VITROS Products Immunodiagnostic

INSTRUCTIONS FOR USE

Testo

VITROS Immunodiagnostic Products Testosterone Reagent Pack	REF	143 5205
VITROS Immunodiagnostic Products Testosterone Calibrators	REF	130 6026

Rx ONLY

Intended Use

For *in vitro* diagnostic use only.

VITROS Immunodiagnostic Products Testosterone Reagent Pack

For the quantitative measurement of testosterone in human serum and plasma (EDTA or heparin) using the VITROS ECi/ECiQ/3600 Immunodiagnostic Systems and the VITROS 5600/XT 7600 Integrated Systems.

VITROS Immunodiagnostic Products Testosterone 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 testosterone in human serum and plasma (EDTA or heparin).

Summary and Explanation of the Test

Testosterone is produced by the adrenals, the theca cells in the ovary and the leydig cells in the testes. As much as 97% of circulating testosterone is bound to serum proteins such as sex hormone binding globulin (SHBG). [1] In the male, testosterone stimulates the maturation of genitalia and secondary sexual characteristics and its measurement is used to investigate sexual dysfunction in juveniles and adults. [2] In females testosterone concentrations are much lower and an elevated concentration may indicate polycystic ovarian syndrome among other conditions. [3] Clinical symptoms of testosterone excess in females include infertility, amenorrhea, obesity and hirsutism. [4]

Principles of the Procedure

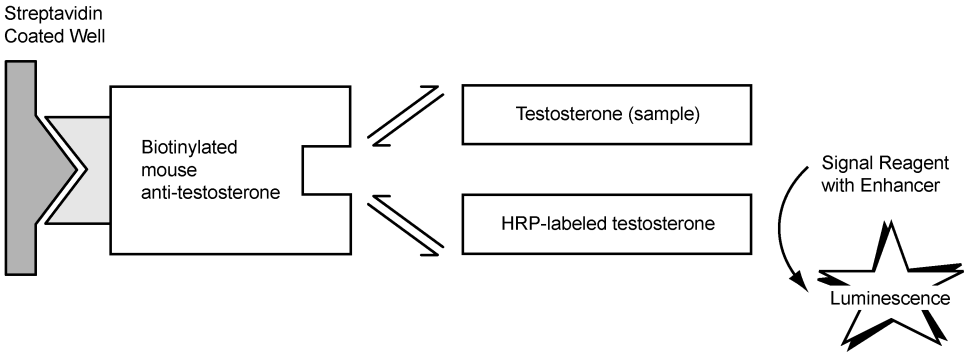
A competitive immunoassay technique is used, which depends on competition between testosterone present in the sample with a horseradish peroxidase (HRP)-labeled testosterone conjugate for a limited number of binding sites on a biotinylated antibody (mouse anti-testosterone). The antigen-antibody complex is captured by streptavidin on the wells. Unbound materials are removed by washing.

The bound HRP conjugate is measured by a luminescent reaction. [5] 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 indirectly proportional to the concentration of testosterone present.

Test Type	System *	Incubation Time	Time to first result	Test Temperature	Reaction Sample Volume
Competitive immunoassay	ECi/ECiQ, 3600, 5600, XT 7600	32 minutes	40 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 Testosterone Reagent Pack and the VITROS Testosterone 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.* *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).* [6]
WARNING:	*Contains Kathon or ProClin 200 (CAS 55965-84-9)* [7] *The VITROS Testosterone Reagent Pack and VITROS Testosterone Calibrators contain 0.5% and 2% Kathon or ProClin 200 respectively. H317: May cause an allergic skin reaction. H319: Causes serious eye irritation. P280: Wear protective gloves, Eye Protection. P302 + P352: IF ON SKIN: Wash with plenty of soap and water. P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P333 + P313: If skin irritation or rash occurs: Get medical advice/attention. P337 + P313: If eye irritation persists: Get medical advice/ attention. P362: Take off contaminated clothing and wash before reuse.*

WARNING

Reagents

Reagent Pack Contents

1 reagent pack containing:

- 100 coated wells (streptavidin, bacterial; binds ≥2 ng biotin/well)
- 8.4 mL conjugate reagent (HRP-testosterone, 60 ng/mL) in buffer with bovine serum albumin and antimicrobial agent
- 13.3 mL biotinylated antibody reagent (biotin-mouse anti-testosterone, binds ≥0.025 nmol testosterone/mL) in buffer with human serum 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 positive 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	≤8 weeks
Opened	Refrigerated	2–8 °C (36–46 °F)	≤8 weeks

- The VITROS Testosterone 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 Testosterone Calibrators 1, 2 and 3 (testosterone in human serum with antimicrobial agent, 2.0 mL); nominal values 1.5; 10 and 50 nmol/L (43.3; 288 and 1442 ng/dL)
- Lot calibration card
- Protocol card
- 24 calibrator bar code labels (8 for each calibrator)

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 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

- VITROS Testosterone Calibrators are supplied ready for use.
- The VITROS Testosterone Calibrators are suitable for use until the expiration date on the carton when 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 Testosterone test uses 25 µL of calibrator for each determination. The VITROS Testosterone 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
- EDTA plasma
- Heparin plasma

Specimens Not Recommended

- Do not use turbid specimens. Turbidity in specimens may affect test results.
- Do not use hemolyzed specimens as hemolysis may affect test results.

Special Precautions

IMPORTANT:	*Certain collection devices have been reported to affect other analytes and tests.*[8] *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.[9-10]
- Thoroughly mix samples by inversion and bring to 15–30 °C (59–86 °F) before use.
- The VITROS Testosterone 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) or 4 weeks at -20 °C (-4 °F).
- Avoid repeated freeze-thaw cycles.

Testing Procedure

Materials Provided

- VITROS Immunodiagnostic Products Testosterone Reagent Pack
- VITROS Immunodiagnostic Products Testosterone Calibrators

Materials Required but Not Provided

- VITROS Immunodiagnostic Products Signal Reagent
- VITROS Immunodiagnostic Products Universal Wash Reagent
- Quality control materials such as VITROS Immunodiagnostic Products Testosterone 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

Testosterone concentrations above the measuring range should be reported as >75.0 nmol/L (2160 ng/dL). The dilution of samples in the VITROS Testosterone test is not supported.

Default Test Name

The default test name which will appear on patient reports is Testosterone. The default short name that will appear on the test selection menus and laboratory reports is Testo. 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

Calibration of the VITROS Testosterone test is traceable to in-house reference calibrators which have been value assigned to correlate to samples measured by isotope-dilution gas-chromatography/mass spectrometry (ID-GCMS).

Calibration Model

A modified four-parameter logistic curve fit function is used to construct the Master Calibration. 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
3600 5600 XT 7600 ECi/ECiQ	0.170–75.0 nmol/L (4.90–2160 ng/dL)

The lower limit reported by the system can be reconfigured if desired. For details on how to reconfigure the lower limit refer to the operating instructions for your system.

Quality Control

Quality Control Material Selection

VITROS Testosterone Controls are recommended for use with the VITROS Immunodiagnostic and VITROS Integrated Systems. The VITROS Testosterone Controls contain 3 suitable levels of testosterone (low, medium and 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 testosterone 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 Testosterone 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. [11]

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 nmol/L or ng/dL. To configure the units, refer to the operating instructions for your system.

Conventional	Alternate
nmol/L (ng/dL× 0.0347)	ng/dL (nmol/L× 28.84)

Limitations of the Procedure

Known Interferences

The VITROS Testosterone test was evaluated for interference consistent with CLSI document EP7. [12] Commonly encountered substances were tested on 2 lots of reagents. The following compounds, when tested, caused the bias shown at the concentrations indicated.

Refer to "Specificity" for a list of other compounds tested that did not show interference.

Interferent	Interferent Concentration		Units = nmol/L		Units = ng/dL	
			Analyte Conc*	Bias**	Analyte Conc*	Bias**
Bilirubin	0.171 mmol/L	10 mg/dL	9.18	1.28	265	36.9
Hemoglobin	0.31 mmol/L	500 mg/dL	14.1	-1.8	407	-50.5

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

** Estimate of the average difference observed.

Note: These results are representative. The degree of interference at concentrations other than those listed might not be predictable from these results. Other interfering substances may be encountered in the patient population.

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.
- 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.

- Inaccurate results may be caused by steroid therapy or physiological conditions causing large changes in serum protein concentrations. Testosterone concentrations may be elevated due to defects in steroid metabolism remote from the hypothalamic-pituitary-gonadal axis.
- Certain drugs and clinical conditions are known to alter testosterone concentrations *in vivo*. For additional information, refer to one of the published summaries. [14- 16]
- Biotin levels in serum remain elevated for up to 24 hours after oral or intravenous biotin administration. [17]

Expected Values and Interpretation of Results

It is recommended that each laboratory establish its own expected values for the population it serves.

Reference Interval

Subject Category	No. of Subjects	Units = nmol/L	Units = ng/dL
Normal males (aged 20–49)	120	4.56–28.2	132–813
Normal males (aged >50)	40	2.49–21.6	71.8–623
Females with normal menstrual cycles	99	0.198–2.67	5.71–77.0

These reference intervals are the central 95% of results of a study of 259 subjects.

Interpretation of Results

For patient samples values outside your established reference interval, the system may be configured to display a flag ‘LO’ or ‘HI’. For detailed information refer to the operating instructions for your system.

Performance Characteristics

Limit of Detection

The Limit of Detection (LoD) for VITROS Testosterone is 0.170 nmol/L (4.90 ng/dL), determined consistent with NCCLS document EP17 [18] and with proportions of false positives (α) less than 5% and false negatives (β) less than 1%; based on 698 determinations, with 1 blank and 5 low-level samples. The Limit of Blank (LoB) is 0.044 nmol/L (1.27 ng/dL).

Limit of Blank and Limit of Detection

LoB*		LoD**	
nmol/L	ng/dL	nmol/L	ng/dL
0.044	1.27	0.170	4.90

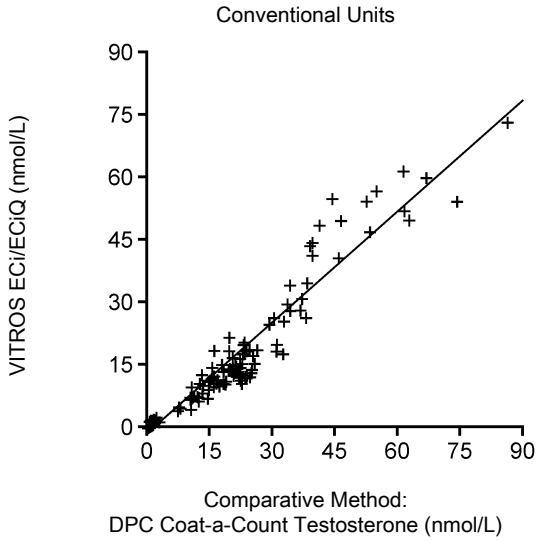
* Limit of Blank, or the highest value likely to be observed with a sample containing no analyte, replaces the term "analytical sensitivity."

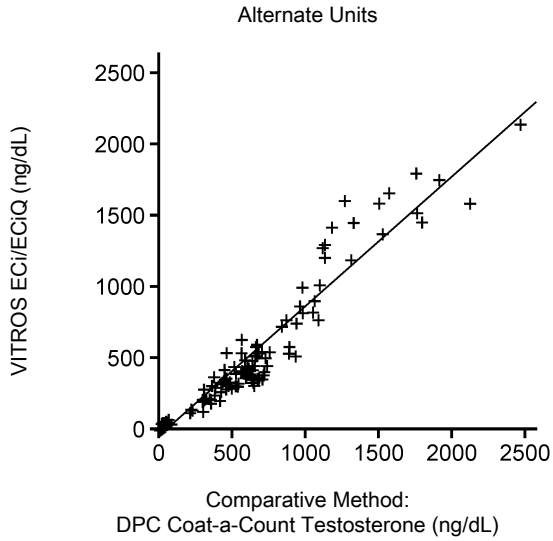
** Proportions of false positives (α) and false negatives (β) were less than 5% and 1% respectively; based on 698 determinations, with 1 blank and 5 low-level samples.

Accuracy (Method Comparison)

Accuracy was evaluated consistent with NCCLS document EP9. [19] The plots and table show the results of a method comparison study using patient serum samples from a variety of clinical categories analyzed on the VITROS ECi/ECiQ Immunodiagnostic System compared with those analyzed using the DPC Coat-a-Count Testosterone test. The relationship between the 2 methods was determined by Deming regression. [20]

The table also shows the results of method comparison studies [21] using patient serum and plasma samples analyzed on the VITROS ECi/ECiQ Immunodiagnostic System compared with those analyzed using the VITROS 3600 Immunodiagnostic System and the VITROS 5600 Integrated System. The relationship between the 2 methods was determined by Deming regression. [20]





System	n	Slope	Correlation Coefficient	Conventional Units (nmol/L) Range of Samples	Conventional Units (nmol/L) Intercept	Alternate Units (ng/dL) Range of Samples	Alternate Units (ng/dL) Intercept
ECi/ECiQ vs. Comparative Method	138	0.922	0.962	0.313–73.6	-2.25	9.03–2123	-64.9
3600 vs. ECi/ECiQ	105	1.04	0.999	0.178–69.0	0.053	5.13–1990	1.53
5600* vs. ECi/ECiQ	106	1.02	0.999	0.178–69.0	-0.296	5.13–1990	-8.54

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

Precision

VITROS ECi/ECiQ Immunodiagnostic System

Precision was evaluated consistent with NCCLS document EP5. [22] Two replicates each of 3 freeze-dried 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. [23] Two replicates each of 3 freeze-dried 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 = nmol/L							No. Observ.	No. Days
	Mean Testosterone Conc.	Within-run*		Within-calibration**		Within-lab***			
		SD	CV (%)	SD	CV (%)	SD	CV (%)		
ECi/ECiQ system 1	1.92	0.0723	3.8	0.153	8.0	0.143	7.4	92	23
	9.38	0.262	2.8	0.617	6.6	0.517	5.5	92	23
	51.8	1.37	2.6	2.98	5.8	2.73	5.3	92	23
ECi/ECiQ system 2	2.04	0.0517	2.5	0.131	6.4	0.132	6.5	92	23
	9.78	0.178	1.8	0.462	4.7	0.479	4.9	92	23
	52.5	1.30	2.5	2.20	4.2	2.18	4.2	92	23
3600	1.89	0.0673	3.6	0.121	6.4	0.108	5.1	88	22
	7.77	0.106	1.4	0.328	4.2	0.329	4.0	88	22
	53.6	0.614	1.1	1.59	3.0	1.71	3.1	88	22
5600 ****	2.22	0.0497	2.2	0.105	4.7	0.116	5.5	88	22
	8.31	0.174	2.1	0.282	3.4	0.314	3.8	88	22
	53.7	0.600	1.1	1.28	2.4	1.33	2.4	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.

System	Units = ng/dL							No. Observ.	No. Days
	Mean Testosterone Conc.	Within-run*		Within-calibration**		Within-lab***			
		SD	CV (%)	SD	CV (%)	SD	CV (%)		
ECi/ECiQ system 1	55.4	2.09	3.8	4.41	8.0	4.12	7.4	92	23
	271	7.56	2.8	17.8	6.6	14.9	5.5	92	23
	1494	39.5	2.6	85.9	5.7	78.7	5.3	92	23
ECi/ECiQ system 2	58.8	1.49	2.5	3.78	6.4	3.81	6.5	92	23
	282	5.13	1.8	13.3	4.7	13.8	4.9	92	23
	1514	37.5	2.5	63.4	4.2	62.9	4.2	92	23
3600	54.5	1.94	3.6	3.49	6.4	3.11	5.1	88	22
	224	3.06	1.4	9.46	4.2	9.49	4.0	88	22
	1546	17.7	1.1	45.9	3.0	49.3	3.1	88	22
5600 ****	64.0	1.43	2.2	3.03	4.7	3.35	5.5	88	22
	240	5.02	2.1	8.13	3.4	9.06	3.8	88	22
	1549	17.3	1.1	36.9	2.4	38.4	2.4	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 Testosterone test was evaluated for interference consistent with CLSI document EP7. [12] Of the compounds tested, none was found to cause a bias of >10% with the test at the concentrations indicated at testosterone concentration of 3.55–10.0 nmol/L (102–288 ng/dL).

Compound	Concentration	
Biotin	40.9 nmol/L	1 µg/dL
Intralipid	300 mg/dL	3 g/L
Triolein	33.9 mmol/L	3000 mg/dL

Cross-Reactivity

The cross-reactivity of the VITROS Testosterone test was evaluated by adding the following substances to control samples containing no testosterone.

Cross-Reactant	Concentration		Mean Value of Cross-reactant Pool		% Cross-reactivity
			nmol/L	ng/dL	
Androsterone	10.0 µmol/L	290 µg/dL	1.87	53.9	0.019
Cortisol	10.0 µmol/L	362 µg/dL	0.640	18.5	0.006
Cortisone	10.0 µmol/L	360 µg/dL	0.534	15.4	0.005
Danazol	10.0 µmol/L	338 µg/dL	0.566	16.3	0.006
DHEA	10.0 µmol/L	288 µg/dL	1.16	33.5	0.012
DHEA-3-sulfate	10.0 µmol/L	391 µg/dL	0.962	27.7	0.010
Epitestosterone	10.0 µmol/L	288 µg/dL	0.977	28.2	0.010
Estradiol	10.0 µmol/L	272 µg/dL	0.916	26.4	0.009
Estrone	10.0 µmol/L	270 µg/dL	1.04	30.0	0.011
17-α-Methyltestosterone	10.0 µmol/L	302 µg/dL	7.19	207	0.072
17-OH-Progesterone	10.0 µmol/L	331 µg/dL	0.874	25.2	0.008
Progesterone	10.0 µmol/L	314 µg/dL	3.17	91.4	0.032

Cross-reactivity was expressed as the mean result obtained for the cross-reactant pool divided by the cross-reactant concentration in percentage term.

$$\% \text{ Cross-reactivity} = \frac{\text{Mean Result for the Cross-reactant Pool}}{\text{Concentration of Cross-reactant}} \times 100$$

Cross-Reactivity at 50% Displacement

Cross-reactivity at 50% displacement was calculated from the dose-response curves obtained for the cross-reactants and from the calibration curve for VITROS Testosterone. The concentrations at 50% displacement of the zero calibrator for the cross-reactant and for VITROS Testosterone were obtained from these curves.

Compound	% Cross-reactivity
11-Ketotestosterone	8.78
11-β-Hydroxytestosterone	5.64
19-Nortestosterone	3.22
5-α-Dihydrotestosterone	0.56
Androstenedione	0.48
5-β-Dihydrotestosterone	0.27
Mesterolone	0.25

$$\% \text{ Cross-reactivity at 50\% displacement} = \frac{\text{Concentration at 50\% displacement for testosterone}}{\text{Concentration at 50\% displacement for Cross-reactant}} \times 100$$

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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	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*
2020-04-10	11.0	• Warnings and Precautions: updated Hazard and Precaution Statements to align with the new Safety Data Sheets

* 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

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