

T-Uptake

Order information

REF	CONTENT	Analyzer(s) on which cobas c pack(s) can be used
20739014 322	T-Uptake (200 tests)	System-ID 07 3901 4 COBAS INTEGRA 400 plus COBAS INTEGRA 800
20762059 322	COBAS FP (4 × 1.0 mL) T-Uptake Calibrators A-D	System-ID 07 6205 9 US # 46205
12149435 122	Precinorm U plus (10 × 3 mL)	System-ID 07 7999 7
12149435 160	Precinorm U plus (10 × 3 mL, for USA)	System-ID 07 7999 7
12149443 122	Precipath U plus (10 × 3 mL)	System-ID 07 8000 6
12149443 160	Precipath U plus (10 × 3 mL, for USA)	System-ID 07 8000 6
20764337 322	COBAS INTEGRA Cleaner Cassette (150 tests)	System-ID 07 6433 7

English

System information

Test T-UP, test ID 0-901.

Intended use

In vitro test for the quantitative determination of T-uptake in human serum and heparinized plasma on COBAS INTEGRA systems.

Summary

The thyroid hormones, thyroxine (T_4) and triiodothyronine (T_3), are transported in serum bound to thyroxine binding proteins, mainly thyroxine binding globulin (TBG).^{1,2} Normally, only a very small fraction (0.03 % of T_4 and 0.3 % of T_3) remains unbound.^{1,3,4} It is generally accepted that in the blood the free, or unbound, thyroid hormones constitute the physiologically active fraction.^{3,4,5} Changes in the concentration of binding proteins such as TBG affect free hormone levels, which in turn trigger the depression or stimulation of hormone production.^{5,6} The T-uptake assay measures the capacity of serum proteins to bind a fluorescein-conjugated analog of T_4 . When used in conjunction with a serum total T_4 assay, the T-uptake measurement allows the calculation of the free thyroxine index (FT₄I), an estimation of the free thyroid hormones.^{7,8,9} This is especially important in certain conditions under which the total T_4 and T-uptake levels may both differ from the expected normal ranges. Examples of these are pregnancy, estrogen therapy, acute viral and chronic active hepatitis, biliary cirrhosis, or congenital disorders.^{7,10,11,12,13} Cassette COBAS INTEGRA T-Uptake results are calculated in comparison to calibrator solutions that contain known amounts of T_4 -analog binding proteins. The calibrator units have been defined from 0 to 2.0, with the average of a euthyroid population reading approximately 1.0. The cassette COBAS INTEGRA T-Uptake directly measures thyroid hormone binding capacity. This is in contrast to other T-uptake assays in which a constant amount of T_3 or T_4 -analog tracer is added to serum and the unbound fraction is then quantitated. Therefore, cassette COBAS INTEGRA T-Uptake units will have an inverse relationship to the reported % uptake units of these assays.

Test principle

Fluorescence polarization.

COBAS INTEGRA T-Uptake measurements are made on COBAS INTEGRA systems using the principle of fluorescence polarization. When a fluorescent molecule, or fluorophore, is irradiated with light of the proper wavelength (the excitation wavelength) some of the light is absorbed. Within a few nanoseconds the absorbed light is emitted, although at a longer wavelength (the emission wavelength). Whether or not the emitted light is polarized depends on the freedom of the fluorophore to rotate in solution. A small molecule, such as fluorescein, can rotate rapidly before light emission occurs, resulting in depolarization of the emitted light. In contrast, a fluorescent macromolecule, such as a fluorescein-labeled protein, will rotate much more slowly. Thus, in the time frame between excitation and emission, the macromolecule will have rotated only very slightly and the emitted light will be polarized.¹⁴

Fluorescence polarization is a reproducible function of the hormone concentration, and is suitable for the quantitative determination of the level of unsaturated thyroxine binding globulin (TBG) in serum for the purpose of thyroid monitoring.

Reagents - working solutions

Note

Use only the products described in this method sheet. The use of other reagents, calibrators, or standards may produce erroneous results.

R1 Barbitol buffer reagent: Buffer, pH 8.5; stabilizers; preservative.

SR Tracer reagent: Fluorescein-labeled T_4 derivative in buffer, pH 8.5; stabilizers; preservative.

R1 is in position B and SR is in position C.

Precautions and warnings

Pay attention to all precautions and warnings listed in Section 1 / Introduction of this Method Manual.

For USA: For prescription use only.

Reagent handling

Ready for use

Storage and stability

Shelf life at 2-8 °C See expiration date on **cobas c** pack label

COBAS INTEGRA 400 plus system

On-board in use at 10-15 °C 12 weeks

COBAS INTEGRA 800 system

On-board in use at 8 °C 26 weeks

Do not use reagents after the expiration date on the **cobas c** pack label. Failure to obtain the proper range of results in the assay of control material may indicate reagent deterioration.

Specimen collection and preparation

For specimen collection and preparation only use suitable tubes or collection containers.

Only the specimens listed below were tested and found acceptable.

Serum: Collect serum using standard sampling tubes. Serum is the specimen of choice.

Plasma: Li-heparin plasma. Do not use EDTA, fluoride or oxalate plasma.

The sample types listed were tested with a selection of sample collection tubes that were commercially available at the time of testing, i.e. not all available tubes of all manufacturers were tested. Sample collection systems from various manufacturers may contain differing materials which could affect the test results in some cases. When processing samples in primary tubes (sample collection systems), follow the instructions of the tube manufacturer.

Specimens should not be repeatedly frozen and thawed. Thawed specimens should be inverted several times prior to testing.

Stability: 8 hours at 15-25 °C
up to 48 hours at 2-8 °C
longer periods at (-20) °C or below

Centrifuge samples containing precipitates before performing the assay.

Materials provided

See "Reagents – working solutions" section for reagents.

Assay

For optimum performance of the assay follow the directions given in this document for the analyzer concerned. Refer to the appropriate operator's manual for analyzer-specific assay instructions.

Application for serum and plasma**COBAS INTEGRA 400 plus test definition**

Measuring mode		FP
Reaction mode		R1-S-SR
Wavelength	excitation	485 nm
	emission	515 nm
Reading cycle blank/test		29/45
Unit		Unit
Pipetting parameters		
		Diluent (H ₂ O)
R1	140 µL	10 µL
Sample	3.5 µL	20 µL
SR	24 µL	10 µL
Total volume	207.5 µL	

COBAS INTEGRA 800 test definition

Measuring mode		FP
Reaction mode		R1-S-SR
Wavelength	excitation	485 nm
	emission	515 nm
Reading cycle blank/test		40/60
Unit		Unit
Pipetting parameters		
		Diluent (H ₂ O)
R1	140 µL	10 µL
Sample	3.5 µL	20 µL
SR	24 µL	10 µL
Total volume	207.5 µL	

Calibration

Calibrator	4 COBAS FP T-Uptake Calibrators
	0, 0.6, 1.4, 2.0 Unit
Calibration mode	Linear regression
Calibration replicate	Duplicate recommended
Deviation low/high	< 10 % at ≥ 0.6 Unit
Calibration interval	COBAS INTEGRA 400 plus systems: Each lot and 20 weeks and as required following quality control procedures COBAS INTEGRA 800 systems: Each lot and 26 weeks and as required following quality control procedures

A calibration curve must be prepared using the COBAS FP T-Uptake Calibrators. Calibrators must be placed from the highest concentration (D) first, to the lowest (A) last, on the CAL/QC rack. This curve is retained in memory by the COBAS INTEGRA systems and recalled for later use.

Quality control

Quality control	Precinorm U plus Precipath U plus
Control interval	24 hours recommended

Control sequence

User defined

Control after calibration

Recommended

Note

Controls should be assayed within two (2) hours of being placed on-board the instrument.

For quality control, use control materials as listed in the "Order information" section. In addition, other suitable control material can be used.

The control intervals and limits should be adapted to each laboratory's individual requirements. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the defined limits.

Follow the applicable government regulations and local guidelines for quality control.

Calculation

COBAS INTEGRA analyzers automatically calculate the analyte concentration of each sample. For more details, please refer to Data Analysis in the Online Help (COBAS INTEGRA 400 plus/800 analyzers).

Limitations - interference

Specimens with assay values greater than the highest calibrator will be flagged by the system. *Do not dilute*. Specimens with high fluorescent backgrounds or those giving polarization values greater than the zero calibrator will also be flagged by the system.

Criterion: Recovery within ± 10 % of initial value.

Icterus:¹⁵ No significant interference up to an I index of 33 for conjugated and unconjugated bilirubin (approximate conjugated and unconjugated bilirubin concentration: 564 µmol/L or 33.4 mg/dL).

Hemolysis:¹⁵ No significant interference up to an H index of 1000 (approximate hemoglobin concentration: 621 µmol/L or 1000 mg/dL).

Lipemia:¹⁵ No significant interference up to a triglycerides level of 5350 mg/dL.

In very rare cases, gammopathy, in particular type IgM (Waldenström's macroglobulinemia), may cause unreliable results.¹⁶

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

ACTION REQUIRED

Special Wash Programming: The use of special wash steps is mandatory when certain test combinations are run together on COBAS INTEGRA analyzers. Refer to the CLEAN Method Sheet for further instructions and for the latest version of the Extra wash cycle list.

Where required, special wash/carry-over evasion programming must be implemented prior to reporting results with this test.

Limits and ranges**Measuring range**

COBAS INTEGRA 400 plus system:
0.02-2.0 Unit

COBAS INTEGRA 800 system:
0.01-2.0 Unit

Lower limits of measurement*Lower detection limit of the test*

COBAS INTEGRA 400 plus system:
0.02 Unit

COBAS INTEGRA 800 system:
0.01 Unit

The lower detection limit represents the lowest measurable analyte level that can be distinguished from the zero calibrator at a 95 % confidence level.

Expected values

As T-uptake concentrations can be influenced by sex, geographic area and other factors, *it is very important* that normal ranges be determined by each laboratory.¹⁷

Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference ranges.

Specific performance data

Representative performance data on the COBAS INTEGRA analyzers are given below. Results obtained in individual laboratories may differ.

Precision

Precision was determined using controls in an internal protocol with repeatability (n = 20) and intermediate precision (2 aliquots per run, 2 runs per day, 20 days). The following results were obtained:

Repeatability	Mean	SD	CV
	Unit		%
III	0.7	0.01	0.9
I	0.8	0.01	1.0
Control C (High)	1.3	0.01	0.7

Intermediate precision	Mean	SD	CV
	Unit		%
III	0.7	0.01	2.0
I	0.8	0.02	2.3
Control C (High)	1.3	0.02	1.6

Method comparison

T-uptake values for human serum samples obtained on a COBAS INTEGRA 700 analyzer with the COBAS INTEGRA T-Uptake reagents were compared to those determined with a commercially available FPIA method.

		FPIA
Number of samples		203
Range of values	min.	0.25 Unit
	max.	≥ 2.0 Unit
Slope		0.903
Intercept		0.109 Unit
Correlation coefficient		0.982

References

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A point (period/stop) is always used in this Method Sheet as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.

Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard.

CONTENT

Contents of kit



Volume after reconstitution or mixing

GTIN

Global Trade Item Number

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Roche Diagnostics warrants that this product will meet the specifications stated in the labeling when used in accordance with such labeling and will be free from defects in material and workmanship until the expiration date printed on the label. THIS LIMITED WARRANTY IS IN LIEU OF ANY OTHER WARRANTY, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR PARTICULAR PURPOSE. IN NO EVENT SHALL ROCHE DIAGNOSTICS BE LIABLE FOR INCIDENTAL, INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES.

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