VITROS® Immunodiagnostic Products

INSTRUCTIONS FOR USE

Syph

VITROS Immunodiagnostic Products Syphilis TPA Controls

REF 684 2805

Intended Use

For *in vitro* diagnostic use only.

For use in monitoring the performance of the VITROS ECi/ECiQ/3600 Immunodiagnostic Systems and the VITROS 5600/XT 7600 Integrated Systems when used for the determination of antibodies to *Treponema pallidum* (TP) specific antigens.

Warnings and Precautions

WARNING: Potentially Infectious Material

Human blood products provided as components of the VITROS Syphilis TPA Controls have been obtained from donors who were tested individually and who were found to be negative for hepatitis B surface antigen, and for antibodies to human immunodeficiency virus (HIV 1+2) and hepatitis C virus (HCV), using approved methods (enzyme immunoassays). 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, HCV, 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]

WARNING: Contains ProClin 950 (2682-20-4)[2]

The VITROS Syphilis TPA Controls contain 1.0% ProClin 950. H315: Causes skin irritation. H317: May cause an allergic skin reaction. H319: Causes serious eye irritation. P280: Wear protective gloves/protective clothing/eye protection/ face protection. P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337 + P313: If eye irritation persists: Get medical advice/attention. P302 + P352: IF ON SKIN: Wash with plenty of soap and water. P333 + P313: If skin irritation or rash occurs: Get medical advice/attention. P321: Specific treatment (see section 4, First aid measures, in Safety Data Sheet).

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

WARNING

Materials Provided

3 sets of VITROS Syphilis TPA Controls 1 and 2 (human plasma with antimicrobial agent, 1.0 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)	13 weeks
Opened	Frozen	≤-20 °C (≤-4 °F)	13 weeks

- VITROS Syphilis TPA Controls are supplied ready for use.
- VITROS Syphilis TPA 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 thoroughly 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.
- Baseline statistics for controls should be entered onto the system. Refer to the operating instructions for your system.
- The expiration date for the controls must be entered onto the system. 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

For Lot specific values, refer to the Controls Values booklet provided with the product.

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*
2019-09-06	6.1	• Glossary of Symbols: updated • Added EC Representative address
2017-09-25	6.0	• Added information for the VITROS XT 7600 Integrated System • Minor formatting and wording updates • Glossary of Symbols: updated

* 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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EC REP

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