VITROS Products
Immunodiagnostic

INSTRUCTIONS FOR USE CEA

VITROS Immunodiagnostic Products CEA Reagent Pack	REF	192 0115
VITROS Immunodiagnostic Products CEA Calibrators	REF	106 2306

Intended Use

For *in vitro* diagnostic use only.

VITROS Immunodiagnostic Products CEA Reagent Pack

For the quantitative measurement of carcinoembryonic antigen (CEA) in human serum and plasma (EDTA or heparin) using the VITROS ECi/ECiQ/3600 Immunodiagnostic Systems and the VITROS 5600/XT 7600 Integrated Systems, to aid in the prognosis and management of cancer patients in whom changing concentrations of CEA are observed.

WARNING:	Due to differences in methodology and reagent specificity, the concentration of CEA in a given specimen can vary in tests from different manufacturers. Reported CEA levels must include the identity of the CEA test used. Values obtained with different CEA tests cannot be used interchangeably. If, in the course of monitoring the patient, the test method used for determining the CEA levels is changed, additional sequential testing should be carried out. Prior to changing tests, the laboratory must confirm baseline values for patients being serially monitored.

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

Summary and Explanation of the Test

Carcinoembryonic antigen (CEA) is a glycoprotein with a molecular weight of approximately 180,000 daltons.[1] CEA is present in normal serum at low concentrations. Originally thought to be specific for digestive tract cancers it may also be elevated in other malignancies as well as in some nonmalignant disorders and behaviors[2-3] CEA testing has become widely accepted in the management of cancer patients. A CEA concentration which falls steadily to reach normal concentrations suggests a good prognosis while an increasing concentration is indicative of treatment failure and a poor prognosis.[4-7] Clinical relevance has been shown in the follow-up management of patients with colorectal, breast, lung, prostatic, pancreatic and ovarian carcinoma. Prognostic significance has been suggested for preoperative CEA concentrations in patients with colorectal, breast and lung carcinoma.[8-9] The CEA test is not recommended as a screening procedure for detection of cancer in the general population or in an otherwise asymptomatic patient but rather as an adjunctive test to aid in predicting prognosis and in management of cancer patients.

Principles of the Procedure

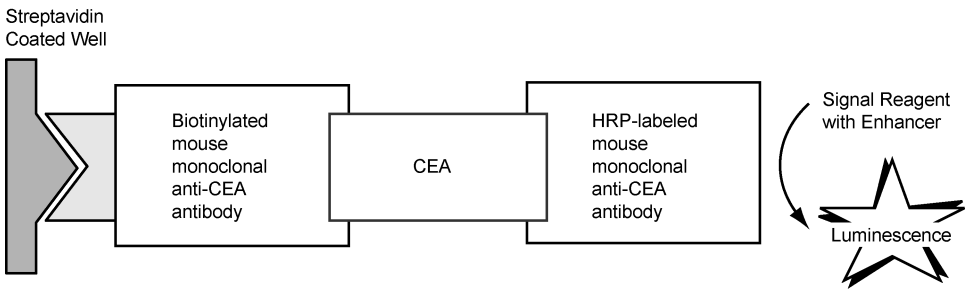
An immunometric immunoassay technique is used. CEA present in the sample reacts simultaneously with a biotinylated antibody (mouse monoclonal anti-CEA) and a horseradish peroxidase (HRP)-labeled antibody conjugate (mouse monoclonal anti-CEA). The antigen-antibody complex is captured by streptavidin on the wells. Unbound materials are removed by washing.

The bound HRP conjugate is measured by a luminescent reaction.[10] 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 CEA present.

Test Type	System *	Incubation Time	Time to first result	Test Temperature	Reaction Sample Volume
Immunometric	ECi/ECiQ, 3600, 5600, XT 7600	30 minutes	38 minutes	37 °C	20 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, 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). [11]

WARNING: Contains ProClin 300 and Kathon or ProClin 200 (CAS 55965-84-9) [12]

The VITROS CEA Reagent Pack contains 0.5% ProClin 300. The VITROS CEA Calibrators contain 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.

Reagents

Reagent Pack Contents

1 reagent pack containing:

- 100 coated wells (streptavidin, bacterial, binds ≥3 ng biotin/well)
- 9.7 mL biotinylated antibody reagent (biotin-mouse monoclonal anti-CEA, binds ≥152.9 ng CEA/mL) in buffer with bovine serum albumin, bovine gamma globulin and antimicrobial agent
- 9.7 mL conjugate reagent (HRP-mouse monoclonal anti-CEA, binds ≥152.9 ng CEA/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 CEA 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 CEA Calibrators 1 and 2 (human CEA in bovine serum with antimicrobial agent, 2 mL); nominal values 3 and 250 ng/mL (µg/L)
- Lot calibration card
- Protocol card
- 16 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 CEA Calibrators are supplied ready for use.
- The VITROS CEA 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 CEA test uses 20 µL of calibrator for each determination. The VITROS CEA 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
- EDTA plasma

Note: Plasma (EDTA) samples show approximately 13% negative bias when compared to matched serum samples.

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. [13] 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. [14- 15]
- Thoroughly mix samples by inversion and bring to 15–30 °C (59–86 °F) before use.
- The VITROS CEA test uses 20 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 CEA Reagent Pack
- VITROS Immunodiagnostic Products CEA 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
- 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 (EDTA or heparin) samples with concentrations greater than the measuring range may be automatically diluted on the system up to 100-fold (1 part sample with 99 parts diluent) by the VITROS Immunodiagnostic and VITROS Integrated Systems with the VITROS High Sample Diluent B Reagent Pack prior to test. Refer to the VITROS High Sample Diluent B Reagent Pack instructions for use.

Default Test Name

The default test name which will appear on patient reports is CEA. The default short name that will appear on the test selection menus and laboratory reports is CEA. 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 CEA test is traceable to in-house reference calibrators which have been value assigned to correlate to another commercially available test with reference to the 1st International Reference Preparation 73/601.

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	0.31*–400 ng/mL (µg/L)

* lower limit of measuring range reported by the system software is based on the Limit of Detection.

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

Controls containing suitable levels of CEA 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 CEA 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 CEA 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. [16]

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

Conventional	Alternate
ng/mL (µg/L× 1)	µg/L (ng/mL× 1)

Limitations of the Procedure

Known Interferences

The VITROS CEA test was evaluated for interference consistent with CLSI document EP7. [17] Commonly encountered substances were tested on 2 lots of reagents. Of the compounds tested, hemoglobin may interfere with the VITROS CEA test. Hemoglobin, when tested, caused a positive bias at the concentration indicated. Refer to "Specificity" for a list of other compounds tested that did not show interference.

Interferent	Interferent Concentration		Units = ng/mL (µg/L)	
			Analyte Conc*	Bias**
Hemoglobin***	0.31 mmol/L	500 mg/dL	5.21	1.32

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

** Maximum bias observed.

*** Hemolysate was added to a series of specimens with a VITROS CEA concentration of 4.27−8.28 ng/mL (µg/L).

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 VITROS CEA test is not recommended as a screening procedure for cancer detection.
- The results from this or any other diagnostic test should be used and interpreted only in the context of the overall clinical picture.
- Samples containing >180,000 ng/mL (µg/L) CEA may read within the measuring range due to a high dose hook effect.
- Different CEA test methods cannot be used interchangeably. CEA in a given patient sample determined with tests from different manufacturers can vary due to differences in test methods and reagent specificity. A change to the test used during serial monitoring of a patient should be accompanied by additional sequential testing to confirm baseline values. The results reported by the laboratory to the physician must include the identity of the CEA test used.

- Patients with confirmed carcinoma frequently have CEA levels in the same range as normal patients. Elevated levels of CEA may be found in smokers or patients with non-malignant conditions. Based on these observations, CEA levels in serum and plasma, regardless of level, should not be interpreted as absolute evidence of the presence or absence of malignant disease.
- Certain drugs and clinical conditions are known to alter CEA concentrations *in vivo*. For additional information, refer to one of the published summaries. [18-20]
- Heterophilic antibodies in serum or plasma samples may cause interference in immunoassays. [21] 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.
- Biotin levels in serum remain elevated for up to 24 hours after oral or intravenous biotin administration. [22]

Expected Values and Interpretation of Results

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

Distribution of Results by Clinical Category

Category	n	Percent (%)			
		0–3.0 ng/mL (µg/L)	>3.0–5.0 ng/mL (µg/L)	>5.0–10.0 ng/mL (µg/L)	>10.0 ng/mL (µg/L)
Healthy Subjects					
Nonsmokers	149	91.9	6.0	0.7	1.3
Smokers	101	67.3	22.8	8.9	1.0
Total	250	82.0	12.8	4.0	1.2
Malignant Diseases					
Colorectal	114	7.0	10.5	9.7	72.8
Breast	69	30.4	13.0	11.6	44.9
Pulminary	56	28.6	19.6	16.1	35.7
Ovarian	51	72.6	15.7	5.9	5.9
Gastrointestinal	40	22.5	17.5	12.5	47.5
Nonmalignant Disease					
Gastrointestinal	42	73.8	19.0	4.8	2.4
Cirrhosis	65	50.8	16.9	20.0	12.3
Hepatitis	31	77.4	16.1	6.5	0.0
Pulmonary	50	76.0	16.0	4.0	4.0

- The table shows the distribution of CEA values for 768 specimens obtained from healthy subjects and diseased patients.
- As a guide, 91.9% of healthy nonsmokers (n=149) and 67.3% of healthy smokers (n=101) were found to have VITROS CEA test concentrations ≤3 ng/mL (µg/L).

Interpretation of Results

For patient sample values outside your established reference interval, the system may be configured to display a flag 'LO' or 'HI'. Refer to the operating instructions for your system.

Performance Characteristics

Limit of Detection

The Limit of Detection (LoD) for VITROS CEA is 0.31 ng/mL (µg/L), determined consistent with NCCLS document EP17 [23] and with proportions of false positives (α) less than 5% and false negatives (β) less than 1%; based on 680 determinations, with 1 blank and 5 low-level samples. The Limit of Blank (LoB) is 0.06 ng/mL (µg/L).

Limit of Blank and Limit of Detection

LoB*	LoD**
ng/mL (µg/L)	ng/mL (µg/L)
0.06	0.31

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

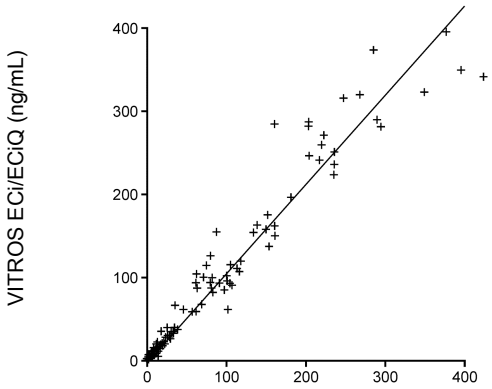
** Proportions of false positives (α) and false negatives (β) were less than 5% and 1% respectively; based on 680 determinations, with 1 blank and 5 low-level samples.

Accuracy (Method Comparison)

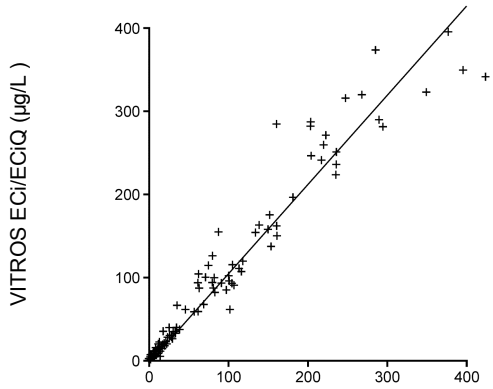
Accuracy was evaluated consistent with NCCLS document EP9. [24] The plots and table show the results of a method comparison study using patient serum samples from a variety of clinical categories analyzed on the VITROS ECi/ECiQ Immunodiagnostic System compared with those analyzed using the *Abbott AxSYM* CEA test. The relationship between the 2 methods was determined by Passing and Bablok regression. [25]

The table also shows the results of method comparison studies [26] 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 Passing and Bablok regression. [25]

Conventional Units



Alternate Units



System	n	Slope	Correlation Coefficient	Conventional Units (ng/mL) Range of Samples	Conventional Units (ng/mL) Intercept	Alternate Units (µg/L) Range of Samples	Alternate Units (µg/L) Intercept
ECi/ECiQ vs. Comparative Method	200	1.06	0.977	0.758–395	0.124	0.758–395	0.124
3600 vs. ECi/ECiQ	105	1.00	0.998	0.440–384	0.120	0.440–384	0.120
5600* vs. ECi/ECiQ	107	0.984	0.998	0.440–395	0.137	0.440–395	0.137

* 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. [27] Two replicates each of 3 serum 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. [28] 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 = ng/mL (µg/L)							No. Observ.	No. Days
	Mean CEA Conc.	Within-run*		Within-calibration**		Within-lab***			
		SD	CV (%)	SD	CV (%)	SD	CV (%)		
ECi/ECiQ system 1	5.21	0.105	2.0	0.222	4.3	0.201	3.9	92	23
	32.3	0.479	1.5	0.964	3.0	0.864	2.7	92	23
	223	4.93	2.2	6.57	2.9	6.51	2.9	92	23
ECi/ECiQ system 2	5.40	0.108	2.0	0.171	3.2	0.160	3.0	88	22
	35.9	0.392	1.1	0.966	2.7	0.969	2.7	92	23
	227	3.56	1.6	6.56	2.9	6.73	3.0	92	23
3600	4.66	0.075	1.6	0.148	3.2	0.142	3.1	88	22
	35.4	0.672	1.9	0.749	2.1	1.14	3.2	88	22
	193	4.18	2.2	5.26	2.7	7.82	3.9	88	22
5600****	4.47	0.094	2.1	0.121	2.7	0.120	2.7	88	22
	35.7	0.479	1.3	0.538	1.5	0.537	1.5	88	22
	197	3.52	1.8	3.77	1.9	3.85	2.0	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 CEA test was evaluated for interference consistent with CLSI document EP7. [17] Of the compounds tested, none was found to cause a bias of >10% with the test at the concentrations indicated at CEA concentrations of:

- 15.1–16.4 ng/mL (µg/L) for Bilirubin, Biotin, and Triolein
- 3.30–4.16 ng/mL (µg/L) for the remaining substances listed

Compound	Concentration	
Acetaminophen	1343 µmol/L	20.3 mg/dL
Acetylsalicylic acid	2.77 mmol/L	50.0 mg/dL
Aminoglutethimide	1.71 mmol/L	39.8 mg/dL
Ascorbic acid	0.341 mmol/L	6.00 mg/dL
Bilirubin	1.7 mmol/L	100 mg/dL
Biotin	40.9 nmol/L	1 µg/dL
Diethylstilbestrol	18.6 µmol/L	0.5 mg/dL
Doxorubicin HCl	89.7 µmol/L	5.2 mg/dL
Etoposide	1.41 mmol/L	83 mg/dL
5-Flourouracil	2.67 mmol/L	34.8 mg/dL
Ibuprofen	3.44 mmol/L	71.0 mg/dL
Methotrexate	35.2 µmol/L	1.6 mg/dL
Mitomycin C	0.165 mmol/L	5.52 mg/dL
Tamoxifen	0.129 mmol/L	4.8 mg/dL
Triolein	33.9 mmol/L	3000 mg/dL
Vinblastine	1.52 mmol/L	138 mg/dL
Vincristine	1.52 mmol/L	140 mg/dL

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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	11.1	• Glossary of Symbols: updated • Added EC Representative address
2017-09-29	11.0	• 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.

When this Instructions For Use is replaced, sign and date below and retain as specified by local regulations or laboratory policies, as appropriate.

Signature

Obsolete Date

Conditions of supply: all supplies are made subject to the standard terms and conditions of Ortho Clinical Diagnostics or its distributors. Copies of these are available on request.

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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

Ortho Clinical Diagnostics