Immunodiagnostic Products SARS-COV-2 Antigen Extraction Buffer

Control Storage, Preparation and Handling

Control	Storage Condition		Stability
Unopened	Frozen	≤-20 °C (≤-4 °F)	expiration date
Opened	Refrigerated	2–8 °C (36–46 °F)	≤10 weeks
Opened	Frozen	≤-20°C (≤-4°F)	≤10 weeks

- The VITROS SARS-CoV-2 Antigen Controls are supplied frozen.
- Opened controls may be stored frozen (with no more than 1 freeze-thaw cycle).
- VITROS SARS-CoV-2 Antigen 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.
- 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) or ≤-20°C (≤-4°F) as soon as possible after use, or load only sufficient volume for a single determination.
- Baseline statistics for controls should be entered onto the system. For further information, refer to the operating instructions for your system.
- 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

For each control:

- Combine 100 µL VITROS SARS-CoV-2 Extraction Buffer and 400 µL of control into a sample container.
- Mix well (e.g. cover sample container with cap/plug and vortex approx. 3-5 seconds).

Load each control onto the system by transferring an aliquot into a sample container, if needed (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 SARS-CoV-2 Antigen Control 1 should generate Non-reactive results.
VITROS SARS-CoV-2 Antigen Control 2 should generate Reactive 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.

Do Not Reuse	Upper Limit of Temperature	Range
Use by or Expiration Date (Year-Month-Day)	Lower Limit of Temperature	Range of Means
LOT Batch Code or Lot Number	Temperature Limitation	Midpoint
SN Serial Number	Consult Instructions for Use	Revised
REF Catalog Number or Product Code	Attention: The Instructions for Use (IFU) has been updated	Supersedes
Caution	S1 For use in Slide Supply 1	Contains Sufficient for "n" Tests
Keep Dry (Protect from Moisture/Humidity)	S2 For use in Slide Supply 2	IVD *in vitro* Diagnostic Medical Device
Manufacturer	SI SI Units	Der Grüne Punkt (the Green Dot). Manufacturer follows certain packaging material waste disposal management regulations
Date of Manufacture	CONV Conventional Units	Estimated within-lab SD
EC REP Authorized Representative in the European Community	Value	
Corrosive	Flammable	Serious Health Hazards
Health Hazards	Acute Toxicity	Environmental or Aquatic Toxicity

Revision History

Date of Revision	Version	Description of Technical Changes*
2022-07-18	3.0	• Control Storage, Preparation and Handling: – Updated refrigerated stability from "≤5 days" to "≤10 weeks" – Added frozen stability information – Removed statement "DO NOT REFREEZE" – Added statement regarding opened controls frozen stability – Updated "single determination" statement

* 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

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