BECKMAN COULTER

CE 2797

RIA FT3

Instruction for use in local language is available at beckmancoulter.com/techdocs.

REVISION HISTORY

Previous version: IFU-IM1579-3320-02	**Current version:** IFU-IM1579-3320-03
IMMUNOTECH s.r.o., Radiova 1, 102 27 Prague 10, Czech Republic	IMMUNOTECH s.r.o., Radiova 1122/1, 102 00 Prague 10, Czech Republic

REF IM1579, IM3320

FOR PROFESSIONAL USE ONLY

INTENDED PURPOSE

RIA FT3 is an in vitro diagnostic manual medical device intended to be used by healthcare professionals for the quantitative measurement of free triiodothyronine (FT3) in human serum and plasma. Measurement of free triiodothyronine is intended to be used as an aid in diagnosis of thyroid disorders in general population [1, 2].

PRINCIPLE

The radioimmunoassay of free triiodothyronine (FT3) is a competition assay. Samples and calibrators are incubated with ^{125}I-labeled monoclonal antibody specific for T3, as a tracer, in tubes coated with an analog of T3 (ligand). There is competition between the free triiodothyronine of the sample and the ligand for the binding to the labeled antibody. After incubation, the contents of tubes are aspirated so as to remove unbound ^{125}I-labeled tracer. The bound radioactivity is then determined in a gamma counter. The FT3 concentrations in the samples are obtained by interpolation from the standard curve. The concentration of FT3 in the samples is indirectly proportional to the radioactivity.

WARNING AND PRECAUTIONS

General remarks:

- The vials with calibrators and controls should be opened as shortly as possible to avoid excessive evaporation.
- Do not mix the reagents from kits of different lots.
- A standard curve must be established with each assay.
- It is recommended to perform the assay in duplicate.
- Each tube must be used only once.

Basic rules of radiation safety

The purchase, possession, utilization, and transfer of radioactive material are subject to the regulations of the country of use. Adherence to the basic rules of radiation safety should provide adequate protection:

- No eating, drinking, smoking or application of cosmetics should be carried out in the presence of radioactive materials.
- No pipetting of radioactive solutions by mouth.
- Avoid all contact with radioactive materials by using gloves and laboratory overalls.
- All manipulation of radioactive substances should be done in an appropriate place, distant from corridors and other busy places.
- Radioactive materials should be stored in the container provided in a designated area.
- A record of receipt and storage of all radioactive products should be kept up to date.
- Laboratory equipment and glassware which are subject to contamination should be segregated to prevent cross-contamination of different radioisotopes.
- Each case of radioactive contamination or loss of radioactive material should be resolved according to established procedures.
- Radioactive waste should be handled according to the rules established in the country of use.

Materials of human origin

The materials of human origin, contained in this kit, were found negative for the presence of antibodies to HIV 1 and HIV 2, antibodies to HCV, as well as of Hepatitis B surface antigen (HBsAg). However, they should be handled as if capable of transmitting disease. No known test method can offer total assurance that no virus is present. Handle this kit with all necessary precautions.

All patient specimens should be handled as potentially infectious and waste should be discarded according to the country rules.

GHS HAZARD CLASSIFICATION

Not classified as hazardous

SDS Safety Data Sheet is available at beckmancoulter.com/techdocs

SPECIMEN COLLECTION, PROCESSING, STORAGE AND DILUTION

- Serum or EDTA plasma are the recommended sample types.
- Allow serum samples to clot completely before centrifugation.
- Serum and plasma samples may be stored at 2-8°C, if the assay is to be performed within 48 hours. For longer storage keep frozen (< -18°C, 6 months maximum), after aliquoting so as to avoid repeated freezing and thawing. Thawing of sample should be performed at room temperature.
- Dilution of samples with concentration greater than the highest calibrator is not recommended.

Serum and EDTA plasma values for 49 samples (serum values ranging from 3.18 to 6.87 pM) were compared using the IM1579 RIA FT3. Results are as follows:

[EDTA-plasma] = 0.9065 [serum] + 0.5258

R = 0.9443

CONTENTS

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76). To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

MATERIALS PROVIDED

All reagents of the kit are stable until the expiry date indicated on the kit label, if stored at 2-8°C. Expiry dates printed on vial labels apply to the long-term storage of components by the manufacturer only, prior to assembly of the kit. Do not take into account.

Kit for determination of free T3, 100 tubes (REF. IM1579)

Tubes: 2 x 50 (ready-to-use)

^{125}I-Tracer: one 45 mL vial (ready-to-use)

The vial contains 225 kBq, at the date of manufacture, of ^{125}I-labeled immunoglobulins in liquid form with bovine serum albumin and sodium azide (<0.1%) and a dye.

Calibrators: five 1 mL vials (ready-to-use)

The calibrator vials contain from 0 to approximately 40 pM of free T3 in human serum and sodium azide (<0.1%). The exact concentration is indicated on each vial label. The calibrators are traceable to an internal reference standard.

Control sample: one 1 mL vial (ready-to-use)

The vial contains T3 in human serum and sodium azide (<0.1%). The concentration range is indicated on a supplement. The control sample is traceable to an internal reference standard.

Kit for determination of free T3, 400 tubes (REF. IM3320)

Tubes: 8 x 50 (ready-to-use)

^{125}I-Tracer: four 45 mL vials (ready-to-use)

Calibrators: five 1 mL vials (ready-to-use)

Control sample: one 1 mL vial (ready-to-use)

REAGENTS NOT PROVIDED

FT3 and FT4 Control sample: five vials (lyophilized)

Supplied upon request: REF. B48021

- The vials contain T3, T4 in human serum with sodium azide (<0.1%). The volume after reconstitution is 2 mL/vial.
- Control sample is intended as an optional additional one-level quality control to monitor the precision in determinations of Beckman Coulter RIA FT3 (IM1579, IM3320) and FT4 RIA KIT (IM1363, IM3321). This reagent can be used with any RIA FT3 or FT4 RIA KIT lot.

MATERIALS REQUIRED, BUT NOT PROVIDED

In addition to standard laboratory equipment, the following items are required:

- Precision micropipette (100 µL).
- Semi-automatic pipette (400 µL).
- Vortex type mixer.
- Horizontal or orbital shaker.
- Aspiration system.
- Gamma counter set for ^{125}I.

PROCEDURE

Preparation of reagents

Let all the reagents come to room temperature.

Assay procedure

Step 1 Additions*	Step 2 Incubation**	Step 3 Counting
To coated tubes add successively: 100 µL of calibrator, control or sample and 400 µL of tracer. Vortex gently 1-2 seconds.	Incubate 2 hours at 18-25°C with shaking (≥280 rpm).	Aspirate carefully the content of tubes (except the 2 tubes «total cpm»). Count bound cpm (B) and total cpm (T) for 1 minute.

*Add 400 µL of tracer to 2 additional tubes to obtain total cpm.
**An incubation time of 1 hour is sufficient if the test is performed automatically. 1-hour incubation values may not be the same in individual samples (see Appendix, § Correlation of 1-hour and 2-hour incubation procedure). The assay precision may be impacted as well.

RESULTS

Results are obtained from the calibrator curve by interpolation. The curve serves for the determination of analyte concentrations in samples measured at the same time as the calibrators.

Standard curve

The results in the quality control department were calculated using *spline* curve fit with logit of *B/T or* B/B_0 on the vertical axis and log of analyte concentration of the calibrators on the horizontal axis.

Other calculation methods may give slightly different results.

Total activity: 85,959 cpm				
Calibrators	**FT3 (pM)**	**cpm (n=3)**	**B/T (%)**	**B/B_0 (%)**
0	0	82,116	95.5	100.0
1	2.10	68,939	80.2	84.0
2	5.10	52,225	60.8	63.6
3	10.4	34,354	40.0	41.8
4	44.0	8,890	10.3	10.8

(Example of standard curve, do not use for calculation).

Samples

For each sample, locate ratio B/T or B/B_0 on the vertical axis and read off the corresponding analyte concentration on the horizontal axis.

To convert pmol/L (pM) into pg/mL, multiply results by 0.651.

EXPECTED VALUES

We recommend each laboratory to establish its own reference values. The following values obtained from healthy subjects are indicative only.

2.5 – 5.8 pM

Remark: The following values were found on several studies on a total of 531 euthyroid patients.

QUALITY CONTROL

Good laboratory practices imply that control samples be used regularly to ensure the quality of the results obtained. These samples must be processed exactly in the same way as the assay samples, and it is recommended that their results be analyzed using appropriate statistical methods.

Failure to obtain the appropriate values for controls may indicate imprecise manipulations, improper sample handling or deterioration of reagents.

In case of packaging deterioration or if data obtained show some performance alteration, please contact your local distributor or use the following e-mail address: imunochem@beckman.com

According to EU regulation 2017/746, any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of EU Member State in which the user and/or patient is located.

PERFORMANCE CHARACTERISTICS

(For more details, see the data sheet "APPENDIX")

Representative data are provided for illustration only. Performance obtained in individual laboratories may vary.

Sensitivity

Limit of Detection (LoD): 0.78 pM

The LoD of the assay is 0.78 pM, determined consistent with guidelines in CLSI document EP17-A2 [3] based on the proportions of false positives (α) less than 5% and false negatives (β) less than 5%; using determinations, with 168 blank and 144 low level samples; and Limit of Blank (LoB) of 0.47 pM.

Specificity

The antibody used in the immunoassay is highly specific for T3. Low cross reactivities were obtained against several related molecules (L-T4, D-T4, etc).

Precision

Repeatability and within-laboratory precision

The precision of the assay was determined consistent with guidelines in CLSI document EP05-A3 [4]. For repeatability the coefficients of variation were found below or equal to 7.66% for serum samples. For within-laboratory precision the coefficients of variation were found below or equal to 9.61% for serum samples.

Accuracy

It is generally accepted that the recovery, dilution and linearity tests may not provide quite satisfactory results when free hormones are determined.

Measurement range (from LoD to the highest calibrator): 0.78 to approximately 40 pM.

LIMITATIONS

Failure to follow these instructions for use (IFU) may significantly affect results.

Results should be interpreted in the light of the total clinical presentation of the patient, including clinical history, data from additional tests and other appropriate information.

Do not use hemolyzed, lipemic or icteric samples. For more details, see Appendix, § Interference.

In immunoassays, the possibility exists for interference by heterophile antibodies in the patient sample. Patients who have been regularly exposed to animals or have received immunotherapy or diagnostic procedures utilizing immunoglobulins or immunoglobulin fragments may produce antibodies, e.g. HAMA, that interfere with immunoassays. Immunoassays may be also affected by presence of anti-avidin or anti-streptavidin antibodies, as well as by the presence of autoantibodies directed against the determined analyte. Such interfering antibodies may cause erroneous results. Carefully evaluate the results of patients suspected of having these antibodies [5, 6, 7].

Shortage of incubation time to 1 hour was tested on SR300 instrument. Performance characteristics of the assay are not guaranteed if different automate is used.

APPENDIX

PERFORMANCE CHARACTERISTICS

Representative data are provided for illustration only. Performance obtained in individual laboratories may vary.

Interference

Serum samples containing FT3 concentrations (low and high) were spiked with multiple concentrations of the substances listed below and assayed using RIA FT3. Values were calculated as described in CLSI EP07, 3rd ed. [8]. Interference was determined by testing controls (no interfering substance added) and matched test samples (with interfering substance added). No interference (defined as a shift in dose > 15 %) was found for addition of interferent up to concentration stated in the table below.

Interferent	Test concentration
Acetylsalicylic acid	35.77 µg/mL
Ascorbic acid	57.81 µg/mL
Biotin	1,586 ng/mL
Conjugated bilirubin	425.3 µg/mL
Hemoglobin	9,883 µg/mL
Heparin	6,851 ng/mL
Cholesterol	3.40 mg/mL
Ibuprofen	114.2 µg/mL
Prednisone	109.1 ng/mL
Prednisolone	1,312 ng/mL
Rheumatoid factor	38.81 IU/mL
Triglycerides	4.36 mg/mL
Unconjugated bilirubin	508.2 µg/mL

In spite of hemoglobin, bilirubin (conjugated, unconjugated) and triglyceride interference data in the table, we advise to avoid using hemolyzed, lipemic or icteric samples.

Specificity

The specificity of the monoclonal antibody was determined by a competition RIA, using labeled T3 and the following compounds:

Analogue	Cross-reactivity (%)
L-3,3',5-triiodothyronine (T3)	100
L-3,3',5-triiodothyroacetic acid	100
L-3,3',5'-triiodothyronine (T3r)	0.03
L-thyroxine	0.15
D-thyroxine	0.07

Effective contribution to concentration of free thyroxine measured

Pooled normal human serum (assayed as 3.7 pM in free T3) was complemented with physiological or therapeutic concentrations of potentially interfering molecules. The free T3 concentration was measured with the Immunotech kit and the interfering contribution of each substance was calculated by subtraction of the free T3 concentration obtained in the absence of the interfering molecule.

Analogue	Added	Free T3 equivalent (pM)
L-3,3',5-triiodothyronine (T3)	0.62 nM	< 0.1
L-3,3',5' -Triiodothyroacetic acid	0.089 nM	0.2
Mono-iodo-tyrosine	0.23 nM	< 0.1
Di-iodo-tyrosine	0.17 nM	0.2
Sodium Salicylate	1.25 mM	0.4

Precision

Repeatability and within-laboratory precision

Samples were assayed for 20 days, 2 runs per day, in triplicates per run. Assays were performed by two lab technicians, by two reagent lots. There were 120 individual measurements per sample with no invalid results.

Serum	Mean (pM)	Repeatability		Within-laboratory precision	
		SD (pM)	C.V. (%)	SD (pM)	C.V. (%)
S1	2.48	0.19	7.66	0.24	9.61
S2	3.92	0.20	5.21	0.29	7.36
S3	5.86	0.29	4.90	0.44	7.59
S4	8.03	0.42	5.18	0.70	8.75
S5	14.83	0.58	3.94	1.04	7.01
S6	25.62	0.57	2.23	1.31	5.11
S7	37.06	0.87	2.34	1.39	3.76

EDTA plasma	Mean (pM)	Repeatability		Within-laboratory precision	
		SD (pM)	C.V. (%)	SD (pM)	C.V. (%)
P1	3.88	0.22	5.73	0.43	11.16
P2	4.85	0.25	5.08	0.57	11.76
P3	10.91	0.43	3.94	1.13	10.37
P4	14.97	0.43	2.86	1.26	8.44
P5	20.25	0.67	3.32	1.85	9.16
P6	38.55	1.07	2.77	2.46	6.38
P7	37.32	0.87	2.33	2.34	6.26

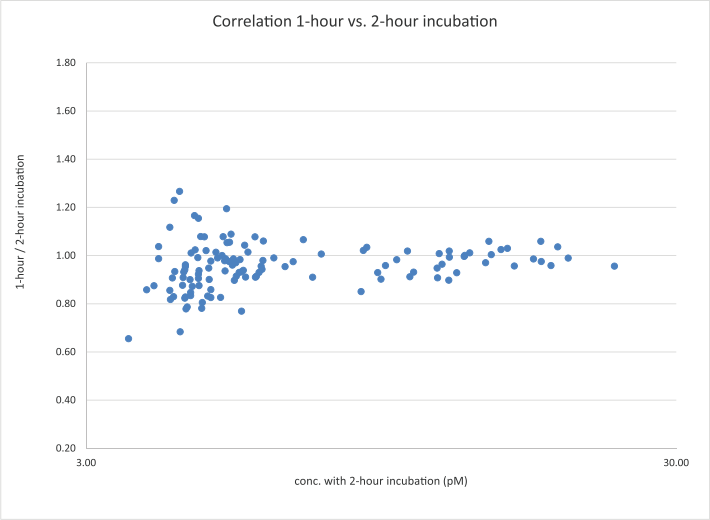
Correlation of 1-hour and 2-hour incubation procedure

Values of 122 serum samples (ranging from 3.54 to 23.6 pM) were determined using standard 2-hour and shortened 1-hour procedure on Stratec SR300. 1-hour incubation values may not be the same in individual samples as shown in the graph. The assay precision may be impacted as well.

Results were as follows:

[1-hour procedure] = 1.0062 x [2-hour procedure] – 0.2883

R = 0.9925



^{125}I Characteristics

$T_{1/2}$ (^{125}I) = 1443 h = 60.14 d

^{125}I	E (MeV)	%
γ	0.035	6.5
K_α X-ray	0.027	112.5
K_β X-ray	0.031	25.4

Symbols Key

REF — Product Reference / Référence du produit / Produktreferenz / Riferimento prodotto / Número de referencia del producto / Referência do produto / Produktreferens / Κωδικός αναφοράς προϊόντος / 产品参考 / Gaminio nuoroda / Termékszám / Dane referencyjne produktu / Reference k produktu / Referenčné označenie výrobku / 제품 참조 자료 / Ürün Referansı / Ссылка на продукт / Референца за производ / 產品參考

IVD — In Vitro Diagnostic / Diagnostic in vitro / In-vitro-Diagnostikum / Diagnostica in vitro / Para diagnóstico in vitro / Diagnóstico in vitro / InVitro-diagnostik / Για διάγνωση in vitro / 体外诊断 / In vitro diagnostika / In vitro diagnosztikai felhasználásra / Diagnostyka in vitro / Diagnostika in vitro / 체외 진단 / İn Vitro Diagnostik / Диагностика in vitro / За ин витро диагностика / 體外診斷

CONTENTS — Contents / Contenu / Inhalt / Contenuto / Contenido / Conteúdo / Περιεχόμενο / 组成 / Rinkinio sudėtis / Tartalom / Zawartość / Obsah / Obsah / 내용물 / İçindekiler / Содержание / Съдържание / 目錄

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Ag 125I / Ab 125I — Tracer / Traceur / Tracer / Marcato / Trazador / Marcador / Tracer / Ανιχνευτής / 追踪剂 / Atsekamoji medžiaga / Nyomjelző / Znacznik / Radioindikátor / Indikátor (tracer) / 트레이서 / Tracer´lar / метка / Индикатор / 追蹤劑

CAL / CAL 0 — Calibrator / Calibrateur / Kalibrator / Calibratore / Calibrador / Calibrador / Kalibrator / Βαθμονομητής / 校准品 / Kalibravimo medžiaga / Kalibrátor / Kalibrator / kalibrátor / Kalibrátor / 보정 물질 / Kalibratör / Калибратор / Калибратор / 校正液

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TUBE — Tubes / tubes / Röhrchen / provette / tubos / Tubos de amostra / Provrör / σωληνάρια / 试管 / Mėgintuvėliai / Csövek / Probówki / Zkumavky / Skúmavky / 튜브 / Tüpler / пробирки / Епруветки / 試管

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