VITROS Products
Immunodiagnostic

INSTRUCTIONS FOR USE FT3

VITROS Immunodiagnostic Products Free T3 Reagent Pack	REF	131 5589
VITROS Immunodiagnostic Products Free T3 Calibrators	REF	111 2820

Rx ONLY

Intended Use

For *in vitro* diagnostic use only.

VITROS Immunodiagnostic Products Free T3 Reagent Pack

For the quantitative measurement of free triiodothyronine (FT3) 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 differential diagnosis of thyroid disease.

VITROS Immunodiagnostic Products Free T3 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 free triiodothyronine (FT3) in human serum and plasma (EDTA or heparin).

Summary and Explanation of the Test

The free fraction of the circulating triiodothyronine (T3) is considered to exert the main influence on metabolic control. In hyperthyroidism, FT3 concentrations are generally elevated and give efficient discrimination at the euthyroid/toxic borderline, providing an effective method for confirming hyperthyroidism and monitoring of its treatment. In hypothyroidism, FT3 concentrations tend to be lower, but the decrease is insufficient to give clear diagnostic information. [1-4] FT3 concentrations are independent of the concentration of thyroid hormone-binding proteins, and may be measured in patients with elevated or reduced binding protein concentrations without the need for additional tests of binding capacity. [5] FT3 determinations should be used as part of a thyroid test strategy, which may include free T4 and high sensitivity TSH tests.

Principles of the Procedure

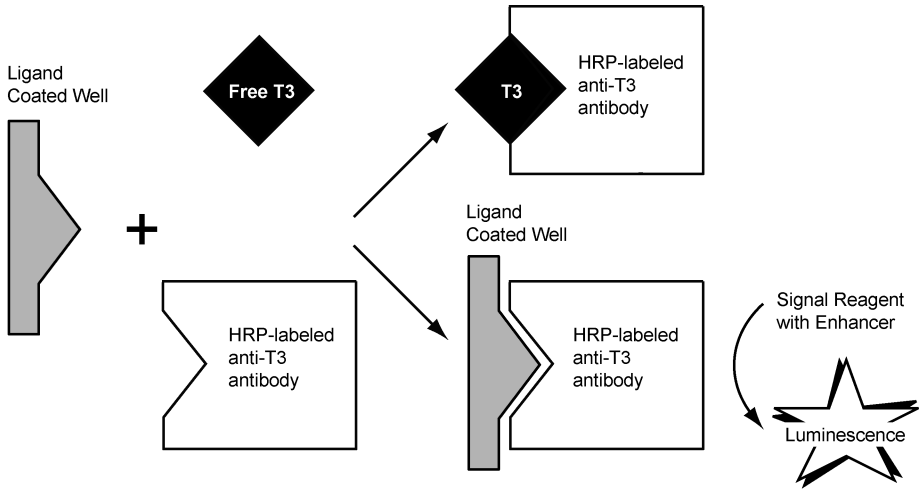
A direct, labeled antibody, competitive immunoassay technique is used. FT3 present in the sample competes with ligand on the modified well surface for a limited number of binding sites on a horseradish peroxidase (HRP)-labeled antibody conjugate (sheep anti-T3). The well surface has been modified to act as a ligand for uncombined conjugate. Unbound material is removed by washing. The test design, with optimal reagent concentrations, ensures that disturbance of the T3/binding protein equilibrium is so small as to be negligible.

The bound HRP conjugate is measured by a luminescent reaction. [6] 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 FT3 present.

Test Type	System *	Incubation Time	Time to first result	Test Temperature	Reaction Sample Volume
Competitive immunoassay	ECi/ECiQ, 3600, 5600, XT 7600	16 minutes	24 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 Free T3 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). [7]

WARNING: Contains Kathon or ProClin 200 (CAS 55965-84-9) [8]

The VITROS Free T3 Reagent Pack contains 0.505% 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.

WARNING

WARNING: Contains Kathon or ProClin 150 (CAS 55965-84-9) [8]

The VITROS Free T3 Calibrator contains 0.5% Kathon or ProClin 150. H317: May cause an allergic skin reaction. P280: Wear protective gloves/protective clothing/eye protection/face protection. P302 + P352: IF ON SKIN: Wash with plenty of soap and water. P333 + P313: If skin irritation or rash occurs: Get medical advice/attention. P363: Wash contaminated clothing before reuse.

Refer to www.Orthoclinicaldiagnostics.com for the Safety Data Sheets and for Ortho contact information.

WARNING

Reagents

Reagent Pack Contents

1 reagent pack containing:

- 100 coated wells (modified ligand, binds ≥3.33 pmol anti-T3 IgG/well)
- 13.3 mL conjugate reagent (HRP-sheep anti-T3, binds ≥12.5 fmol FT3/mL) in buffer with bovine gamma globulin, bovine gelatin 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 Free T3 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.
- Minimize exposure of the reagent pack to light.

Calibrator Contents

- 3 sets of VITROS Free T3 Calibrators 1, 2 and 3 (freeze-dried, T3 in human serum with antimicrobial agent, reconstitution volume 1 mL); nominal values 0; 5 and 10 pmol/L (0; 3.26 and 6.51 pg/mL)
- 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-reconstituted	Refrigerated	2–8 °C (36–46 °F)	≤4 weeks
Opened-reconstituted	Frozen	≤-20 °C (≤-4 °F)	≤4 weeks

- VITROS Free T3 Calibrators are supplied freeze-dried.
- VITROS Free T3 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 mL distilled water.
- Opened, reconstituted calibrators may be stored frozen (with no more than 1 freeze-thaw cycle).
- The VITROS Free T3 test uses 25 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
- Heparin plasma
- 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. [9] 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. [10- 11]
- Thoroughly mix samples by inversion and bring to 15–30 °C (59–86 °F) before use.
- The VITROS Free T3 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 Free T3 Reagent Pack
- VITROS Immunodiagnostic Products Free T3 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 Free Thyroid Controls
- VITROS Immunodiagnostic Products Reagent Pack Storage Box (optional) with desiccant
- Calibrated pipette, distilled water and sample containers for reconstitution of VITROS Free T3 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 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

Free T3 concentrations above the measuring range should be reported as >35 pmol/L (22.8 pg/mL). The dilution of samples in VITROS Free T3 test is not supported as dilution will disturb the normal equilibrium that exists between the free and total hormone present in the sample.

Default Test Name

The default test name which will appear on patient reports is Free T3. The default short name that will appear on the test selection menus and laboratory reports is FT3. 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 Free T3 test is traceable to in-house reference calibrators, which have been value assigned to correlate with another commercially available test.

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	0.77*–35.0 pmol/L (0.50-22.8 pg/mL)

* 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

VITROS Free Thyroid Controls are recommended for use with the VITROS Immunodiagnostic and VITROS Integrated Systems. The VITROS Free Thyroid Controls contain 3 levels of Free T3 (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 Free T3 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 Free T3 test.

Heat treated samples give elevated FT3 values due to protein denaturation and disturbance of the FT3/T3 equilibrium. In highly processed sera, e.g. some quality control material, the thyroid hormone binding capacity may be reduced, leading to elevated FT3 results.

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. [12]

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

Conventional	Alternate
pmol/L (pg/mL× 1.54)	pg/mL (pmol/L× 0.651)

Limitations of the Procedure

Known Interferences

Substances that bind to the thyroid hormone binding proteins are known [13-16] to cause an increase in the apparent free thyroid hormone concentration. In those cases, the change in FT3 concentration represents the actual increases in free hormone and should not be considered an interference of the assay.

The effects of drugs and metabolites on the VITROS Free T3 test were evaluated as recommended by CLSI document EP7. [17] 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 = pmol/L		Units = pg/mL	
			Analyte Conc*	Bias**	Analyte Conc*	Bias**
o-Acetylsalicylic Acid (Aspirin)***	2.77 mmol/L	50.0 mg/dL	10.0	15.2	6.51	9.90
Bilirubin	0.342 mmol/L	20.0 mg/dL	10.6	2.05	6.90	1.30
Diphenylhydantoin (Phenytoin)***	0.396 mmol/L	10.0 mg/dL	9.54	23.3	6.21	15.2
Dipyrone	3.00 mmol/L	100 mg/dL	9.54	2.47	6.21	1.61
Furosemide***	0.605 mmol/L	20.0 mg/dL	9.54	16.3	6.21	10.6
Mefenamic Acid***	0.414 mmol/L	10.0 mg/dL	9.54	****	6.21	****
Phenylbutazone***	3.24 mmol/L	100 mg/dL	11.5	****	7.49	****
6n-Propyl-2-Thiouracil (PTU)***	0.588 mmol/L	10.0 mg/dL	9.54	1.52	6.21	0.990
Sodium Salicylate***	3.12 mmol/L	50.0 mg/dL	9.54	5.22	6.21	3.40
D-Thyroxine***	2.57 µmol/L	200 µg/dL	9.54	****	6.21	****
L-Thyroxine***	75.4 nmol/L	6.70 µg/dL	9.54	4.02	6.21	2.62
L-3,3’,5-Triiodothyroacetic acid (TRIAC)***	1.88 µmol/L	117 µg/dL	9.54	****	6.21	****

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

** Estimate of the average difference observed.

*** Substances reported to modify the binding of T3 to plasma proteins. [13-16]

**** Results over test range, therefore unable to calculate bias.

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.
- Thyroid hormone autoantibodies in serum samples may cause interference in free-hormone immunoassays. [18] Results which are inconsistent with clinical observations indicate the need for additional testing.
- Heat treated samples give elevated FT3 values due to protein denaturation and disturbance of the FT3/T3 equilibrium. In highly processed sera, e.g. some quality control material, the thyroid hormone binding capacity may be reduced, leading to elevated FT3 results.
- Certain drugs and clinical conditions are known to alter Free T3 concentrations *in vivo*. For additional information, refer to one of the published summaries. [19-21]
- When interpreting FT3 results, note the potential effects of certain drugs on the free-hormone equilibrium. [22]
- Heterophilic antibodies in the serum or plasma of certain individuals are known to cause interference with immunoassays. [23] These antibodies may be present in blood samples from individuals regularly exposed to animals or who have been treated with animal serum products. Results that are inconsistent with clinical observations indicate the need for additional testing.
- Do not use quality control materials preserved with azide.

Expected Values and Interpretation of Results

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

Euthyroid Reference Interval

Units = pmol/L	Units = pg/mL
4.26–8.10	2.77–5.27
Median: 5.85	Median: 3.81

This reference interval is the central 95% of results of a study of 545 patients of euthyroid status who were not on thyroid treatment. The range of results obtained was 3.48–9.46 pmol/L (2.27–6.16 pg/mL).

- Of 96 hyperthyroid patients tested, 93% had FT3 concentrations >8.10 pmol/L (5.27 pg/mL).
- Of 121 patients with non-thyroidal illnesses, 62% were within the euthyroid reference interval.

The study demonstrated lowered FT3 concentrations in elderly subjects. The median and ranges for various age groups were as follows:

Age Group (Years)	Median Value		Range		No. of Samples
	pmol/L	pg/mL	pmol/L	pg/mL	
<20	5.32	3.46	3.50-7.39	2.28-4.81	31
20-39	5.94	3.87	3.56-9.35	2.32-6.09	134
40-59	5.94	3.87	4.17-9.46	2.71-6.16	140
60-79	5.86	3.81	3.76-9.11	2.45-5.93	147
>79	5.31	3.46	3.60-8.62	2.34-5.61	43

A study of apparently euthyroid pregnant women produced the following results:

Trimester	Median Value		Range		No. of Samples
	pmol/L	pg/mL	pmol/L	pg/mL	
First	5.65	3.68	4.42–6.63	2.88–4.32	39
Second	4.99	3.25	3.93–6.77	2.56–4.41	40
Third	4.76	3.10	3.79–7.27	2.47–4.73	40

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 FT3 is 0.77 pmol/L (0.50 pg/mL), determined consistent with NCCLS document EP17 [24] 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 0.18 pmol/L (0.12 pg/mL).

Limit of Blank and Limit of Detection

LoB*		LoD**	
pmol/L	pg/mL	pmol/L	pg/mL
0.18	0.12	0.77	0.50

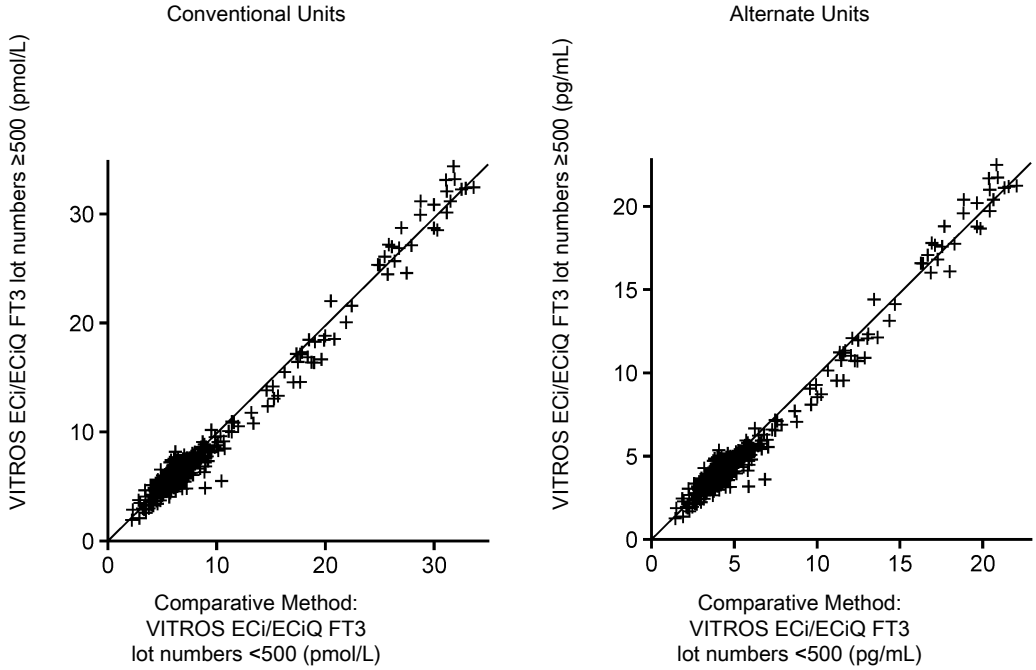
* Limit of Blank, or the highest value likely to be observed with a sample containing no analyte, replaces the term "analytical sensitivity."

** 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. [25] The plots and table show the results of a method comparison study using patient samples from a variety of clinical categories analyzed on the VITROS ECi/ECiQ Immunodiagnostic System using the VITROS Free T3 test Lots <500 compared with those analyzed using the VITROS Free T3 test Lots ≥500. The relationship between the 2 methods was determined by Deming regression. [26]

The table also shows the results of method comparison studies [27] 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. [28]



System	n	Slope	Correlation Coefficient	Conventional Units (pmol/L) Range of Samples	Conventional Units (pmol/L) Intercept	Alternate Units (pg/mL) Range of Samples	Alternate Units (pg/mL) Intercept
ECi/ECiQ vs. Comparative Method	890	0.998	0.986	1.93–34.5	-0.32	1.26–22.5	-0.21
3600 vs. ECi/ECiQ	108	1.000	0.998	1.77–32.6	0.10	1.15–21.2	0.07
5600* vs. ECi/ECiQ	109	0.992	0.998	1.77–32.6	-0.01	1.15–21.2	-0.01

* 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. [29] 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 3 reagent lots on 3 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. [30] 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 = pmol/L							No. Observ.	No. Days
	Mean FT3 Conc.	Within-run*		Within-calibration**		Within-lab***			
		SD	CV (%)	SD	CV (%)	SD	CV (%)		
ECi/ECiQ system 1	3.99	0.086	2.2	0.252	6.3	0.259	6.5	96	24
	8.09	0.169	2.1	0.380	4.7	0.378	4.7	96	24
	24.1	0.255	1.1	0.707	2.9	0.732	3.0	96	24
ECi/ECiQ system 2	3.07	0.123	4.0	0.348	11.3	0.450	14.7	84	21
	6.99	0.200	2.9	0.428	6.1	0.519	7.4	84	21
	20.6	0.502	2.4	0.989	4.8	1.17	5.7	84	21
ECi/ECiQ system 3	3.54	0.113	3.2	0.313	8.8	0.360	10.2	92	23
	7.32	0.212	2.9	0.419	5.7	0.469	6.4	92	23
	20.5	0.312	1.5	0.823	4.0	0.885	4.3	92	23
3600	4.26	0.109	2.6	0.193	4.5	0.191	4.6	88	22
	9.80	0.160	1.6	0.272	2.8	0.316	3.3	88	22
	18.9	0.260	1.4	0.386	2.0	0.433	2.3	88	22
5600****	4.50	0.092	2.1	0.189	4.2	0.192	4.7	88	22
	10.1	0.176	1.7	0.308	3.0	0.321	3.4	88	22
	19.2	0.262	1.4	0.474	2.5	0.514	2.8	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 = pg/mL							No. Observ.	No. Days
	Mean FT3 Conc.	Within-run*		Within-calibration**		Within-lab***			
		SD	CV (%)	SD	CV (%)	SD	CV (%)		
ECi/ECiQ system 1	2.60	0.056	2.2	0.164	6.3	0.169	6.5	96	24
	5.27	0.110	2.1	0.247	4.7	0.246	4.7	96	24
	15.7	0.166	1.1	0.460	2.9	0.477	3.0	96	24
ECi/ECiQ system 2	2.00	0.080	4.0	0.226	11.3	0.293	14.7	84	21
	4.55	0.130	2.9	0.279	6.1	0.338	7.4	84	21
	13.4	0.327	2.4	0.644	4.8	0.762	5.7	84	21
ECi/ECiQ system 3	2.30	0.074	3.2	0.204	8.8	0.234	10.2	92	23
	4.77	0.138	2.9	0.273	5.7	0.305	6.4	92	23
	13.3	0.203	1.5	0.536	4.0	0.576	4.3	92	23
3600	2.77	0.071	2.6	0.126	4.5	0.124	4.6	88	22
	6.38	0.104	1.6	0.177	2.8	0.205	3.3	88	22
	12.3	0.169	1.4	0.251	2.0	0.282	2.3	88	22
5600****	2.93	0.060	2.1	0.123	4.2	0.125	4.7	88	22
	6.58	0.115	1.7	0.201	3.0	0.209	3.4	88	22
	12.5	0.171	1.4	0.309	2.5	0.335	2.8	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 Free T3 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 FT3 concentrations of 7.95–11.6 pmol/L (5.18–7.55 pg/mL).

Compound	Concentration	
Amiodarone*	0.293 mmol/L	20.0 mg/dL
Bilirubin	0.160 mmol/L	9.36 mg/dL
3,5-Diidothyronine (T2)*	73.0 pmol/L	0.383 ng/dL
3,5-Diiodo-L-tyrosine (DIT)*	176 pmol/L	7.60 ng/dL
Hemoglobin**	0.310 mmol/L	500 mg/dL
3-Iodo-L-tyrosine (MIT)*	234 pmol/L	7.20 ng/dL
Methimazole	87.6 µmol/L	1.00 mg/dL
L-3,3',5'-Triiodothyronine (rT3)*	691 pmol/L	45.0 ng/dL
Triolein	33.9 mmol/L	3000 mg/dL

* Substances reported to modify the binding of T3 to plasma proteins. [13- 16]

** Hemolysate was added to a series of specimens with VITROS FT3 concentrations of 4.00–15.8 pmol/L (2.60–10.3 pg/mL).

Note: No significant interference was seen with this test in a study of patients taking the non-steroidal anti-inflammatory drugs diclofenac and fenoprofen.

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

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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	
EC REP Authorized Representative in the European Community	Value	σ Estimated within-lab SD
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	12.1	• Glossary of Symbols: updated • Added EC Representative address
2018-02-12	12.0	• 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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