VITROS Products Immunodiagnostic

# INSTRUCTIONS FOR USE aHBs

| | | |
|---|---|---|
| VITROS Immunodiagnostic Products Anti-HBs Reagent Pack | REF | 178 7753 |
| VITROS Immunodiagnostic Products Anti-HBs Calibrators | REF | 152 4693 |

## Intended Use

For *in vitro* diagnostic use only.

### VITROS Immunodiagnostic Products Anti-HBs Reagent Pack

For the quantitative measurement of antibody to hepatitis B surface antigen (anti-HBs) in human serum and plasma (heparin or citrate) following hepatitis B virus (HBV) vaccination or infection using the VITROS ECi/ECiQ/3600 Immunodiagnostic Systems and the VITROS 5600/XT 7600 Integrated Systems.

### VITROS Immunodiagnostic Products Anti-HBs Calibrators

For use in the calibration of the VITROS ECi/ECiQ/3600 Immunodiagnostic Systems and the VITROS 5600/XT 7600 Integrated Systems for the quantitative measurement of anti-HBs in human serum and plasma (heparin or citrate).

## Summary and Explanation of the Test

Anti-HBs tests may be used to monitor the immune response to hepatitis B vaccination. The measurement of anti-HBs for the quantitative evaluation of the immune response after vaccination can identify “inadequate responders” and “non-responders” or monitor changes in antibody level. It is currently recognized that an anti-HBs titre of 10 mIU/mL is probably protective. [1]

Anti-HBs tests may also be used to monitor convalescence and recovery from an acute HBV infection. Detection of anti-HBs is an indication that infection has run its course and the patient has become immune, since this antibody is virus neutralizing. [2]

## Principles of the Procedure

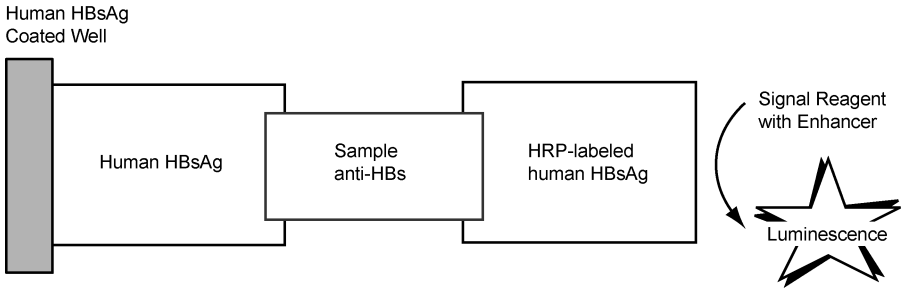
An immunometric technique is used, this involves the reaction of anti-HBs in the sample with hepatitis B surface antigen (HBsAg) coated onto the wells. A horseradish peroxidase (HRP)-labeled HBsAg conjugate then complexes with the bound anti-HBs forming an “antigen sandwich”. Unbound materials are removed by washing.

The bound HRP conjugate is measured by a luminescent reaction. [3] A reagent containing luminogenic substrates (a luminol derivative and a peracid salt) and an electron transfer agent, is added to the wells. The HRP in the bound conjugate catalyzes the oxidation of the luminol derivative, producing light. The electron transfer agent (a substituted acetanilide) increases the level of light produced and prolongs its emission. The light signals are read by the system. The amount of HRP conjugate bound is directly proportional to the concentration of anti-HBs present.

| Test Type | System * | Incubation Time | Time to first result | Test Temperature | Reaction Sample Volume |
|---|---|---|---|---|---|
| Immunometric | ECi/ECiQ, 3600, 5600, XT 7600 | 45 minutes | 55 minutes | 37 °C | 80 µL |

* Not all products and systems are available in all countries.

***Reaction Scheme***




## Warnings and Precautions

**WARNING:** Potentially Infectious Material

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). [4]

The conjugate reagent and coated wells provided as part of the VITROS Anti-HBs Reagent Pack contain purified hepatitis B surface antigen (HBsAg) obtained from donors who were tested individually and who were found to be negative for antibodies to human immunodeficiency virus (HIV 1+2) and hepatitis C virus (HCV), using approved methods (enzyme immunoassays, EIA). The purified HBsAg has been heat inactivated (10 hours at 60 °C). Treat as if capable of transmitting infection.

Human blood products provided as components of the VITROS Anti-HBs Reagent Pack and the VITROS Anti-HBs Calibrators 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.

**WARNING:** Contains Kathon or ProClin 200 (CAS 55965-84-9) [5]

The VITROS Anti-HBs Reagent Pack contains 2% Kathon or ProClin 200. **H317**: May cause an allergic skin reaction. **P280**: Wear protective gloves/protective clothing/eye protection/face protection. **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**

## Reagents

### Reagent Pack Contents

1 reagent pack containing:

- 100 coated wells (heat inactivated HBsAg subtypes ad and ay, coated at 40 P.E.I. Units*/well)
- 13.3 mL conjugate reagent (HRP-HBsAg (heat inactivated) subtypes ad and ay, 0.33 µg/mL) in buffer with bovine serum albumin, human serum and antimicrobial agent

- 6.2 mL assay reagent with antimicrobial agent

* Paul-Ehrlich-Institute HBsAg Reference Material.

### Reagent Pack Handling

- The reagent pack is supplied ready for use.
- The reagent pack contains homogeneous liquid reagents that do not require shaking or mixing prior to loading onto the system.
- Handle the reagent pack with care. Avoid the following:
  - allowing condensation to form on the pack
  - causing reagents to foam
  - agitation of the pack

### Reagent Pack Storage and Preparation

| Reagent | Storage Condition | | Stability |
|---|---|---|---|
| Unopened | Refrigerated | 2–8 °C (36–46 °F) | expiration date |
| Opened | On system | System turned on | ≤8 weeks |
| Opened | Refrigerated | 2–8 °C (36–46 °F) | ≤8 weeks |

- The VITROS Anti-HBs Reagent Pack is suitable for use until the expiration date on the carton when stored and handled as specified. Do not use beyond the expiration date.
- Do not freeze unopened reagent packs.
- Load reagent packs directly from refrigerated storage to minimize condensation.
- Store opened refrigerated reagent packs in a sealed reagent pack storage box that contains dry desiccant.

### Calibrator Contents

- 1 set of VITROS Anti-HBs Calibrators 1, 2 and 3 (human plasma with antimicrobial agent, 2 mL); nominal values 0; 30 and 250 mIU/mL* (World Health Organization (WHO) 1st International Reference Preparation (1977))
- Lot calibration card
- Protocol card
- 24 calibrator bar code labels (8 for each calibrator)

*Equivalent values in terms of the Paul-Ehrlich-Institute anti-HBs-IgG reference material (mU/mL).

### Calibrator Handling

- Use only with reagent packs of the same lot number. Mix thoroughly by inversion and bring to 15–30 °C (59–86 °F) before use. Each pack contains sufficient for a minimum of 6 determinations of each calibrator.
- Handle calibrators in stoppered containers to avoid contamination and evaporation. To avoid evaporation, limit the amount of time calibrators are on the VITROS Immunodiagnostic and VITROS Integrated Systems. 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.

### Calibrator Storage and Preparation

| Calibrator | 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 Anti-HBs Calibrators are supplied ready for use.
- The VITROS Anti-HBs Calibrators are suitable for use until the expiration date on the carton when they are stored and handled as specified. Do not use beyond the expiration date.
- Opened calibrators may be stored frozen (with no more than 1 freeze-thaw cycle).
- The VITROS Anti-HBs test uses 80 µL of calibrator for each determination. The VITROS Anti-HBs Calibrators may be used directly on the VITROS Immunodiagnostic and VITROS Integrated Systems. Alternatively, transfer an aliquot of each calibrator into a sample container (taking account of the minimum fill volume of the container), which may be bar coded with the labels provided. For details on minimum fill volume of sample cups or containers, refer to the operating instructions for your system.

## Specimen Collection, Preparation and Storage

### Patient Preparation

No special patient preparation is necessary.

### Specimens Recommended

- Serum
- Heparin plasma
- Citrate plasma

| Note: | Results from citrate plasma samples will be proportionally lower due to dilution by the liquid anticoagulant. |
|---|---|

### Specimens Not Recommended

Do not use turbid specimens. Turbidity in specimens may affect test results.

### Special Precautions

| IMPORTANT: | Certain collection devices have been reported to affect other analytes and tests. [6] Owing to the variety of specimen collection devices available, Ortho Clinical Diagnostics is unable to provide a definitive statement on the performance of its products with these devices. Confirm that your collection devices are compatible with this test. |
|---|---|

### Specimen Collection and Preparation

- Collect specimens using standard procedures. [7- 8]
- Samples should be thoroughly separated from all cellular material. Failure to do so may lead to an erroneous result.
- Thoroughly mix samples by inversion and bring to 15–30 °C (59–86 °F) before use.
- The VITROS Anti-HBs test uses 80 µL of sample for each determination. This does not take account of the minimum fill volume of the chosen sample container. For details on minimum fill volume of sample cups or containers, refer to the operating instructions for your system.

### Handling and Storage Conditions

- Handle samples in stoppered containers to avoid contamination and evaporation.
- The amount of time samples are on the system prior to analysis should be limited to avoid evaporation. Refer to the operating instructions for your system.
- Return to 2–8 °C (36–46 °F) as soon as possible after use, or load sufficient volume for a single determination.
- Serum and plasma samples may be stored for up to 5 days at 2–8 °C (36–46 °F). Serum and plasma samples tested initially and after 4 weeks storage at –20 °C (-4 °F) showed no differences in clinical performance.
- Avoid repeated freeze-thaw cycles.

## Testing Procedure

### Materials Provided

- VITROS Immunodiagnostic Products Anti-HBs Reagent Pack
- VITROS Immunodiagnostic Products Anti-HBs Calibrators

### Materials Required but Not Provided

- VITROS Immunodiagnostic Products Signal Reagent
- VITROS Immunodiagnostic Products Universal Wash Reagent
- VITROS Immunodiagnostic Products High Sample Diluent B
- Quality control materials such as VITROS Immunodiagnostic Products Anti-HBs Controls
- VITROS Immunodiagnostic Products Reagent Pack Storage Box (optional) with desiccant

### Operating Instructions

Check the inventory regularly to aid the management of reagents and ensure that sufficient VITROS Signal Reagent, VITROS Universal Wash Reagent and calibrated reagent lots are available for the work planned. When performing panels of tests on a single sample, ensure that the sample volume is sufficient for the tests ordered.

For detailed information refer to the operating instructions for your system.

| Note: | Do not use visibly damaged product. |
|---|---|

### Sample Dilution

Serum or plasma (heparin or citrate) samples with values greater than the calibration range may be diluted up to 1/20 by the VITROS Immunodiagnostic and VITROS Integrated System with the VITROS High Sample Diluent B Reagent Pack prior to test. Refer to the High Sample Diluent B Reagent Pack instructions for Use.

### Default Test Name

The default test name which will appear on patient reports is Anti-HBs. The default short name that will appear on the test selection menus and laboratory reports is aHBs. These defaults may be reconfigured, if required. For detailed information refer to the operating instructions for your system.

## Calibration

### Calibration Procedure

- Calibration is lot specific; reagent packs and calibrators are linked by lot number. Reagent packs from the same lot may use the same calibration.
- A Master Calibration (a dose response curve covering the full calibration range) is established for each new reagent lot. Concentrations for the linked lot of calibrators are determined from the Master Calibration.
- Ensure that the Master Calibration for each new reagent lot is available on your system.
- Process calibrators in the same manner as samples. Calibration need not be programmed if bar code labels are used; load the calibrators in any order, calibration will be initiated automatically.
- When the calibrators are processed the signal expected for each calibrator is compared against the actual signal obtained. The Master Calibration is then rescaled to reflect the differences between the actual and expected signals. The validity of this calibration curve is assessed against a range of quality parameters, and if acceptable, it is stored for use with any reagent pack of that lot.
- The quality of calibration cannot be completely described by a single parameter. The calibration report should be used in conjunction with acceptable control values to determine the validity of the calibration.
- Recalibration is required after a pre-determined calibration interval, or when a different reagent lot is loaded.
- Calibration results are assessed against a range of quality parameters. Failure to meet any of the defined quality parameter ranges will be coded in the calibration report. For actions to be taken following a failed calibration refer to the operating instructions for your system.

Refer to the operating instructions for your system for detailed instructions on the calibration process.

### When to Calibrate

- Calibrate when the reagent pack and calibrator lot changes.
- Calibrate every 28 days.
- After specified service procedures have been performed.
- If quality control results are consistently outside of your acceptable range.

For additional information on when to calibrate, refer to the operating instructions for your system.

### Traceability of Calibration

The calibration of the VITROS Anti-HBs test is traceable to in-house reference calibrators, which have been value-assigned to correlate to the W.H.O. 1st International Reference Preparation (1977).

The VITROS Anti-HBs test was also assessed against dilutions of the Paul-Ehrlich-Institute (P.E.I.) Anti-HBs IgG reference material (1000 mU/mL). The VITROS Anti-HBs test gave equivalent results for the W.H.O. and the P.E.I. reference materials.

### Calibration Model

A modified four-parameter logistic curve fit function is used to construct the Master Calibration encoded on the lot calibration card. The calibration process rescales the Master Calibration to establish a valid stored curve for the VITROS Immunodiagnostic and VITROS Integrated Systems.

### Measuring (Reportable) Range

| System | Measuring (Reportable) Range |
|---|---|
| ECi/ECiQ, 3600, 5600, XT 7600 | 4.23*–1000 mIU/mL |

* Lower limit of measuring range is based on the Limit of Detection. The lowest result reported by the system software is 0 mIU/mL. Values between 0–4.23 mIU/mL should be interpreted as not having detectable anti-HBs.

## Quality Control

### Quality Control Material Selection

VITROS Anti-HBs Controls are recommended for use with the VITROS Immunodiagnostic and VITROS Integrated Systems. The VITROS Anti-HBs Controls contain 3 levels of anti-HBs (low, medium, high). The performance of other commercial control fluids should be evaluated for compatibility with this test before they are used for quality control.

Control materials may show a difference when compared with other anti-HBs methods if they contain high concentrations of preservatives, stabilizers, or other nonphysiological additives, or otherwise depart from a true human sample matrix.
Appropriate quality control value ranges must be established for all quality control materials used with the VITROS Anti-HBs test.

### Quality Control Procedure Recommendations

- Good laboratory practice requires that controls be processed to verify the performance of the test.
- Choose control levels that check the clinically relevant concentrations.
- To verify system performance, analyze control materials:
  - After calibration
  - According to local regulations or at least once each day that the test is being performed
  - After specified service procedures are performed

If quality control procedures within your laboratory require more frequent use of controls, follow those procedures.

- Analyze quality control materials in the same manner as patient specimens.
- If control results fall outside your acceptable range, investigate the cause before deciding whether to report patient results.
- Refer to published guidelines for general quality control recommendations. [9]

For more detailed information, refer to the operating instructions for your system.

### Quality Control Material Preparation and Storage

Refer to the manufacturer's product literature for preparation, storage, and stability information.

## Results

Results are automatically calculated by the VITROS Immunodiagnostic and VITROS Integrated Systems.

### Reporting Units and Unit Conversion

Analyte results are quoted in units of mIU/mL. To configure the units, refer to the operating instructions for your system.

### Interpretation of Results

Samples with results <8 mIU/mL will be flagged as 'Antibody Neg', samples with results between 8 and 12 mIU/mL will be flagged as 'Borderline' and samples with results >12 mIU/mL will be flagged as 'Antibody Pos'.
An 'Antibody Pos' result suggests immunity to HBV infection.
A 'Borderline' result is indicative of an antibody level within 20% of the World Health Organization (W.H.O.) recommended cutoff for immunity of 10 mIU/mL. A sample which gives a repeated borderline result may not contain sufficient antibody to confer immunity. [1]
Antibody levels below the borderline region are flagged as 'Antibody Neg' in this test. Low levels of antibody may indicate past infection by HBV.
The status of a patient with a low antibody level should be confirmed using tests for other markers of hepatitis infection.

## Limitations of the Procedure

### Known Interferences

The VITROS Anti-HBs test was evaluated for interference consistent with CLSI document EP7. [10] Of the compounds tested, none was found to interfere with the clinical interpretation of the test. Refer to "Specificity" for a list of compounds tested that did not show interference.

### Other Limitations

- The results from this or any other diagnostic test should be used and interpreted only in the context of the overall clinical picture.
- Certain drugs and clinical conditions are known to alter anti-HBs concentrations *in vivo*. For additional information, refer to one of the published summaries. [11- 13]
- Non-specific reactives may be obtained with any highly sensitive immunoassay. The most common source of non-specific reactives is poor specimen quality.

## Expected Values

It is recommended that each laboratory establish its own expected values for the population it serves.
In a random population of 615 blood donor samples, 40 (6.5%) were reactive for anti-HBs (≥10 mIU/mL) in the VITROS Anti-HBs test. In a population of samples non-reactive for anti-HBs, 100% (575/575) were non-reactive in the VITROS Anti-HBs test.

In a population of samples reactive for anti-HBs, 99.7% (290/291) were found to be reactive in the VITROS Anti-HBs test.

# Performance Characteristics

## Sensitivity

A population of 291 samples, previously found reactive for anti-HBs (≥10 mIU/mL) by another commercially available test with the same intended use, were tested in the VITROS Anti-HBs test. Discordant results were resolved by testing in a third anti-HBs test.

| 291 Samples Tested | | Comparison Method | |
|---|---|---|---|
| | | Positive (≥10 mIU/mL) | Negative (<10 mIU/mL) |
| VITROS Anti-HBs Test | Antibody Pos (>12 mIU/mL) | 290 | 0 |
| | Borderline (8-12 mIU/mL) | 1 | 0 |
| | Antibody Neg (<8 mIU/mL) | 0 | 0 |

Sensitivity = 99.7% (290/291) versus the Comparison method (based on a 10 mIU/mL cutoff).

## Specificity

A population of 575 apparently normal blood donors, previously found non-reactive for anti-HBs (<10 mIU/mL) by another commercially available test with the same intended use, were tested in the VITROS Anti-HBs test. Discordant results were resolved by testing in a third anti-HBs test.

| 575 Samples Tested | | Comparison Method | |
|---|---|---|---|
| | | Positive (≥10 mIU/mL) | Negative (<10 mIU/mL) |
| VITROS Anti-HBs Test | Antibody Pos (>12 mIU/mL) | 0 | 0 |
| | Borderline (8-12 mIU/mL) | 0 | 0 |
| | Antibody Neg (<8 mIU/mL) | 0 | 575 |

Specificity = 100% (575/575) versus the Comparison method (based on a 10 mIU/mL cut-off).
In this population of 575 anti-HBs negatives, 98% of samples gave results <1 mIU/mL in the VITROS Anti-HBs test.
Additionally 65 samples from the following potentially cross-reacting sub-groups were tested in the VITROS Anti-HBs test: anti-HAV IgM positive, anti-HBc IgM positive, CMV IgM positive, EBV IgM positive, anti-HCV positive, non-viral liver disease, rheumatoid factor positive and autoimmune disease. Of these samples none were found to be repeatedly reactive in the VITROS Anti-HBs test.

## Limit of Detection

The lowest amount of anti-HBs that can be detected with the VITROS Anti-HBs Quantitative assay was determined in accordance with NCCLS EP17. [14] Based upon 274 positive determinations, the Limit of Detection (LoD) is 4.23 mIU/mL of anti-HBs, with a 95% probability of obtaining a measurable response at that level. A Limit of Blank (LoB) of 3.08 mIU/mL was used.

## Precision

### *VITROS ECi/ECiQ Immunodiagnostic System*

Precision was evaluated consistent with NCCLS document EP5. [15] Two replicates each of 3 freeze-dried control samples were tested once per day on at least 20 different days. The experiment was performed using 2 reagent lots on 2 different systems. The data presented are a representation of the product performance.

### *VITROS 3600 Immunodiagnostic System and VITROS 5600 Integrated System*

Precision was evaluated consistent with NCCLS document EP5. [16] Two replicates each of 4 patient sample pools were tested on 2 separate occasions per day on at least 20 different days. The experiment was performed using 1 reagent lot on each system. The data presented are a representation of the product performance.

| System | Units = mIU/mL | | | | | | | No. Observ. | No. Days |
|---|---|---|---|---|---|---|---|---|---|
| | Mean VITROS aHBs Conc. | Within-run* | | Within-calibration** | | Within-lab*** | | | |
| | | SD | CV (%) | SD | CV (%) | SD | CV (%) | | |
| ECi/ECiQ system 1 | 22.2 | 0.256 | 1.2 | 0.603 | 2.7 | 0.720 | 3.2 | 54 | 27 |
| | 86.1 | 0.616 | 0.7 | 1.77 | 2.1 | 2.20 | 2.6 | 56 | 28 |
| | 373 | 3.31 | 0.9 | 8.87 | 2.4 | 9.85 | 2.6 | 56 | 28 |
| ECi/ECiQ system 2 | 21.2 | 0.217 | 1.0 | 0.898 | 4.2 | 1.01 | 4.8 | 58 | 29 |
| | 82.2 | 0.914 | 1.1 | 3.08 | 3.7 | 3.59 | 4.4 | 58 | 29 |
| | 358 | 3.97 | 1.1 | 12.1 | 3.4 | 15.9 | 4.4 | 58 | 29 |
| 3600 | 8.83 | 0.211 | 2.4 | 0.325 | 3.7 | 0.443 | 4.8 | 88 | 22 |
| | 14.6 | 0.220 | 1.5 | 0.400 | 2.7 | 0.587 | 3.8 | 88 | 22 |
| | 25.9 | 0.348 | 1.3 | 0.560 | 2.2 | 0.953 | 3.5 | 88 | 22 |
| | 750 | 11.4 | 1.5 | 16.8 | 2.2 | 27.6 | 3.5 | 88 | 22 |
| 5600**** | 9.37 | 0.262 | 2.8 | 0.470 | 5.0 | 0.510 | 5.3 | 88 | 22 |
| | 14.9 | 0.198 | 1.3 | 0.369 | 2.5 | 0.406 | 2.7 | 88 | 22 |
| | 27.0 | 0.374 | 1.4 | 0.579 | 2.1 | 0.699 | 2.5 | 88 | 22 |
| | 766 | 13.8 | 1.8 | 18.5 | 2.4 | 23.4 | 2.9 | 88 | 22 |

* Within-run (repeatability). Between Duplicate precision averaged over all runs

** Within-calibration. Total precision with weighted components of within-run, between–run and between-day variation

*** Within-lab. A measure of the effect of recalibration on total precision, calculated within reagent lot, using data from at least 4 calibrations

**** Performance characteristics for the VITROS 5600 System are applicable to the VITROS XT 7600 System.

### Substances that do not Interfere

The VITROS Anti-HBs test was evaluated for interference consistent with CLSI document EP7. [10] The VITROS Anti-HBs test was evaluated for interference by testing the following substances. Testing was performed using matched pairs of negative donor serum and negative donor serum spiked with anti-HBs to a concentration near 20 mIU/mL. None of the compounds at the levels tested was found to interfere with the clinical interpretation of the test.

| Compound | Concentration | |
|---|---|---|
| Bilirubin | 0.35 mmol/L | 20 mg/dL |
| Hemoglobin | 0.31 mmol/L | 500 mg/dL |
| Triolein | 33.9 mmol/L | 3000 mg/dL |

## References

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## 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 | Σ 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 | σ 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 | 8.2 | • Glossary of Symbols: updated<br>• Added EC Representative address |
| 2019-05-16 | 8.1 | Removed statement “Not Intended for Use in Canada” from the header |

| Date of Revision | Version | Description of Technical Changes* |
|---|---|---|
| 2017-09-29 | 8.0 | • Added information for the VITROS XT 7600 Integrated System<br>• Minor formatting and wording updates<br>• References: updated<br>• 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.

CE
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EC REP
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Date: 2022.10.13 12:24:32 EEST
Reason: MoldSign Signature
Location: Moldova



Ortho Clinical Diagnostics

Co-developed with

GRIFOLS