VITROS Products
Immunodiagnostic

INSTRUCTIONS FOR USE Syph

VITROS Immunodiagnostic Products Syphilis TPA Reagent Pack	REF	684 2803
VITROS Immunodiagnostic Products Syphilis TPA Calibrator	REF	684 2804

Intended Use

For *in vitro* diagnostic use only.

VITROS Immunodiagnostic Products Syphilis TPA Reagent Pack

For the qualitative determination of total (IgG and IgM) antibodies to *Treponema pallidum* (TP) specific antigens in human serum and plasma (heparin, EDTA and citrate) using the VITROS ECi/ECiQ/3600 Immunodiagnostic Systems and the VITROS 5600/XT 7600 Integrated Systems.

The presence of antibodies to *Treponema pallidum* (TP) specific antigens, in conjunction with non-treponemal laboratory tests and clinical findings may aid in the diagnosis of recent, past or treated syphilis infection.

VITROS Immunodiagnostic Products Syphilis TPA Calibrator

For use in the calibration of the VITROS ECi/ECiQ/3600 Immunodiagnostic Systems and the VITROS 5600/XT 7600 Integrated Systems for the qualitative determination of antibodies to *Treponema pallidum* (TP) in human serum and plasma (heparin, EDTA and citrate).

Summary and Explanation of the Test

Syphilis is a sexually transmitted bacterial disease caused by the spirochete *Treponema pallidum*. The infection may be passed congenitally from mother to unborn child, causing birth defects or fetal death. [1]

Symptoms, particularly in the early stages of infection, may be mild. In the early stages (primary syphilis) symptoms include a small, painless, but highly infectious sore, with swelling in nearby lymph nodes. The sore develops ten days to three months after infection and lasts for two to six weeks. A few weeks after the sore disappears, the next stage (secondary syphilis) develops. Symptoms include a sore throat or a non-itchy skin rash, often on hands and feet. This stage resolves in a few weeks. Symptoms may come and go but the disease can remain latent and symptomless for years. If diagnosed early, syphilis can be easily treated with antibiotics, however, if it is not treated, syphilis can progress to a more dangerous form of the disease (tertiary syphilis) causing serious conditions such as stroke, paralysis, blindness or even death. [2]

Serological tests for *Treponema pallidum* may aid in the early diagnosis of syphilis. Specific IgM is detectable towards the end of the second week of infection and IgG after about four weeks. By the time symptoms develop most patients have detectable anti-treponemal antibodies. Current serological tests include the non-treponemal Venereal Disease Reference Lab (VDRL) test and the Rapid Plasma Reagin (RPR) test and the more specific anti-treponemal fluorescent treponemal antibody-absorbed test (FTA-abs) and enzyme immunoassay (EIA) tests. [3] More recently, EIAs using recombinant *Treponema pallidum* proteins have been introduced.

Principles of the Procedure

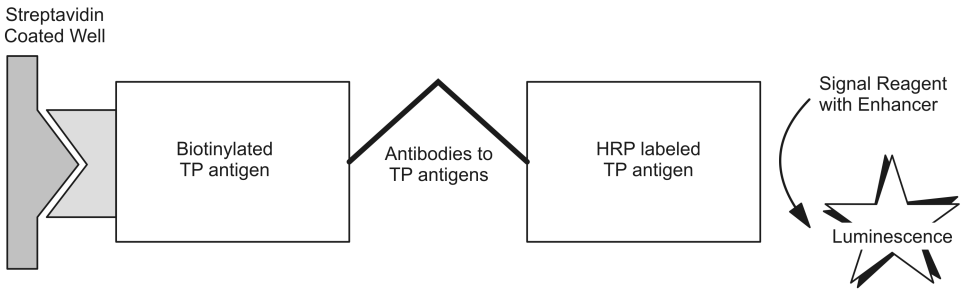
An immunometric immunoassay technique is used, which involves the reaction of IgG, IgM or IgA antibodies present in the sample with a biotinylated TP antigen and a horseradish peroxidase (HRP)-labeled TP antigen conjugate. The antibody-antigen complex is captured by streptavidin on the wells. Unbound materials are removed by washing.

The bound HRP conjugate is measured by a luminescent reaction. [4] 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 bound HRP conjugate is directly proportional to the concentration of anti-TP antibody present.

Test Type	System *	Incubation Time	Time to first result	Test Temperature	Reaction Sample Volume
Immunometric	ECi/ECiQ, 3600, 5600, XT 7600	16 mins first incubation 8 mins second incubation	35 minutes	37 °C	25 µL

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

Reaction Scheme



Warnings and Precautions

WARNING: Potentially Infectious Material

Human blood products provided as components of the VITROS Syphilis TPA Calibrator 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, hepatitis C virus (HCV), human immunodeficiency virus (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). [5]

WARNING: Contains ProClin 950 (CAS 2682-20-4) [6]

The VITROS Syphilis TPA Reagent Pack contains 0.5% ProClin 950. 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.

WARNING

WARNING: Contains ProClin 950 (CAS 2682-20-4) [6]

The VITROS Syphilis TPA Calibrator contains 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

Reagents

Reagent Pack Contents

1 reagent pack containing:

- 100 coated wells (streptavidin, bacterial; binds ≥2 ng biotin/well)
- 13.1 mL biotinylated antigen reagent (biotin-recombinant TP antigens 0.15 µg/mL) in buffer with bovine gamma globulin, bovine serum albumin, and antimicrobial agent
- 20.4 mL conjugate reagent (HRP-recombinant TP antigens, 0.15 µg/mL) in buffer with bovine serum albumin and antimicrobial agent

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 on the system.
- As with all immunoassay protein-based solutions, inappropriate handling of the reagent pack can cause foam to occur on the surface of the reagent. Avoid agitation, which may cause foaming or the formation of bubbles.
  - If reagent packs are dropped or agitated, small levels of fine foam could be generated that may not be detected by the system.
  - Reagent packs containing fine foam that is not detected by the system, may show a bias.
- If you must use a dropped or agitated reagent pack before it has been allowed to settle, you should verify performance by running high and low quality control samples in duplicate after loading the pack on the system.

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	≤12 weeks
Opened	Refrigerated	2–8 °C (36–46 °F)	≤12 weeks

- The VITROS Syphilis TPA 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 VITROS Syphilis TPA Calibrator (human syphilis IgG positive plasma, 2.2 mL) with antimicrobial agent
- Lot calibration card
- Protocol card
- 8 calibrator bar code labels

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 calibration events.
- Handle calibrator in stoppered containers to avoid contamination and evaporation. To avoid evaporation, limit the amount of time the calibrator is 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.

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

- The VITROS Syphilis TPA Calibrator is supplied ready for use.
- The VITROS Syphilis TPA Calibrator is suitable for use until the expiration date on the carton when it is 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 Syphilis TPA test uses 25 µL of calibrator for each determination. The VITROS Syphilis TPA Calibrators may be used directly on the VITROS Immunodiagnostic and VITROS Integrated Systems. Alternatively, transfer an aliquot of the 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
- EDTA 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. [7] 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. [8-9]
- 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 Syphilis TPA test uses 25 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 7 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 Syphilis TPA Reagent Pack
- VITROS Immunodiagnostic Products Syphilis TPA Calibrator

Materials Required but Not Provided

- VITROS Immunodiagnostic Products Signal Reagent

- VITROS Immunodiagnostic Products Universal Wash Reagent
- Quality control materials such as VITROS Immunodiagnostic Products Syphilis TPA 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.

Default Test Name

The default test name which will appear on patient reports is Syphilis TPA. The default short name that will appear on the test selection menus and laboratory reports is Syph. 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 calibrator are linked by lot number. Reagent packs from the same lot may use the same calibration.
- A Master Calibration is established for each new reagent lot by performing multiple tests. This is the process by which a lot-specific parameter [a] which links the cutoff (cutoff value) to the calibrator signal is determined.
  Cutoff value = (a × Signal of Cal 1)
  The lot-specific parameter, the expected calibrator signal and the data, which enables a VITROS Immunodiagnostic System to calculate the cutoff value, are encoded on the lot calibration card or ADD.
- Ensure that the Master Calibration for each new reagent lot is available on your system.
- Process the calibrator in the same manner as samples. Load sufficient for the automatic duplicate determination. Calibration need not be programmed if bar code labels are used; Calibration will be initiated automatically.
- When the calibrator is processed the validity of the calibration is assessed against quality parameters which compares the actual signal of the calibrator with the expected signal. If the calibration is acceptable the cutoff value is calculated and 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 two quality parameters. Failure to meet either 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

Calibration of the VITROS Syphilis TPA test is traceable to an in-house reference calibrator which has been value-assigned to optimize the clinical performance of the test.

Calibration Model

Results are calculated as a normalized signal, relative to a cutoff value. During the calibration process a lot-specific parameter is used to determine a valid stored cutoff value for the VITROS Immunodiagnostic and VITROS Integrated Systems.

Quality Control

Quality Control Material Selection

VITROS Syphilis TPA Controls are recommended for use with the VITROS Immunodiagnostic and VITROS Integrated Systems. There are two VITROS Syphilis TPA Controls (anti-syphilis negative and anti-syphilis positive). 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 Syphilis TPA 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 Syphilis TPA 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. [10]

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.

Result Calculation

$$\text{Result} = \frac{\text{Signal for test sample}}{\text{Signal at Cutoff (Cutoff Value)}}$$

Interpretation of Results

Samples with results <0.80 will be flagged as "negative", samples with results ≥0.80 and <1.20 will be flagged as "borderline" and samples with results ≥1.20 will be flagged as "reactive".

VITROS Syphilis TPA Test Result (S/C)	Status	Interpretation
<0.80	Negative	Indicates no active or previous infection with *Treponema pallidum.*
≥0.80 and <1.20	Borderline	Unable to determine if *Treponema pallidum* infection has occurred. The sample should be re-tested.*
≥1.20	Reactive	Indicates active or previous infection with *Treponema pallidum.*

* Samples that still test as "borderline" should have a second sample collected, if possible, within a reasonable period of time (e.g. one week) and re-tested or be examined by an alternate method.

Note: The results from this or any other diagnostic test should be used and interpreted only in the context of the overall clinical picture. A negative test does not exclude the possibility of recent exposure to *Treponema pallidum.* Levels of anti-T.pallidum antibodies may be below the cutoff in early infection.

Limitations of the Procedure

Known Interferences

The VITROS Syphilis TPA test was evaluated for interference consistent with CLSI document EP7. [11] Commonly encountered substances were tested on 2 lots of reagents. Of the compounds tested, hemoglobin may interfere with the VITROS Syphilis TPA test. Hemoglobin, when tested, caused the bias shown at the concentration indicated.
Refer to “Substances that do not Interfere” for a list of other compounds tested that did not show interference.

Interferent	Interferent Concentration		Units = S/C	
			Analyte Result*	Bias**
Hemoglobin	0.620 mmol/L	1000 mg/dL	0.02	+0.46
			2.57	+0.76

* Average test result of replicate determinations using 2 different lots of reagent.

** Estimate of the average difference observed.

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.
- Biotin levels in serum remain elevated for up to 24 hours after oral or intravenous biotin administration. [12]
- Heterophilic antibodies in serum or plasma samples may cause interference in immunoassays. [13] These antibodies may be present in blood samples from individuals regularly exposed to animals or who have been treated with animal serum products. Results which are inconsistent with clinical observations indicate the need for additional testing.
- Certain drugs and clinical conditions are known to alter antibody concentrations *in vivo*. For additional information, refer to one of the published summaries. [14- 16]
- Do not use quality control materials preserved with azide.

Performance Characteristics

Clinical Performance

Initial Sensitivity and Specificity

4290 samples were tested in the VITROS Syphilis TPA test and in a commercially available Immunoassay (IA 1) for antibodies to *Treponema pallidum*. An initial analysis in the VITROS Syphilis TPA test gave the following results:

		VITROS Syphilis TPA test			
		Reactive	Borderline	Negative	Total
IA 1	Reactive	266	0	8	274
	Negative	0	1	4015	4016
	Total	266	1	4023	4290

The initial specificity, including borderline samples (4015/4016) was 99.98% (exact 95% CI 99.9–100.0%). Initial sensitivity, including borderline samples (266/274) was 97.08% (exact 95% CI 94.3–98.7%). One (0.025%) sample was borderline in the VITROS Syphilis TPA test. The commercially available test did not have a borderline region.

Relative Specificity and Sensitivity after resolution of uninterpretable samples

Samples where there was a difference in classification from the commercial test (reactive/negative) were defined as discordant. Samples that resulted in discordant or borderline results (in either the VITROS or IA 1 test) were further tested to determine relative sensitivity and specificity.
A total of 9 discordant and borderline samples were further tested by first repeating the VITROS Syphilis TPA test in duplicate. A total of 9 discordant and borderline samples remained discordant with IA 1 after repeat testing in the VITROS Syphilis TPA test. The 9 samples were also tested in up to 4 additional commercially available Syphilis TPA tests. The median VITROS Syphilis TPA result was then compared to the consensus classification of the other 4 commercially available tests.
Using this algorithm:
8 samples were resolved as Syphilis antibody Negative.
1 sample remained borderline in the VITROS Syphilis TPA test.
After resolution of discordant results, the relative specificity of the VITROS Syphilis TPA test to the IA 1 test was calculated (4023/4024) as 99.98% (exact CI 99.9–100.0%) and relative sensitivity (266/266) as 100% (exact CI 98.6–100.0%).

		VITROS Syphilis TPA test			
		Reactive	Borderline	Negative	Total
IA 1	Reactive	266	0	0	266
	Negative	0	1	4023	4024
	Totals	266	1	4023	4290

Potentially Cross-Reacting Subgroups

149 samples from the following potentially cross-reacting sub-groups were tested in the VITROS Syphilis TPA test and in a commercially available test (EIA1): HAV IgG and IgM, HBV IgG and IgM, HCV IgG and IgM, EBV IgG and IgM, anti-HSV IgG and IgM, anti-HIV1/2 IgG and IgM, CMV IgG and IgM, Rubella IgG and IgM, ANA/SLE, *Borrelia burgdorferi* infection (European and US strain), *Toxoplasma gondii* infections IgG and IgM, heterophilic antibodies/HAMA and Rheumatoid factor. An analysis in the VITROS Syphilis TPA test gave the following results:

		VITROS Syphilis TPA test			
		Reactive	Borderline	Negative	Total
EIA1	Positive	12	0	0	12
	Negative	0	0	137	137
	Totals	12	0	137	149

The specificity (137/137 was 100.0% (95% CI: 97.3–100.0%). Sensitivity (12/12) was 100.0% (95% CI: 73.5–100.0%). No discordant samples were observed and all results were in line with the expected clinical performance in the commercially available test.

Precision

VITROS ECi/ECiQ Immunodiagnostic System

Precision was evaluated consistent with NCCLS document EP5. [17] Two replicates each of 4 patient sample pools and 4 control samples were tested on 2 separate occasions 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. [17]Two replicates of each of 4 patient sample pools and 4 control samples 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 = S/C							No. Observ.	No. Days
	Mean Syph Result	Within-run*		Within-calibration**		Within-lab***			
		SD	CV (%)	SD	CV (%)	SD	CV (%)		
ECi/ECiQ system 1	2.33	0.045	2.0	0.140	6.1	0.134	5.6	88	22
	0.73	0.012	1.7	0.055	7.7	0.059	8.0	88	22
	1.42	0.045	3.2	0.089	6.4	0.093	6.4	88	22
	5.27	0.079	1.5	0.195	3.8	0.210	3.9	88	22
	22.7	0.329	1.5	0.716	3.2	0.728	3.1	88	22
	5.27	0.062	1.2	0.236	4.6	0.228	4.2	88	22
	2.16	0.038	1.8	0.103	4.9	0.109	5.0	88	22
	27.7	0.382	1.4	0.979	3.6	1.00	3.5	88	22
ECi/ECiQ system 2	2.70	0.037	1.4	0.108	4.0	0.095	3.5	88	22
	0.80	0.016	2.0	0.052	6.6	0.048	5.9	88	22
	1.70	0.026	1.5	0.073	4.3	0.068	4.0	88	22
	5.75	0.093	1.6	0.189	3.3	0.174	3.0	88	22
	24.6	0.645	2.7	0.961	4.0	0.948	3.8	88	22
	5.72	0.080	1.3	0.174	2.9	0.168	3.1	88	22
	2.36	0.029	1.2	0.091	3.9	0.081	3.4	88	22
	30.4	0.439	1.5	0.969	3.2	0.900	2.9	88	22

System	Units = S/C							No. Observ.	No. Days
	Mean Syph Result	Within-run*		Within-calibration**		Within-lab***			
		SD	CV (%)	SD	CV (%)	SD	CV (%)		
3600	2.38	0.032	1.4	0.153	6.5	0.130	5.4	88	22
	0.74	0.013	1.8	0.066	9.0	0.063	8.5	88	22
	1.43	0.026	1.8	0.105	7.4	0.093	6.5	88	22
	5.31	0.085	1.6	0.216	4.1	0.176	3.3	88	22
	23.3	0.217	0.9	0.628	2.7	0.491	2.1	88	22
	5.32	0.057	1.1	0.174	3.3	0.198	3.7	88	22
	2.22	0.032	1.5	0.127	5.8	0.113	5.0	88	22
	28.5	0.370	1.3	0.897	3.2	0.711	2.5	88	22
5600****	2.69	0.044	1.6	0.166	6.1	0.170	6.3	88	22
	0.80	0.018	2.3	0.071	8.9	0.072	9.0	88	22
	1.72	0.023	1.3	0.103	6.0	0.106	6.2	88	22
	5.68	0.104	1.8	0.241	4.2	0.257	4.5	88	22
	24.0	0.385	1.6	0.717	3.0	0.825	3.5	88	22
	6.25	0.072	1.1	0.206	3.3	0.234	3.8	88	22
	2.36	0.030	1.3	0.127	5.4	0.126	5.4	88	22
	29.4	0.500	1.7	0.924	3.1	1.00	3.4	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.

Specificity

Substances that do not Interfere

The VITROS Syphilis TPA test was evaluated for interference consistent with CLSI document EP7. [11] Of the compounds tested, none was found interfere with the clinical interpretation of the test at the concentrations indicated.

Compound	Concentration	
Azide (sodium)	20 mg/dL	3.06 mmol/L
Bilirubin	20 mg/dL	0.342 mmol/L
Biotin	1000 ng/dL	40.8 nmol/L
BSA (High Protein)	5 g/dL (total ~12 g/dL)	N/A
Cholesterol	250 mg/dL	N/A
Hemoglobin (hemolysate)	500 mg/dL	0.155 mmol/L
Intralipid	850 mg/dL	N/A
Triolein	3000 mg/dL	33.96 mmol/L

References

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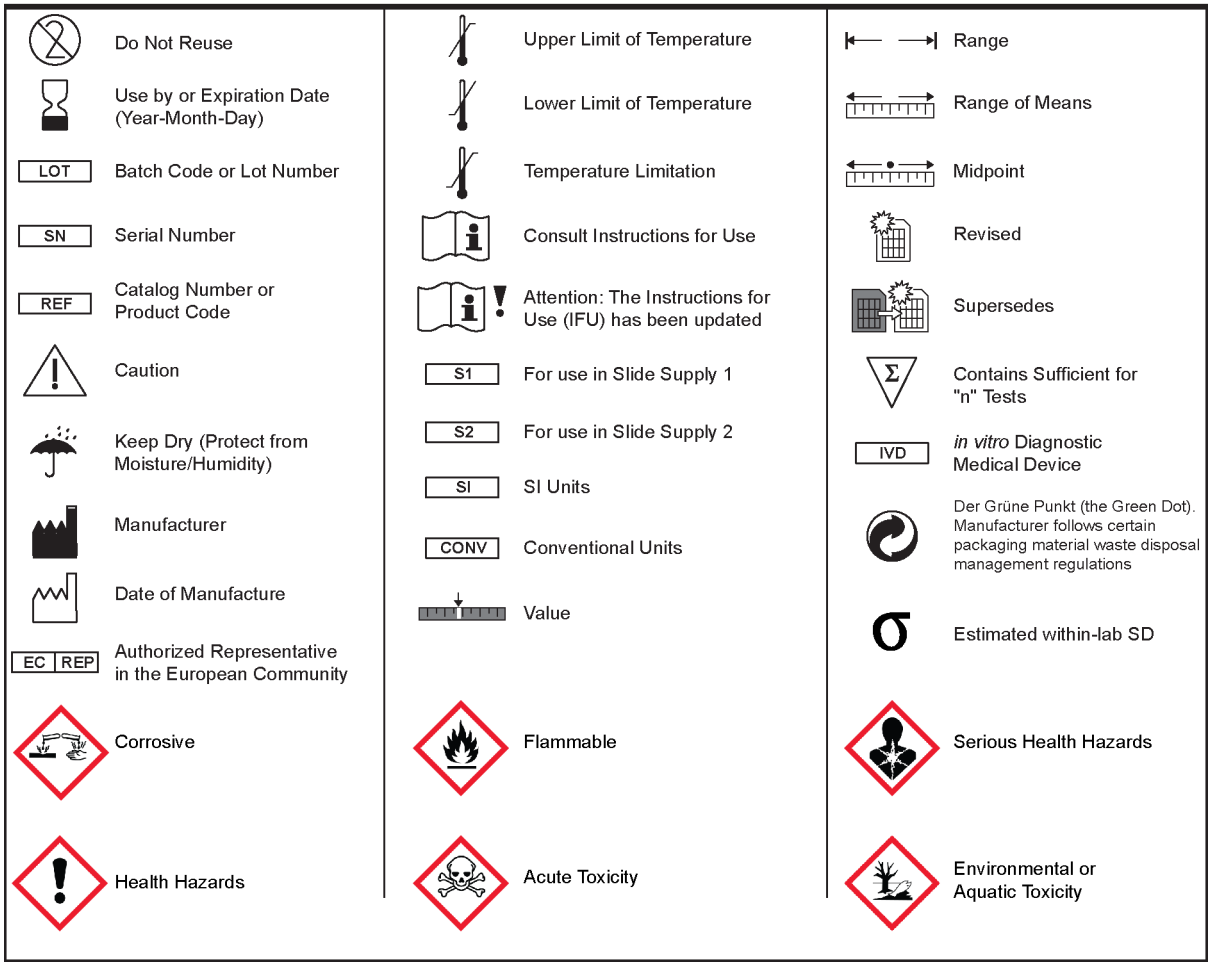
Glossary of Symbols

The following symbols may have been used in the labeling of this product.



Revision History

Date of Revision	Version	Description of Technical Changes*
2019-09-06	6.1	• Glossary of Symbols: updated • Added EC Representative address
2017-09-20	6.0	• Added information for the VITROS XT 7600 Integrated System • Minor formatting and wording updates • References: updated • 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.

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

Ortho-Clinical Diagnostics
Felindre Meadows
Pencoed
Bridgend
CF35 5PZ
United Kingdom

Digitally signed by Maftei Tatiana
Date: 2022.10.13 12:26:52 EEST
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