BECKMAN COULTER

CE 2797

FT4 Plus RIA

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

REVISION HISTORY

Previous version: IFU-C55856-C55857-02	**Current version:** IFU-C55856-C55857-03
CE	CE 2797
Radioactivity table in the chapter APPENDIX.	Better specification of Iodine 125 characteristics table at the end of the chapter Appendix.

REF C55856, C55857

FOR PROFESSIONAL USE ONLY

INTENDED PURPOSE

FT4 Plus RIA is an in vitro diagnostic manual medical device intended to be used by healthcare professionals for the quantitative measurement of free thyroxine (FT4) in human serum and plasma. Measurement of free thyroxine is intended to be used as an aid in diagnosis of thyroid disorders in general population [1, 2, 3, 4].

PRINCIPLE

The radioimmunoassay of free thyroxine (FT4) is a competition assay. Samples and calibrators are incubated with ^{125}I-labeled monoclonal antibody specific for T4, as a tracer, in tubes coated with biotinylated analog of thyroxine (ligand). There is competition between the free thyroxine of the sample and the ligand for the binding to the labeled antibody. After incubation, the content of tubes is aspirated so as to remove unbound ^{125}I-labeled tracer. The bound radioactivity is determined in a gamma counter. The FT4 concentrations in the samples are obtained by interpolation from the standard curve. The concentration of FT4 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.

Sodium azide

Some reagents contain sodium azide as a preservative. Sodium azide can react with lead, copper or brass to form explosive metal azides. Sodium azide disposal must be in accordance with appropriate local regulations.

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 (at < -18°C, 1 year 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 32 samples (serum values ranging from 12.77 to 18.51 pM) were compared using the C55856, C55857 FT4 Plus RIA. Results are as follows:

[EDTA-plasma] = 1.0244[serum] - 0.4527, R = 0.954

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.

Storage conditions for reagents after reconstitution are indicated in paragraph Procedure.

Kit for determination of free T4, 100 tubes (REF. C55856)

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

^{125}I-Tracer: one 55 mL vial (ready-to-use)

The vial contains 310 kBq, at the date of manufacture, of ^{125}I-labeled immunoglobulins in liquid form with bovine serum albumin, sodium azide (<0.1%) and a dye.

Calibrators: five 0.5 mL vials (ready-to-use)

The calibrator vials contain from 0 to approximately 75 pM of FT4 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 samples: two vials (lyophilized)

The vials contain T4 in human serum with sodium azide (<0.1%). The concentration range is indicated on a supplement. The control samples are traceable to an internal reference standard.

Attention: All liquid reagents should be examined for the absence of precipitates; the antibody solution should be clear and blue-green, the calibrators may be opalescent.

Kit for determination of free T4, 400 tubes (REF. C55857)

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

^{125}I-Tracer: four 55 mL vials (ready-to-use)

Calibrators: five 0.5 mL vials (ready-to-use)

Control samples: two vials (lyophilized)

MATERIALS REQUIRED, BUT NOT PROVIDED

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

- Precision micropipette (25 µL).
- Semi-automatic pipette (500 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.

Reconstitution of control samples

The content of the vial is reconstituted with the volume of distilled water indicated on the label. Wait for 10 min following reconstitution and mix gently to avoid foaming before dispensing. Store the reconstituted solutions at 2-8°C until the expiry date of the kit.

Assay procedure

Step 1* Additions	Step 2 Incubations**	Step 3 Counting
To coated tubes add successively: 25 µL of calibrators, controls or samples and 500 µL of tracer. Vortex gently 1-2 seconds.	Incubate 1 hour at 18-25°C with shaking (≥350 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 500 µL of tracer to 2 additional tubes to obtain total cpm.

**. An incubation time of 30 min at room temperature is sufficient if the test is performed automatically.

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: 107,382 cpm				
Calibrators	**free T4 (pM)**	**cpm (n=3)**	**B/T (%)**	**B/B_0 (%)**
0	0	61,794	57.55	100.0
1	3.50	51,783	48.22	83.80
2	11.5	36,661	34.14	59.33
3	27.5	15,144	14.10	24.51
4	85.0	4,413	4.11	7.14

· *(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) to ng/100 mL, multiply results by 0.0777.

EXPECTED VALUES

We recommend each laboratory to establish its own reference values. The following values obtained from 231 healthy subjects are indicative only.

12.4 - 27.4 pM

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): 0.94 pM

The LoD of the assay is 0.94 pM, determined consistent with guidelines in CLSI document EP17-A2 [5] based on the proportions of false positives (α) less than 5% and false negatives (β) less than 5%; using determinations, with 224 blank and 168 low level samples; and Limit of Blank (LoB) of 0.94 pM.

Specificity

The antibody used in the immunoassay is highly specific for T4. Extremely low cross reactivities were obtained against several related molecules (D-T4, T3, T3r, etc.) or therapeutic drugs that may be present in patient samples (Amiodarone).

Precision

Repeatability and within-laboratory precision

The precision of the assay was determined consistent with guidelines in CLSI document EP05-A3 [6]. For repeatability the coefficients of variation were found below or equal to 5.14 % for serum samples. For within-laboratory precision the coefficients of variation were found below or equal to 11.05 % 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): 0.94 to approximately 75 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 [7, 8, 9].

Shortage of incubation time to 30 minutes was tested on SR300 instrument. Performance characteristics of the assay are not guaranteed if different automate is used.

The kit has not been validated on neonatal specimens.

It is recommended to finish pipetting within 30 minutes.

APPENDIX

PERFORMANCE CHARACTERISTICS

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

Interference

Serum samples containing FT4 concentrations (low and high) were spiked with multiple concentrations of the substances listed below and assayed using FT4 Plus RIA. Values were calculated as described in CLSI EP07, 3rd ed. [10]. 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	45.10 µg/mL
Ascorbic acid	71.87 µg/mL
Biotin	1,888 ng/mL
Conjugated bilirubin	476.2 ug/mL
Hemoglobin	10,337 ug/mL
Heparin	8,585 ng/mL
Cholesterol	5.07 mg/mL
Ibuprofen	536.8 ug/mL
Prednisone	143.4 ng/mL
Prednisolone	1,450 ng/mL
Rheumatoid factor	53.85 IU/mL
TAG	8.50 mg/mL
Unconjugated bilirubin	509.5 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 cross-reactivity of the FT4 has been measured against the following compounds according to CLSI recommendations (EP07, 3rd ed.) [10]. The percent cross-reactivity is expressed as the ratio of measured minus true FT4 concentration and concentration of added cross-reactant.

COMPOUND	Pooled depleted serum	
	Crossreactant Conc. (ng/mL)	Cross Reactivity (%)
L-3,3',5-triiodothyronine (T3r)	49.41	0.030
L-3,3',5'-triiodothyronine (T3)	2,484	0.0007
Tetraiodothyroacetic acid (Tetrac)	1,657	0.0008
Amiodarone HCl	88,147	ND*

*. ND = Non-Detectable (<0.0001%)

Precision

Repeatability and within-laboratory precision

Samples were assayed for 20 days, 2 runs per day, 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.

Sample	Mean	Repeatability		Within laboratory precision	
	pM	SD, pM	C.V., %	SD, pM	C.V., %
S1	9.72	0.35	3.60	0.64	6.61
S2	6.43	0.33	5.14	0.71	11.05
S3	27.84	0.78	2.81	0.98	3.52
S4	16.63	0.34	2.07	0.56	3.36
S5	21.87	0.46	2.11	0.70	3.21
S6	47.28	1.90	4.02	3.10	6.56
S7	68.63	3.14	4.57	5.25	7.65

Sample	Mean	Repeatability		Within laboratory precision	
	pM	SD, pM	C.V., %	SD, pM	C.V., %
P1	5.68	0.46	8.18	0.76	13.39
P2	9.09	0.32	3.52	0.65	7.11
P3	15.68	0.49	3.15	0.72	4.62
P4	28.22	0.88	3.13	1.41	4.99
P5	21.80	0.74	3.39	0.95	4.36
P6	46.73	2.26	4.85	4.82	10.32
P7	67.59	2.94	4.35	6.99	10.35

^{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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Consult Instructions for Use / Consultez le mode d'emploi / Siehe Gebrauchsanweisung / Consultare le istruzioni per l'uso / Consulte las Instrucciones de uso / Instruções de utilização / Konsultera bruksanvisning / Συμβουλευτείτε τις οδηγίες χρήσης / 请参阅使用说明 / Skaitykite naudojimo instrukciją / Olvassa el a használati utasítást / Zapoznać się z instrukcją użycia / Postupujte podle návodu k použití / Prečítajte si návod na použitie / 사용 안내 문의 / Kullanma Talimatına Başvurun / Обратитесь к инструкциям / Вижте Инструкциите за употреба / 請參閱使用說明

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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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