INSTRUCTIONS FOR USE BhCG2

VITROS Immunodiagnostic Products Total β-hCG II Reagent Pack	REF	619 9334
VITROS Immunodiagnostic Products Total β-hCG II Calibrators	REF	619 9327

Rx ONLY

Intended Use

For *in vitro* diagnostic use only.

VITROS Immunodiagnostic Products Total Total β-hCG II Reagent Pack

For the quantitative measurement of human chorionic gonadotropin (hCG) and its β-subunit in human serum and plasma (heparin and EDTA) using the VITROS ECi/ECiQ/3600 Immunodiagnostic Systems and the VITROS 5600/XT 7600 Integrated Systems to aid in the early detection of pregnancy.

VITROS Immunodiagnostic Products Total β-hCG II 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 human chorionic gonadotropin (hCG) and its β-subunit in human serum and plasma (heparin and EDTA).

Summary and Explanation of the Test

The detection of hCG in urine or blood within 3–4 weeks of the last menstrual period is the most reliable indicator for the confirmation of pregnancy. hCG is initially secreted by the trophoblast, and later by the chorion and placenta. Levels rise exponentially to a peak during the first trimester, declining to a plateau during the second and third trimesters. Measurement of hCG has also been applied in the diagnosis of ectopic pregnancy, threatened abortion, and multiple gestation. [1-4]

Principles of the Procedure

An immunometric immunoassay technique is used, which involves the reaction of hCG present in the sample with a microwell coated with biotinylated antibody (mouse monoclonal anti-β-hCG) bound to streptavidin, and a horseradish peroxidase (HRP)-labeled antibody conjugate (mouse monoclonal anti-β-hCG). Unbound materials are removed by washing.

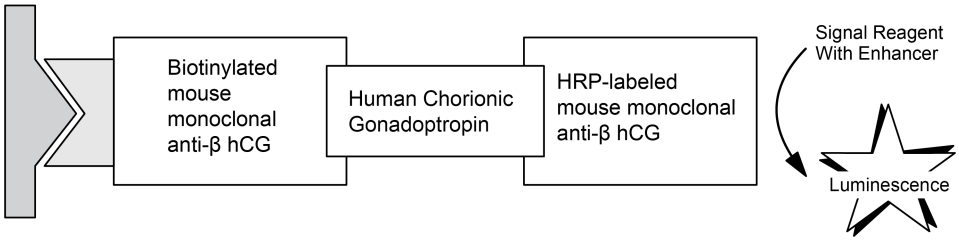
The bound HRP conjugate is measured by a luminescent reaction. [5] A reagent containing luminogenic substrates (a luminol derivative and a peracid salt) and an electron transfer agent, is added to the wells. The HRP in the bound conjugate catalyzes the oxidation of the luminol derivative, producing light. 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 directly proportional to the concentration of hCG present.

Test Type	System*	Incubation Time	Time to first result	Test Temperature	Reaction Sample Volume
Immunometric	ECi/ECiQ, 3600, 5600, XT 7600	13 minutes, 20 seconds	24 minutes	37 °C	40 µL

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

Reaction Scheme

Streptavidin/Biotinylated anti-β hCG Coated Well



Warnings and Precautions

WARNING: *Potentially Infectious Material*

Human blood products provided as components of the VITROS Total β-hCG II 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 Mixture, 3(2H)-isothiazolone, 5-chloro-2-methyl- with 2-methyl-3(2H)-isothiazolone (CAS 55965-84-9)*[7]

The VITROS Total β-hCG II Reagent Pack and VITROS Total β-hCG II Calibrators contain 0.03% Mixture, 3(2H)-isothiazolone, 5-chloro-2-methyl- with 2-methyl-3(2H)-isothiazolone. H317: May cause an allergic skin reaction. P261: Avoid breathing dust/fume/gas/mist/vapors and spray. P272: Contaminated work clothing must not be allowed out of the workplace. P280: Wear protective gloves. P302 + P350: IF ON SKIN: Wash with plenty of water and soap. P333 + P313: If skin irritation or rash occurs: Get medical advice/attention. P363: Wash contaminated clothing before reuse. P501: Dispose of contents/container to an approved waste disposal plant.

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 (antibody, mouse monoclonal anti-β-hCG, binds ≥600 mIU hCG/well)
- 14.4 mL assay reagent (buffer containing mouse serum, bovine serum albumin, bovine gamma globulin and antimicrobial agent)
- 19.2 mL conjugate reagent (HRP-mouse monoclonal anti-β-hCG, binds ≥4005 mIU hCG/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 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 Total β-hCG II 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.
- Opened reagent packs are moisture/humidity sensitive. Store opened refrigerated reagent packs in a sealed VITROS Immunodiagnostic Products Reagent Pack storage box with desiccant.

Calibrator Contents

- 3 sets of VITROS Total β-hCG II Calibrators 1, 2 and 3, (freeze-dried, recombinant hCG in human plasma with antimicrobial agent, reconstitution volume 1.0 mL), nominal values 0; 3,000; 14,000 mIU/mL (IU/L)
- 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 volume 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 volume for a single determination.

Calibrator Storage and Preparation

Calibrator	Storage Condition		Stability
Unopened	Refrigerated	2–8 °C (36–46 °F)	expiration date
Opened-reconstituted	Refrigerated	2–8 °C (36–46 °F)	≤13 weeks
Opened-reconstituted	Frozen	≤-20 °C (≤-4 °F)	≤13 weeks

- VITROS Total β-hCG II Calibrators are supplied freeze-dried.
- VITROS Total β-hCG II 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.
- Reconstitute with 1.0 mL distilled water.
- Opened, reconstituted calibrators may be stored frozen (with no more than 1 freeze-thaw cycle).

- The VITROS Total β-hCG II test uses 40 µL of calibrator for each determination. 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
- Lithium-Heparin plasma
- K2-EDTA plasma

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.*[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]
- 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 Total β-hCG II test uses 40 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) or 4 weeks at -20 °C (-4 °F).
- Avoid repeated freeze-thaw cycles.

Testing Procedure

Materials Provided

- VITROS Immunodiagnostic Products Total β-hCG II Reagent Pack
- VITROS Immunodiagnostic Products Total β-hCG II 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
- VITROS Immunodiagnostic Products Reagent Pack Storage Box with desiccant
- Calibrated pipette, distilled water and sample containers for reconstitution of VITROS Total β-hCG II Calibrators

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 lot 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

Samples with concentrations greater than the measuring range may be diluted automatically on the system up to 400-fold (1 part sample with 399 parts diluent) by the VITROS Immunodiagnostic and VITROS Integrated Systems with 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 Total β-hCG II. The default short name that will appear on the test selection menus and laboratory reports is BhCG2. 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 test reagent 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 Total β-hCG II test is traceable to in-house reference calibrators, which have been value-assigned with reference to the 4th International Standard (NIBSC 75/589).

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	2.39*–15,000 mIU/mL (IU/L)

* Lower limit of measuring range reported by the system software is based on the Limit of Quantitation.

Quality Control

Quality Control Material Selection

Controls containing suitable levels of Total β-hCG II are recommended for use with the VITROS Immunodiagnostic and VITROS Integrated Systems. The performance of 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 hCG 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 Total β-hCG II 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
  - If the system is turned off for more than 2 hours
  - After reloading reagent packs that have been removed from the MicroWell Supply and stored for later use
  - 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

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

Conventional	Alternate
mIU/mL (IU/L× 1)	IU/L (mIU/mL× 1)

Limitations of the Procedure

Known Interferences

The VITROS Total β-hCG II test was screened for interfering substances at hCG concentrations of approximately 5.00 mIU/mL (IU/L), 50.00 mIU/mL (IU/L) and 10,000 mIU/mL (IU/L) following CLSI EP07 [12] and EP37. [13] Of the compounds tested, none was found to cause a bias of >10%.

For substances that were tested and did not interfere, refer to "Specificity - Substances that do not Interfere".

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

Other Limitations

- The results from this 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. [14] 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.
- Falsely elevated hCG results in serum and plasma [15- 19] might be due to the presence of heterophilic antibodies, such as anti-mouse antibodies (HAMA), to nonspecific protein binding, and to hCG-like substances.
- If the hCG result is inconsistent with the clinical picture and is persistently elevated, the hCG result should be confirmed with a urine hCG test or by repeating the serum or plasma test on a different test system. [15]
- Interpretation of hCG results should be done in the context of an overall medical management protocol that includes results of other tests, clinical impressions and symptoms.
- Exogenous hCG administered within 7–10 days of sampling may give a detectable test result. When using the determination of hCG to confirm pregnancy, care should be taken to exclude the possibility of hCG secreting tumors.
- The concentration of hCG in maternal serum rises rapidly in early pregnancy. hCG levels less than 25 mIU/mL do not exclude pregnancy. [20] A further sample should be tested after 48 hours if pregnancy is suspected.

Expected Values and Interpretation of Results

It is recommended that each laboratory establish its own expected values for the population it serves. As a guide, the following ranges were determined. Concentrations of hCG measured in samples from apparently healthy, non-pregnant individuals were determined to be ≤4.83 mIU/mL (IU/L) (290 samples).

Sample type	Number of samples	Units = mIU/mL (IU/L)				
		Mean	Min	Max	2.5th Percentile	97.5th Percentile
Normal Male	98	0.02	0.00	1.06	0.00	0.08
Normal Female	123	0.46	0.00	5.42	0.00	4.32
Post menopausal	69	1.52	0.00	6.66	0.00	6.46
Total	290	0.56	0.00	6.66	0.00	4.83

Concentrations of hCG measured in the sera of pregnant females at defined gestational ages are summarized below.

Sample type	Number of samples	Units = mIU/mL (IU/L)				
		Mean	Min	Max	2.5th Percentile	97.5th percentile
Pregnant gestational age 1–10 weeks	112	31,142	44.71	256,740	63.7	150,854
Pregnant gestational age 11–15 weeks	43	55,425	11,556	265,380	11795	151,996
Pregnant gestational age 16–22 weeks	50	27,023	7480.8	111,954	9383.8	61,410
Pregnant gestational age 23–40 weeks	45	24,031	1531.1	101,566	1737.2	98,576

Interpretation of Results

According to the literature, [21] hCG results greater than or equal to 25 mIU/mL (IU/L) are considered positive.

Performance Characteristics

Limit of Detection

The Limit of Blank (LoB) for the VITROS Total β-hCG II test is 0.05 mIU/mL (IU/L), determined consistent with CLSI document EP17. [22] The Limit of Detection (LoD) for the VITROS Total β-hCG II test is 0.70 mIU/mL (IU/L), determined consistent with CLSI document EP17. [22] The Limit of Quantitation (LoQ) is 2.39 mIU/mL (IU/L), determined consistent with CLSI document EP17. [22]

Limit of Blank, Limit of Detection and Limit of Quantitation

LoB	LoD	LoQ
mIU/mL (IU/L)	mIU/mL (IU/L)	mIU/mL (IU/L)
0.05	0.70	2.39

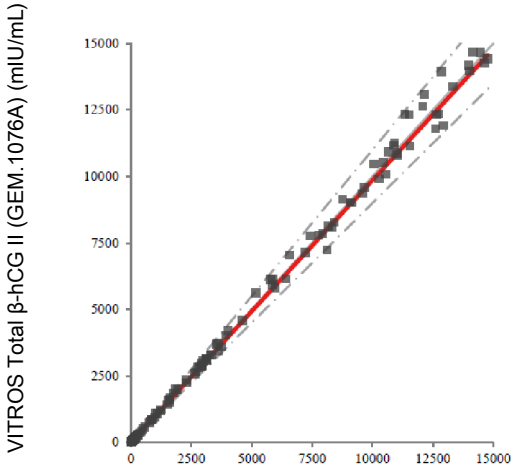
Linearity

Linearity was established in accordance with the CLSI guideline EP06. [23] In a study with 20 levels run on 1 reagent lot on one VITROS 5600 Integrated System. Results support linearity from 1.51 mIU/mL (IU/L) to 15695 mIU/mL (IU/L).

Accuracy (Method Comparison)

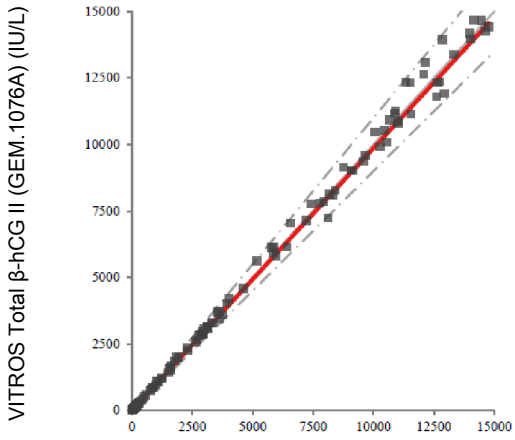
Accuracy was evaluated consistent with CLSI document EP09. [24] The plot and table show the results of a method comparison study using patient serum samples analyzed on the VITROS 5600 Integrated System compared with those analyzed using the VITROS Total β-hCG II (GEM.1076) test. The relationship between the two methods was determined by Weighted Deming regression. [25]

Conventional Units



Comparative Method: VITROS Total β-hCG (GEM.1076) (mIU/mL)

Alternate Units



Comparative Method: VITROS Total β-hCG (GEM.1076) (IU/L)

System	n	Slope (95% CI)	Correlation Coefficient	Conventional Units (mIU/mL)		Alternate Units (IU/L)	
				Range of Samples	Intercept (95% CI)	Range of Samples	Intercept (95% CI)
5600 vs. Comparative Method	135	0.99 (0.977–0.995)	0.998	2.78–14,675	-0.0215 (-0.160–0.117)	2.78–14,675	-0.0215 (-0.160–0.117)

Systems Comparison

The table shows the results of serum 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 Passing and Bablok regression. [26]

System	n	Slope	Correlation Coefficient	Conventional Units**(mIU/mL)	
				Range of Samples	Intercept
3600 vs. ECi/ECiQ	64	0.99	0.999	2.97–14887	0.214
5600* vs. ECi/ECiQ	64	0.98	0.999	2.97–14887	0.625

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

** Alternate Units (IU/L) are equivalent to Conventional Units (mIU/mL).

Precision

Precision was evaluated with patient pools on the systems in the table below following the CLSI document EP05. [27] The data presented are a representation of test performance and are provided as a guideline. Variables such as sample handling and storage, reagent handling and storage, laboratory environment, and system maintenance can affect reproducibility of test results.

System	Units = mIU/mL (IU/L)*					No. of Obs.	No. of Days
	Mean hCG Conc.	Repeatability**		Within Lab***			
		SD	%CV	SD	%CV		
ECi/ECiQ	5.20	0.090	1.70%	0.253	4.90%	80	20
	15.32	0.226	1.50%	0.470	3.10%	80	20
	46.4	0.427	0.90%	1.48	3.20%	80	20
	300.82	2.98	1.00%	10.61	3.50%	80	20
	4466.5	69.47	1.60%	159.58	3.60%	80	20
	8939.7	193.35	2.20%	428.99	4.80%	80	20
3600	5.03	0.106	2.10%	0.325	6.50%	80	20
	15.26	0.22	1.40%	0.491	3.20%	80	20
	46.02	0.593	1.30%	1.13	2.50%	80	20
	301.18	3.87	1.30%	8.95	3.00%	80	20
	4918.0	95.52	1.90%	175.01	3.60%	80	20
	10827	323.34	3.00%	574.35	5.30%	80	20
5600****	5.33	0.095	1.80%	0.281	5.30%	80	20
	15.46	0.181	1.20%	0.706	4.60%	80	20
	45.67	0.666	1.50%	1.56	3.40%	80	20
	297.34	4.97	1.70%	8.64	2.90%	80	20
	4708.5	82.29	1.70%	151.22	3.20%	80	20
	9651.0	286.71	3.00%	464.48	4.80%	80	20

* Alternate Units (IU/L) are equivalent to Conventional Units (mIU/mL).

** Repeatability (formerly called within-run precision) was determined using two replicates per run.

*** Within Lab precision was determined using a single reagent lot and a single calibration.

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

Specificity

Substances that do not Interfere

The substances listed in the table below were tested with the VITROS Total β-hCG II test following CLSI EP07 [12] and EP37 [13] and found not to cause bias > 10% at hCG concentrations of approximately 5.00 mIU/mL (IU/L), 50.00 mIU/mL (IU/L) and 10,000 mIU/mL (IU/L) at the test concentrations shown.

Substance	Concentration	
Acetaminophen	15.6 mg/dL	1032 µmol/L
N-Acetylcysteine	15.0 mg/dL	920 µmol/L
Alpha-tocopherol	6.45 mg/dL	150 µmol/L
Amoxicillin	5.40 mg/dL	148 µmol/L
Ascorbic Acid	5.25 mg/dL	298 µmol/L
Bilirubin, conjugated	40 mg/dL	475 µmol/L
Bilirubin, unconjugated	40 mg/dL	475 µmol/L
Biotin	0.351 mg/dL	14.3 µmol/L
Carbamazepine	4.50 mg/dL	191 µmol/L
Cefoxitin sodium	695 mg/dL	15.5 mmol/L
Cholesterol	400 mg/dL	10.3 mmol/L
Codeine	0.141 mg/dL	5 µmol/L
Colecalciferol	19.2 µg/dL	0.5 µmol/L
Cotinine	0.24 mg/dL	13.6 µmol/L
Dextran 40	2400 mg/dL	600 µmol/L

Substance	Concentration	
Dextromethorphan	0.00156 mg/dL	0.042 µmol/L
Dipyrone	100 mg/dL	N/A
Enoxaparin	360 U/dL	N/A
Ethanol	600 mg/dL	130 mmol/L
Furosemide	1.59 mg/dL	48 µmol/L
Gamma globulin	6 g/dL	N/A
HAMA (Human Anti-Mouse Antibodies)	800 µg/L	0.005 µmol/L
Hemoglobin	1000 mg/dL	155 µmol/L
Hydralazine Hydrochloride	1.44 mg/dL	73.2 µmol/L
Hydrocodone	0.0072 mg/dL	0.2 µmol/L
Ibuprofen	21.9 mg/dL	1.06 mmol/L
Intralipid	2000 mg/dL	19.2 mmol/L
Levothyroxine	0.0429 mg/dL	0.552 µmol/L
Loratadine	0.0087 mg/dL	0.227 µmol/L
Naproxen	36.0 mg/dL	1.43 mmol/L
Nifedipine	0.0588 mg/dL	1.7 µmol/L
Nitrofurantoin	0.213 mg/dL	8.94 µmol/L
Omeprazole	0.840 mg/dL	24.3 µmol/L
Phenytoin	6.00 mg/dL	238 µmol/L
Prednisone	0.010 mg/dL	0.280 µmol/L
Propranolol HCl	0.115 mg/dL	3.89 µmol/L
Rheumatoid Factor	900 IU/mL	N/A
Salicylic Acid	2.86 mg/dL	207 mmol/L
Sodium Azide	100 mg/dL	15.4 mmol/L
Sulfamethoxazole	40 mg/dL	1.58 mmol/L
Theophylline	6.0 mg/dL	333 µmol/L
Total Protein	15 g/dL	17.1 nmol/L
Triglycerides	1500 mg/dL	16.9 mmol/L
Trimethoprim	4.2 mg/dL	145 µmol/L
Vancomycin hydrochloride	12.3 mg/dL	8.28 mmol/L

Cross-Reactivity

Each potential cross-reactant was spiked into hCG pools at hCG concentrations of approximately 0 mIU/mL and 25 mIU/mL. Test substances were spiked at a volume that constituted no more than 5% of the volume of the test sample.

Test Substance (0 mIU/mL)	Concentration	% Cross-reactivity
FSH	400 mIU/mL	ND*
LH	400 mIU/mL	ND*
TSH	200 mIU/mL	ND*

* Not Detectable (ND). Concentration was below the measuring interval of the test, 2.39 to 15,000 mIU/mL (IU/L).

Cross-reactivity at 0 mIU/mL was expressed as the mean result obtained for the cross-reactant sample divided by the cross-reactant concentration in percentage terms:

$$\% \text{ Cross-reactivity} = \frac{\text{Mean Result of Cross-Reactant Sample}}{\text{Concentration of Cross-reactant}} \times 100$$

Test Substance (25 mIU/mL)	Cncentration	% Cross-reactivity
FSH	400 mIU/mL	0.6%
LH	400 mIU/mL	-0.3%
TSH	200 mIU/mL	0.4%

Cross-reactivity at 25 mIU/mL was expressed as the mean result obtained for the cross-reactant sample divided by the cross-reactant concentration in percentage terms:

$$\% \text{ Cross-reactivity} = \frac{\text{Mean Result of Cross-Reactant Sample} - \text{Mean Result of Control Sample}}{\text{Concentration of Cross-reactant}} \times 100$$

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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	σ Estimated within-lab SD
EC REP Authorized Representative in the European Community	Value	
Corrosive	CH REP Authorized Representative in Switzerland	Serious Health Hazards
Health Hazards	Flammable	Environmental or Aquatic Toxicity
	Acute Toxicity	

Revision History

Date of Revision	Version	Description of Technical Changes*
2024-05-07	1.0	Initial version of Instructions for Use

* 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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