INSTRUCTIONS FOR USE

VITROS Chemistry Products 7% BSA

7% BSA

REF **826 2487**

Rx ONLY

Intended Use

For *in vitro* diagnostic and laboratory professional use.

VITROS Chemistry Products 7% BSA is used to dilute samples when assay values exceed the reportable (dynamic) range using the automated VITROS 250/350/5,1 FS/4600/XT 3400 Chemistry Systems and VITROS 5600/XT 7600 Integrated Systems.

Reagents

VITROS 7% BSA is an aqueous solution of bovine serum, inorganic salts, and preservatives.

Reactive Ingredients

None

Other Ingredients

7% bovine serum albumin, inorganic salts and preservatives

Warnings and Precautions

For *in vitro* diagnostic use only.

WARNING:	***While these products are bovine in origin, they should be handled using the same precautions as with any other blood or blood-derived product.***
WARNING:	***The packaging (vial stopper) of this product contains dry natural rubber, which may cause allergic reactions in some individuals.***

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.

Not all products and systems are available in all countries.

Storage

Storage and Stability

Reagent	Storage Condition		Stability
Unopened	Frozen	≤-18 °C (≤0 °F)	Until expiration date
	Refrigerated	2–8 °C (36–46 °F)	Until expiration date
Opened	Refrigerated	2–8 °C (36–46 °F)	≤28 days if tightly stoppered
	On-analyzer*		≤7 days
	On-analyzer** (2 mL cup)		≤24 hours

* VITROS 250/350/XT 3400 Systems only.

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For additional information and instructions, refer to the operating instructions for your system.

Materials Provided

12 vials (5 mL each) of VITROS 7% BSA

Materials Required but Not Provided

An accurate pipette for performing dilutions

Testing Procedure

Caution:	**Do not use visibly damaged product or product with incompletely sealed packaging.**

1. Warm fluid to room temperature, 18–28 °C (64–82 °F), prior to use (approximately 30 minutes when taken from the refrigerator, 60 minutes from the freezer).
2. Mix thoroughly by gentle inversion. DO NOT SHAKE.
3. After thorough mixing, remove the seal and stopper from each bottle just prior to use. Keep all fluids tightly stoppered when not in use. Upon opening the bottle for first time use, it is recommended to write your initials and the date on the bottle.
4. Refer to the Instructions for Use for the appropriate test for dilution directions.
5. Analyze the specimen according to the operating instructions for your system.
6. Store the tightly stoppered bottle of VITROS 7% BSA in the refrigerator.
7. Discard any unused portion in the cup following testing.

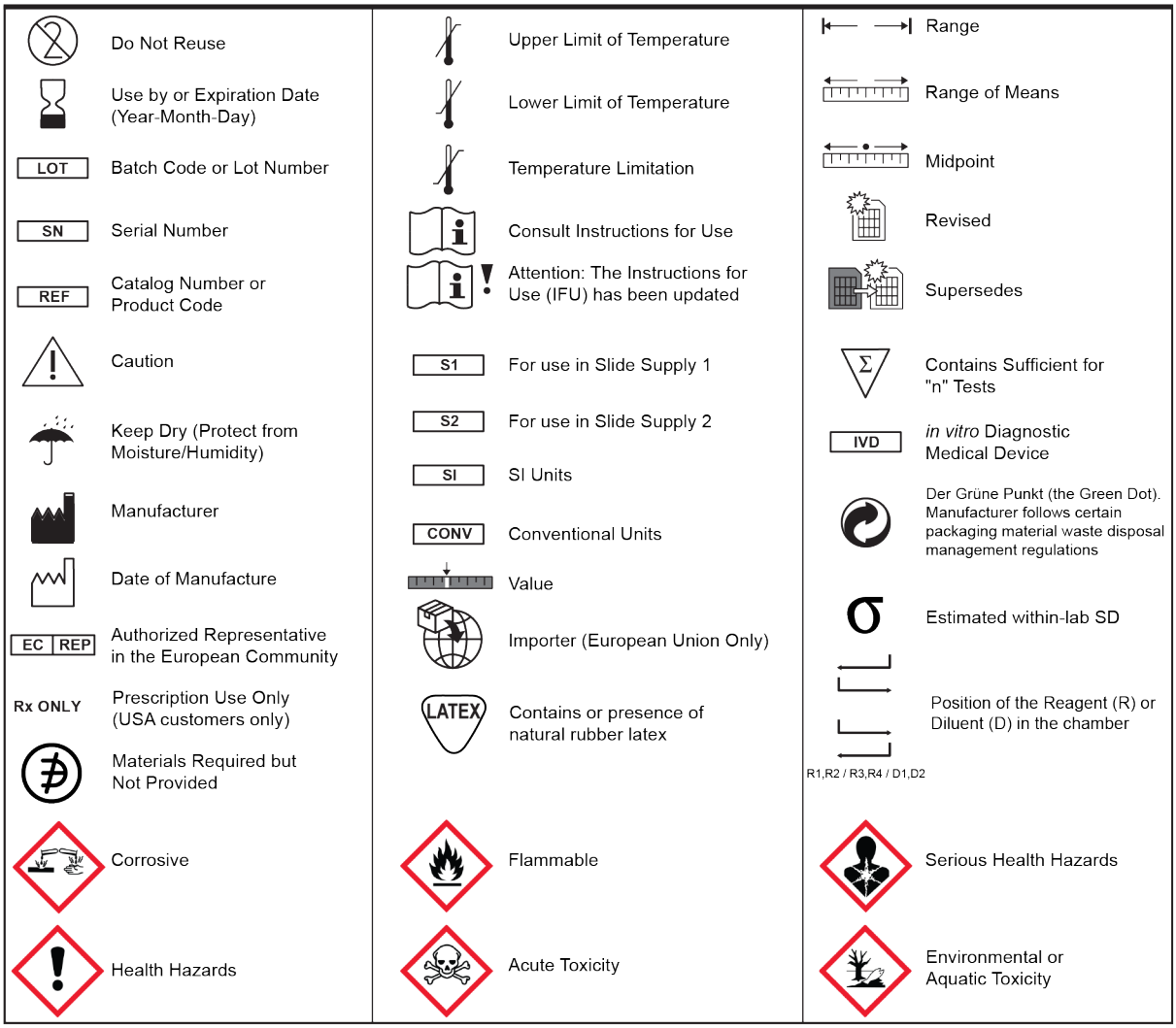
Serious Incident

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.

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*
2022-03-25	11.0	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

CE

EC REP

Ortho-Clinical Diagnostics
1500 Boulevard Sébastien Brant
B.P. 30335
67411 Illkirch
CEDEX, France

Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, NY 14626
USA

Ortho Clinical Diagnostics