BECKMAN COULTER

CE 2797

RIA Testosterone, direct

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

REVISION HISTORY

Previous version: PI-IM1119-07	**Current version:** IFU-IM1119-01
—	IVDR requirements incorporated
Chapter INTENDED USE removed	Chapter INTENDED PURPOSE added
—	Chapter APPENDIX: Interference data added

REF IM1119

FOR PROFESSIONAL USE ONLY

INTENDED PURPOSE

RIA Testosterone, direct is an in vitro diagnostic manual medical device intended to be used by healthcare professionals for the quantitative measurement of testosterone in human serum and plasma. Measurement of testosterone is intended to be used for the assessment of fertility status and sexual development. It is used in diagnosis and monitoring of androgen excess states in females. In males, it is used in diagnosis and monitoring of androgen insufficiency states and differential diagnosis of hypogonadism, hypopituitarism and hyperprolactinemia and as aid in diagnosis of precocious and delayed puberty in boys [1, 2, 3, 4].

PRINCIPLE

The radioimmunoassay of testosterone is a competition assay. Samples and calibrators are incubated with ^{125}I-labeled testosterone, as a tracer, in polyclonal antibody-coated tubes. After incubation, the contents of the tubes are rinsed so as to remove unbound ^{125}I-labeled tracer. The bound radioactivity is then determined in a gamma counter. The testosterone concentrations in the samples are obtained by interpolation from the standard curve. The concentration of testosterone 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

Tracer	WARNING	
		
	H315	Causes skin irritation.
	H319	Causes serious eye irritation.
	P280	Wear protective gloves, protective clothing and eye/face protection.
	P337+P313	If eye irritation persists: Get medical advice/attention.
		Acetic Acid 1 - 2%
Wash Solution U (20x)	DANGER	
		
	H360	May damage fertility or the unborn child.
	P201	Obtain special instructions before use.
	P280	Wear protective gloves, protective clothing and eye/face protection.
	P308+P313	IF exposed or concerned: Get medical advice/attention.
		Boric Acid 0.1 - 0.3%
		Sodium Borate Decahydrate 0.1 - 0.3%

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 24 hours. For longer storage keep frozen (at <-20°C) for up to 1 year, after aliquoting so as to avoid repeated freezing and thawing. Thawing of sample should be performed at room temperature.
- If samples have concentrations greater than the highest calibrator, they must be diluted into the zero calibrator.

Serum and EDTA plasma values for 30 samples (serum values ranging from 0.18 to 7.35 ng/mL) were compared using the IM1119 RIA Testosterone, direct. Results were as follows:

[EDTA-plasma] = 0.9742[serum] + 0.0651

R = 0.9863

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 dilution are indicated in paragraph Procedure.

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

^{125}I-Tracer: one 33 mL vial (ready-to-use)

The vial contains 370 kBq, at the date of manufacture, of ^{125}I-labeled testosterone in liquid form containing gelatine and a dye.

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

The calibrator vials contain from 0 to approximately 20 ng/mL (from 0 to approximately 69 nM) of testosterone in buffer with bovine serum albumin and sodium azide (<0.1%). The exact concentration is indicated on each vial label. The calibrators are traceable to a certified reference material (Cerilliant).

Control samples: two 0.5 mL vials (ready-to-use)

The vials contain testosterone in human serum with sodium azide (<0.1%). The concentration range is indicated on a supplement. The control samples are traceable to a certified reference material (Cerilliant).

Wash solution U (20X): one 50 mL vial

Concentrated solution has to be diluted before use. It may be ordered separately, too (REF. A54825).

MATERIALS REQUIRED, BUT NOT PROVIDED

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

- Precision micropipette (50 µL).
- Semi-automatic pipette (300 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.

Preparation of the wash solution

Pour the content of the vial into 950 mL of distilled water and homogenize. The diluted solution can be stored at 2-8°C until the expiry date of the kit.

Assay procedure

Step 1 Additions*	Step 2 Incubation	Step 3 Counting
To coated tubes add successively: 50 µL of calibrator, control or sample and 300 µL of tracer. Vortex gently 1-2 seconds.	Incubate 1 hour at 18-25°C with shaking (≥ 400 rpm).	Aspirate carefully the content of tubes (except the 2 tubes «total cpm»). Wash once with 2 mL of wash solution. Count bound cpm (B) and total cpm (T) for 1 minute.

*Add 300 µL of tracer to 2 additional tubes to obtain "total cpm".

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: 154,874 cpm				
Calibrators	**Testosterone (ng/mL)**	**cpm (n = 3)**	**B/T (%)**	**B/B_0 (%)**
0	0	43,362	28.0	100.0
1	0.09	38,638	24.9	89.1
2	0.34	28,331	18.3	65.3
3	0.85	20,306	13.1	46.8
4	4.10	10,288	6.64	23.7
5	20.5	4,609	2.98	10.6

(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 concentrations from ng/mL to nmol/L (nM), multiply results by 3.47.

EXPECTED VALUES

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

Men (Age in years)	No.	Median	Min.	Max.	2.5th percentile	97.5th percentile
		(ng/mL)				
20 - 29	40	5.27	3.18	9.14	3.19	9.13
30 - 39	41	4.49	1.70	6.54	2.73	6.28
40 - 49	50	3.66	1.14	7.31	1.39	6.36
50 - 59	49	3.22	0.97	7.03	1.85	5.97
60 and above	26	2.60	1.19	4.29	1.46	4.03
All	206	3.90	0.97	9.14	1.63	7.01

Women	No.	Median	Min.	Max.	2.5th percentile	97.5th percentile
		(ng/mL)				
Follicular Phase	60	0.68	0.24	1.10	0.33	1.03
Preovulatory peak	50	0.71	0.30	1.25	0.43	1.16
Luteal phase	60	0.66	0.35	1.44	0.41	1.12
All Fertile	170	0.68	0.24	1.44	0.36	1.10
Postmenopausal	30	0.54	0.18	1.46	0.27	1.00

Detail information about expected values for children (sorted according to age and sex) can be found in the data sheet "APPENDIX".

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

Analytical sensitivity: 0.04 ng/mL

Functional sensitivity: 0.05 ng/mL

Specificity

The antibody used in the immunoassay is specific for testosterone.

Precision

Intra-assay

Serum samples were assayed 25 times in the same serie. The coefficients of variation were found below or equal to 10.6%.

Inter-assay

Serum samples were assayed in duplicate in 10 different series. The coefficients of variation were found below or equal to 19.0%.

Accuracy

Dilution test

High-concentration serum samples were serially diluted with the zero calibrator. The recovery percentages obtained were between 82.2% and 109%.

Recovery test

Low-concentration serum samples were spiked with known quantities of testosterone. The recovery percentages obtained were between 80.8% and 108%.

Measurement range (from analytical sensitivity to the highest calibrator): 0.04 to approximately 20 ng/mL.

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].

APPENDIX

PERFORMANCE CHARACTERISTICS

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

Interference

Serum samples containing testosterone concentrations (low and high) were spiked with multiple concentrations of the substances listed below and assayed using RIA Testosterone, direct. 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
Biotin	1,664 ng/mL
Conjugated bilirubin	127.5 µg/mL
Hemoglobin	3,426 µg/mL
Triglycerides	16.85 mg/mL
Unconjugated bilirubin	220.4 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 has been measured against various compounds in this assay. The percent cross-reactivity is expressed as the ratio of the testosterone concentration to the concentration of the reacting compound at 50% (70%) binding of the testosterone zero calibrator.

Steroid	Cross-reactivity (%)
Testosterone	100
DHT	26.8
19-Nortestosterone	14.0
11β-Hydroxytestosterone	5.8
Mesterolone	4.8
Methyltestosterone	4.3
Androstenediol	2.0
Androstenedione	1.8
5α-Androstane-3β, 17β-diol	1.5
5β-Androstane-3α, 17β-diol (70%)	0.8
19-Hydroxytestosterone	0.5
Epitestosterone	0.2
Epiandrosterone	0.06
Progesterone	0.05
Androsterone	0.03
DHEA	0.03
Deoxycorticosterone	0.02
Pregnenolone	0.01
Estradiol	0.004
17-OHP	0.004
Estrone	0.003
DHEA-S	0.002
Corticosterone	0.001
Desoxycortisol	ND
Cortisol	ND

ND – not detectable

Precision

Intra-assay

Serum	S1	S2	S3
Number of determinations	25	25	25
Mean value, ng/mL	0.33	2.61	5.95
C.V., %	10.60	4.98	6.14

EDTA plasma	P1	P2	P3
Number of determinations	25	25	25
Mean value, ng/mL	0.23	2.16	5.87
C.V., %	8.46	6.69	4.29

Inter-assay

Serum	S1	S2	S3
Number of determinations	10	10	10
Mean value, ng/mL	0.47	3.65	7.18
C.V., %	19.03	7.05	12.31

EDTA plasma	P1	P2	P3
Number of determinations	10	10	10
Mean value, ng/mL	0.33	5.12	18.32
C.V., %	16.37	13.26	12.57

Accuracy

Dilution test

Samples were diluted in zero calibrator and assayed according to the assay procedure of the kit.

Serum	Dilution	Measured	Expected	Ratio (%) Measured/ Expected
		(ng/mL)		
S1	-	5.50	-	-
	1:2	2.38	2.75	86.55
	1:4	1.21	1.38	88.00
	1:8	0.61	0.69	88.73
S2	-	5.45	-	-
	1:2	2.24	2.73	82.20
	1:4	1.20	1.36	88.07
	1:8	0.68	0.68	99.82
S3	-	2.72	-	-
	1:2	1.22	1.36	89.71
	1:4	0.66	0.68	97.06
	1:8	0.37	0.34	108.8

EDTA plasma	Dilution	Measured	Expected	Ratio (%) Measured/ Expected
		(ng/mL)		
P1	-	4.06	-	-
	1:2	2.10	2.03	103.4
	1:4	1.02	1.02	100.5
	1:8	0.55	0.51	108.4
P2	-	3.87	-	-
	1:2	1.72	1.94	88.89
	1:4	0.94	0.97	97.16
	1:8	0.58	0.48	119.9
P3	-	4.69	-	-
	1:2	2.03	2.35	86.57
	1:4	0.98	1.17	83.58
	1:8	0.55	0.59	93.82

Recovery test

Samples were spiked with known quantities of testosterone and assayed according to the assay procedure of the kit.

Serum	Endogen. conc.	Added conc.	Expected conc.	Measured conc.	Ratio (%) Measured/ Expected
	(ng/mL)				
S1	4.06	3.34	7.40	6.22	84.02
	3.91	7.24	11.15	10.67	95.70
	3.81	14.40	18.21	18.10	99.40
S2	1.43	1.91	3.34	2.70	80.83
	1.41	3.75	5.16	4.73	91.75
	1.36	7.24	8.60	9.05	105.2
S3	5.38	3.95	9.32	8.97	96.22
	5.19	7.61	12.80	12.98	101.4
	5.07	14.40	19.47	20.96	107.6

EDTA plasma	Endogen. conc.	Added conc.	Expected conc.	Measured conc.	Ratio (%) Measured/ Expected
	(ng/mL)				
P1	3.14	3.14	6.28	7.13	113.6
	3.05	6.10	9.15	8.66	94.65
	3.04	9.53	12.56	13.34	106.2
P2	3.15	2.73	5.88	5.12	87.08
	3.06	5.72	8.78	7.88	89.80
	2.96	13.08	16.04	15.77	98.30
P3	2.61	2.73	5.34	5.13	96.00
	2.54	5.52	8.07	7.71	95.59
	2.54	8.40	10.94	12.10	110.6

Expected data for children

Results are sorted according to the age and sex.

Girls	N	Testosterone (ng/mL)				
		Median	Min.	Max.	2.5th percentile	97.5th percentile
< 1 month	20	1.25	0.59	3.91	0.61	3.55
1 - 5 months	22	0.41	0.16	1.11	0.19	0.95
6 months - 8 years	33	0.14	0.01	0.52	0.04	0.47
9 years	28	0.34	0.11	0.68	0.14	0.63
10 years	29	0.39	0.10	0.65	0.14	0.63
11 years	30	0.39	0.15	0.94	0.18	0.88
12 years	26	0.39	0.18	1.23	0.18	1.08
13 years	31	0.61	0.26	1.67	0.29	1.41
14 years	30	0.72	0.36	1.14	0.39	1.09

Boys	N	Testosterone (ng/mL)				
		Median	Min.	Max.	2.5th percentile	97.5th percentile
< 1 month	22	1.67	0.77	6.87	0.88	5.49
1 - 3 months	27	1.06	0.14	3.19	0.20	2.34
4 - 8 months	21	0.35	0.06	1.32	0.13	1.09
9 months - 8 years	30	0.32	0.18	0.58	0.20	0.55
9 - 10 years	67	0.39	0.07	1.97	0.16	1.23
11 years	32	0.57	0.03	3.18	0.21	2.87
12 years	32	0.65	0.15	5.33	0.17	5.00
13 years	31	1.75	0.07	7.95	0.15	6.78
14 years	30	3.62	0.38	7.65	0.41	6.83

^{125}I Characteristics

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

^{125}I	E (MeV)	%
γ	0.035	
X	0.027	114
	0.032	25

Symbols Key

DANGER — Danger / Danger / Gefahr / Pericolo / Peligro / Perigo / Fara / Κίνδυνος / 危険 / Pavojus / Veszély! / Niebezpieczeństwo / Nebezpečí / Nebezpečenstvo / 위험 / Tehlike / Опасно! / Опасност / 危險

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

Manufactured by / Fabriqué par / Hergestellt von / Prodotto da / Fabricado por / Tillverkas av / Κατασκευαστής / 制造商 / Gamintojas / Gyártó: / Producent / Výrobce / Výrobca / 제조 / Üretici / Изготовлено / Произведено от / 製造商

Contains sufficient for <n> tests / Contenu suffisant pour "n" tests / Inhalt ausreichend für <n> Prüfungen / Contenuto sufficiente per "n" saggi / Contenido suficiente para <n> ensayos / Conteúdo suficiente para "n" ensaios / Räcker till "n" antal tester / Περιεχόμενο επαρκές για "ν" εξετάσεις / 含量足够 <n> 次测试 / Turinio pakanka < n > tyrim / <n> teszthez elegendő mennyiséget tartalmaz / Zawartość wystarcza na <n> testów / Lze použít pro <n> testů / Obsah vystačí na < n > testov / <n> 테스트에 대해 충분한 양 포함 / <n> sayıda test için yeterlidir / Содержит достаточно для количества тестов: <n> / Съдържа достатъчно за <n> теста / 內容物足夠執行 <n> 次測試

CE Mark / Marquage CE / CE-Kennzeichnung / Marchio CE / Marcado CE / Marcação CE / CE-märkning / Σήμανση CE / CE 标志 / CE ženklas / CE jelzés / Znak CE / Značka CE / Označenie CE / CE 표시 / CE İşareti / Маркировка CE / CE маркировка / CE 標識

SDS — Safety Data Sheet / Fiche technique santé-sécurité / Sicherheitsdatenblatt / Scheda dati di sicurezza / Hoja de datos de seguridad / Ficha de Dados de Segurança / Säkerhetsdatablad / Φύλλο Δεδομένων Ασφάλειας / 安全数据单 / Saugos duomenų lapas / Biztonsági adatlap / Karta Charakterystyki Bezpieczeństwa / Bezpečnostní list / Bezpečnostný list / 안전보건자료 / Güvenlik Bilgi Formu / Паспорт безопасности / Информационен Лист За Безопасност / 安全性資料表

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

Temperature range(s) / Plage(s) de température / Temperaturbereich(e) / Intervallo/i di temperatura / Intervalo(s) de temperatura / Intervalo(s) de temperatura / Temperaturintervall / Εύρος(-η) θερμοκρασίας / 温度范围 / Temperatūros diapazonas (-ai) / Hőmérséklet-tartomány(ok) / Zakres(y) temperatury / Rozsahy teplot / Rozsah(y) teploty / 온도 범위 / Sıcaklık aralıkları / Диапазон(-ы) температуры / Температурен(ни) диапазон(и) / 溫度範圍 請參閱使用說明

Caution / Précaution / Achtung / Attenzione / Precaución / Atenção / Försiktighet / Προσοχή / 注意事项 / Įspėjimas / Figyelem / Uwaga / Upozornění / Upozornenie / 주의 / Dikkat / Внимание / 注意

Expiration Date / Date D'expiration / Verfallsdatum, Verw. bis: / Data Di Scadenza / Fecha De Caducidad / Data de validade / Utgångsdatum / Ημερομηνία λήξης / 失效日期 / Galiojimo data / Lejárati idő / Data ważności / Datum exspirace / Dátum exspirácie / 만료 날짜 / Son Kullanma Tarihi / Срок годности / Срок на годност / 到期日

LOT — Lot Number / Numéro de lot / Chargennummer / Numero di lotto / Lote número / Número de lote / Satsnummer / Αριθ. παρτίδας / 批次号 / partijos numeris / Tételszám / Numer serii / Číslo šarže / 로트 번호 / Lot Numarası / Номер партии / Номер на партида / 批號

Date of Manufacture / Date de Fabrication / Herstellungsdatum / Data di Fabbricazione / Fecha de Fabricación / Data de Fabrico / Produktionsdatum / Ημερομηνία Παραγωγής / 生产日期 / Pagaminimo Data / Gyártás Dátuma / Data Produkcji / Datum Výroby / Dátum Výroby / 제조 일자 / Üretim Tarihi / Дата Производства / Дата на Производство / 製造日期

Biohazard / Risque biologique / Biogefährdung / Rischio biologico / Riesgo biológico / Risco biológico / Biologisk fara / Βιολογικός κίνδυνος / 生物危害 / Biologisk fara / Veszélyes biológiai anyag / Zagrożenie biologiczne / Biologické riziko / Biologické riziko / 생물학적 위험 / Biyolojik tehlike / Биологическая опасность / Биологична опасност / 生物危害

Radioactive / Radioactif / Radioaktiv / Radioattivo / Radiactivo / Radioactivo / Radioaktivt / Ραδιενεργό / 放射性 / Radioaktyvioji medžiaga / Radioaktív / Radioaktywny / Radioaktivní / Rádioaktívny / 방사성 / Radyoaktif / Радиоактивный / Радиоактивен / 具放射性

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

CTRL — Control / Contrôle / Kontrolle / Controllo / Control / Controlo / Kontrolle / Μάρτυρας / 质控品 / Kontrolinė / Kontroll / Kontrola / Kontrola / Kontrola / 정도관리 / Kontrol / Контроль / Контролна / 質控品

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

IFU — Instruction for Use / Mode d'emploi / Gebrauchsanweisung / Istruzioni per l'uso / Instrucciones de uso / Instruções de utilização / Bruksanvisning / Οδηγίες χρήσης / 使用说明 / Naudojimo instrukcija / Használati utasítás / Instrukcja użycia / Návod k použití / Návod na použitie / 사용 안내 / Kullanma Talimatı / Инструкции / Инструкции за употреба / 使用說明

SOLN WASH 20X — Wash Solution Concentrate 20X / Solution de lavage concentrée 20X / Waschlösungskonzentrat 20X / Concentrato di soluzione di lavaggio 20X / Solución de lavado concentrada 20X / Concentrado de solução de lavagem 20X / Tvättlösningskoncentrat 20X / Συμπυκνωμένο διάλυμα πλύσης 20X / 浓缩清洗液 20X / Plovimo tirpalo koncentratas 20X / 20X mosóoldat-koncentrátum / Koncentrat 20X roztworu płuczącego / Koncentrát mycího roztoku 20X / Koncentrát premývacieho roztoku 20X / 농축 세척액(20배) / Yıkama Çözeltisi Konsantresi 20X / Концентрат промывочного раствора 20X / Концентрат на разтвор за промиване 20X / 清洗溶液濃縮 20X

REFERENCES

1. Legro RS, Arslanian SA, Ehrmann DA, Hoeger KM, Murad MH, Pasquali R, Welt CK; Endocrine Society. Diagnosis and treatment of polycystic ovary syndrome: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2013 Dec;98(12):4565-92
2. Gordon CM, Ackerman KE, Berga SL, Kaplan JR, Mastorakos G, Misra M, Murad MH, Santoro NF, Warren MP. Functional Hypothalamic Amenorrhea: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2017 May 1;102(5):1413-1439
3. Martin KA, Anderson RR, Chang RJ, Ehrmann DA, Lobo RA, Murad MH, Pugeat MM, Rosenfield RL. Evaluation and Treatment of Hirsutism in Premenopausal Women: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2018 Apr 1;103(4):1233-1257
4. Bhasin S, Brito JP, Cunningham GR, Hayes FJ, Hodis HN, Matsumoto AM, Snyder PJ, Swerdloff RS, Wu FC, Yialamas MA. Testosterone Therapy in Men With Hypogonadism: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2018 May 1;103(5):1715-1744
5. J Bjerner et al. - Immunometric Assay Interference - Incidence and Prevention; Clin Chem 48;4; 613-621, 2002
6. L J Kricka - Interferences in Immunoassay - Still a Threat; Clin Chem 46, No. 8, 2000
7. A. Dasgupta: Biotin and Other Interferences in Immunoassays – A Conchise Guide. Elsevier, St. Louis, 2019
8. Approved Guideline - Interference Testing in Clinical Chemistry, EP07 3rd Edition. April 2018. Clinical and Laboratory Standards Institute.

IMMUNOTECH s.r.o., Radiova 1122/1, 102 00 Prague 10, Czech Republic
www.beckmancoulter.com