INSTRUCTIONS FOR USE

VITROS Immunodiagnostic Products SARS-CoV-2 Antigen Extraction Buffer

REF 619 9944

Rx ONLY

Intended Use

For *in vitro* diagnostic and laboratory professional use.

For use to extract nucleocapsid protein from SARS-CoV-2 in swab samples placed in appropriate transport media for use on the automated VITROS 3600 Immunodiagnostic System and the VITROS 5600/XT 7600 Integrated Systems.

Warnings and Precautions

WARNING:	*Potentially Infectious Material* *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 Mixture, 3(2H)-isothiazolone, 5-chloro-2-methyl- with 2-methyl-3(2H)-isothiazolone (CAS 55965-84-9)*[2] *The VITROS SARS-CoV-2 Antigen Extraction Buffer contains ≥0.0015–<0.06% of Mixture, 3(2H)-isothiazolone, 5-chloro-2-methyl- with 2-methyl-3(2H)-isothiazolone. H317: May cause an allergic skin reaction. P280: Wear protective gloves. P333 + P313: If skin irritation or rash occurs: Get medical advice/attention. P362 + P364: Take off contaminated clothing and wash before reuse.* *Refer to www.orthoclinicaldiagnostics.com for the Safety Data Sheets and for Ortho contact information.*

WARNING

Safe Disposal

Follow local disposal regulations based on your location along with recommendations and content in the Safety Data Sheet to determine the safe disposal of this product.

Materials Provided

1 extraction buffer pack containing:

- 4 bottles of VITROS SARS-CoV-2 Antigen Extraction Buffer (28 mL) with antimicrobial agent

Materials Required but Not Provided

- Appropriate volume pipette and sample containers for extraction

Refer to the VITROS Immunodiagnostic Products SARS-CoV-2 Antigen Reagent Pack and Calibrator instructions for use.

Storage, Preparation and Handling

Extraction Buffer	Storage Condition		Stability
Unopened	Refrigerated	2–8 °C (36–46 °F)	Expiration date
Opened	Refrigerated	2–8 °C (36–46 °F)	≤4 weeks

- VITROS SARS-CoV-2 Ag Extraction Buffer is supplied ready to use.
- Do not freeze.

Testing Procedure

Refer to the VITROS Immunodiagnostic Products SARS-CoV-2 Antigen Reagent Pack and Calibrator instructions for use.

Note: Do not use visibly damaged product.

Not all products and systems are available in all countries.

Serious Incident

For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation 2017/746/EU on IVD Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorized representative and to your national authority.

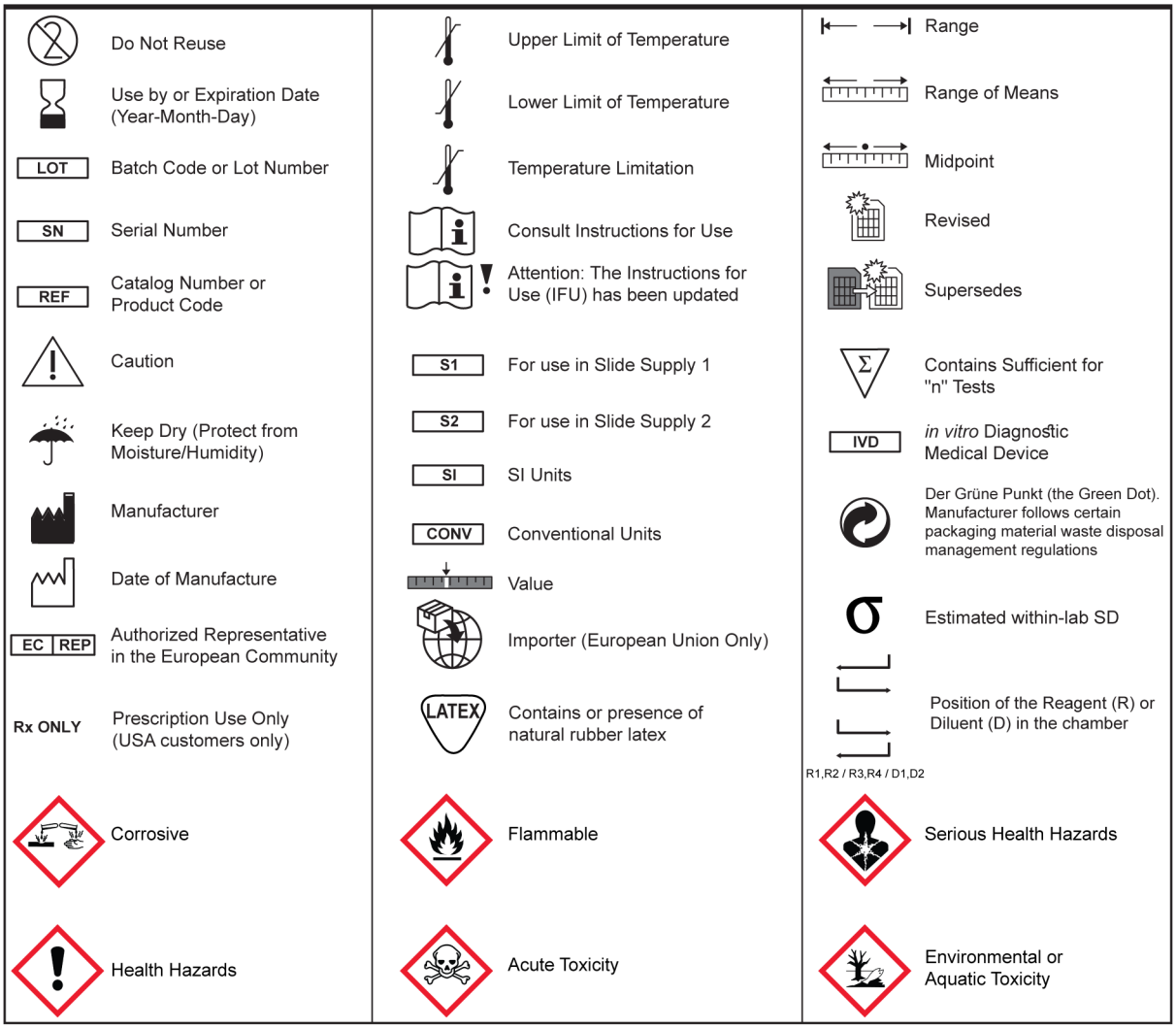
The manufacturer can be contacted via the company website address: www.orthoclinicaldiagnostics.com or by phoning the Ortho Care™ Technical Solutions Center number, which can be found on the website.

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*
2021-11-08	3.0	Updated to comply with IVDR 2017/746 - Annex I Chapter III (20.0 to 20.4)

* 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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