BECKMAN COULTER

CE 2797

PSA total IRMA KIT

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

REVISION HISTORY

Previous version:	Current version:
PI-IM1950-06	IFU-IM1950-01
—	IVDR requirements incorporated
Chapter INTENDED USE removed	Chapter INTENDED PURPOSE added
—	Chapter APPENDIX: Interference data added
—	CLSI guidelines incorporated
Calibration against the 1st IS NIBSC 96/670 removed	Traceability to the 2nd IS NIBSC 17/100 added

REF IM1950

FOR PROFESSIONAL USE ONLY

INTENDED PURPOSE

PSA total IRMA KIT is an in vitro diagnostic manual medical device intended to be used by healthcare professionals for the quantitative measurement of total prostate specific antigen (PSA) in human serum. Measurement of total prostate specific antigen is intended to be used in diagnosis, prognosis and monitoring of prostate cancer. In combination with free PSA, it is used for differential diagnosis between prostate cancer and benign prostate hyperplasia in men [1, 2, 3, 4].

PRINCIPLE

The immunoradiometric assay of total prostate specific antigen is a sandwich-type assay. Mouse monoclonal antibodies directed against two different epitopes of PSA and hence not competing are used. Samples or calibrators are incubated in tubes coated with the first monoclonal antibody in the presence of the second monoclonal antibody labeled with iodine 125. After incubation, the contents of the tubes are rinsed so as to remove unbound ^{125}I-labeled antibody. The bound radioactivity is then determined in a gamma counter. The PSA concentrations in the samples are obtained by interpolation from the standard curve. The concentration of total PSA in the samples is directly 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.

The summary of safety and performance for this in vitro diagnostic medical device is available to the public in the European database on medical device (EUDAMED) when this database is available, and the information has been uploaded by the Notified Body. The web address of the EUDAMED public web site is: https://ec.europa.eu/tools/eudamed.

To search the information about this product in EUDAMED, use BUDI-DI: 150995905IM19506A.

GHS HAZARD CLASSIFICATION

Not classified as hazardous

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

SPECIMEN COLLECTION, PROCESSING, STORAGE AND DILUTION

- Serum is the recommended sample type.
- Allow serum samples to clot completely before centrifugation.
- Serum samples may be stored at 2-8°C, if the assay is to be performed within 24 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 must be performed at room temperature.
- If samples have concentrations greater than the highest calibrator, they must be diluted into the zero calibrator (namely the samples from patients with the developed prostate carcinoma accomplished by bone metastases).

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 or dilution are indicated in paragraph Procedure.

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

^{125}I-Tracer: one 11 mL vial (ready-to-use)

The vial contains 580 kBq, at the date of manufacture, of ^{125}I-labeled antibody in buffer containing bovine serum albumin, sodium azide (<0.1%) and a dye.

Calibrators: five 0.8 mL vials and one 2 mL vial of «zero» calibrator (ready-to-use)

The calibrator vials contain from 0 to approximately 100 ng/mL of human PSA 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 the 2nd IS NIBSC 17/100.

Control samples: two vials (lyophilized)

The vials contain human PSA lyophilized in bovine serum and sodium azide (<0.1%). The concentration range is indicated on a supplement. The control samples are traceable to the 2nd IS NIBSC 17/100.

Wash solution (500x): one 1 mL vial

Concentrated solution has to be diluted before use.

MATERIALS REQUIRED, BUT NOT PROVIDED

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

- Precision micropipette (100 µL).
- Semi-automatic pipette (100 µL, 2 mL).
- 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 vials is reconstituted with the volume of distilled water indicated on the vial label. Wait at least 10 minutes and mix gently to avoid foaming before dispensing. Store the reconstituted solutions at 2-8°C for one day or frozen and aliquoted at <-18°C until the expiry date of the kit.

Preparation of the wash solution

Pour the content of the vial into 500 mL of distilled water and homogenize. The diluted solution may 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:	Incubate 2 hours at 18-25°C with shaking (≥ 280 rpm).	Aspirate carefully the content of tubes (except the 2 tubes «total cpm»).
100 µL of calibrator, control or sample and 100 µL of tracer.		Wash twice with 2 mL of wash solution. Aspirate.
Vortex gently 1-2 seconds.		Count bound cpm (B) and total cpm (T) for 1 minute.

*Add 100 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 log of determined radioactivity *(cpm_{cal}-cpm_{cal0})* or *B/T* **after subtraction of Blank** 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: 201,267 cpm				
Calibrators	**PSA (ng/mL)**	**cpm (n=3)**	**B/T (%)**	**cpm_{cal} – cpm_{cal0}**
0	0	76	-	-
1	1	1,104	0.51	1,028
2	3	3,098	1.50	3,022
3	10	9,171	4.52	9,095
4	30	24,917	12.3	24,841
5	100	70,472	35.0	70,396

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

Samples

For each sample, locate cpm (cpm_{sample} - cpm_{cal0}) or B/T **after subtraction of Blank** on the vertical axis and read off the corresponding analyte concentration on the horizontal axis.

EXPECTED VALUES

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

The PSA total concentrations in 146 sera from healthy men were determined using this PSA total IRMA KIT. The average concentration was 0.77 ng/mL with the standard deviation 0.76 ng/mL. 95% of samples showed PSA total level below 1.8 ng/mL and 99% of samples below 4.2 ng/mL.

To estimate the clinical utility of this kit, 99 sera of patients with benign diseases (benign hyperplasia and benign prostate tumor) and 86 sera of patients with prostate cancer were assayed. The optimum cut-off value to distinguish primary benign and malignant prostate diseases corresponding to 90% of clinical specificity was 10.1 ng/mL, with 75.6% sensitivity. The relative distribution of PSA concentrations in patients with prostate carcinoma and patients with non-malignant diseases is presented in the following table.

PSA total concentration			
	0 - 4 ng/mL	**4 - 10 ng/mL**	**> 10 ng/mL**
Non-malignant diseases occurrence	46.5%	42.4%	11.1%
Prostate carcinoma occurrence	7%	17.4%	75.6%

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): 0.48 ng/mL

The LoD of the assay is 0.48 ng/mL, 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 168 blank and 168 low level samples; and Limit of Blank (LoB) of 0.35 ng/mL.

Specificity

The antibodies used in this kit do not cross-react with CEA, AFP, prolactin and hCG. The cross-reactivity with PAP is 0.15%.

The PSA total IRMA assay is an equimolar assay in which sample recovery is unaffected by the ratio of PSA forms in serum.

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 9.33 % for serum samples. For within-laboratory precision the coefficients of variation were found below or equal to 9.38 % for serum samples.

Accuracy

Linearity

The assay demonstrated to be linear from 0.48 to 100.4 ng/mL using serum samples (determined consistent with guidelines in CLSI document EP06-A [7]).

Dilution test

High-concentration samples were serially diluted with the zero calibrator. The recovery percentages obtained were between 97.4% and 119%.

Recovery test

Low-concentration samples were spiked with known quantities of PSA. The recovery percentages obtained were between 80.2% and 96.6%.

Measurement range (from LoD to the highest calibrator): 0.48 to approximately 100 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 [8, 9, 10].

In the case of patients treated with high concentrations of biotin (5 mg/day), blood samples must be taken at least 8 hours after the last administration of biotin [11].

"Hook effect": no hook effect was observed until 5,000 ng/mL.

APPENDIX

PERFORMANCE CHARACTERISTICS

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

Interference

Serum samples containing total PSA concentrations (low and high) were spiked with multiple concentrations of the substances listed below and assayed using PSA total IRMA KIT. Values were calculated as described in CLSI EP07, 3rd ed. [12]. 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	31.49 µg/mL
Ascorbic acid	59.02 µg/mL
Biotin	25.16 ng/mL
Conjugated bilirubin	368.8 µg/mL
Hemoglobin	6,406 µg/mL
Heparin	6,282 ng/mL
Cholesterol	4.43 mg/mL
Ibuprofen	275.2 µg/mL
Prednisone	103.8 ng/mL
Prednisolone	1,195 ng/mL
Rheumatoid factor	11.83 IU/mL
Triglycerides	16.42 mg/mL
Unconjugated bilirubin	276.9 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.

Precision

Repeatability and within-laboratory precision

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

Serum	Mean (ng/mL)	Repeatability		Within laboratory precision	
		SD (ng/mL)	C.V. (%)	SD (ng/mL)	C.V. (%)
S1	2.70	0.25	9.31	0.25	9.38
S2	4.59	0.38	8.37	0.39	8.50
S3	6.20	0.50	8.12	0.50	8.12
S4	13.50	1.00	7.42	1.04	7.71
S5	47.70	4.45	9.33	4.45	9.33
S6	67.85	5.52	8.13	5.55	8.19

Accuracy

Dilution test

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

Serum	Dilution factor	Measured (ng/mL)	Expected (ng/mL)	Ratio (%) Measured/ Expected
S1	-	21.05	-	-
	1:2	11.45	10.53	108.8
	1:4	5.78	5.26	109.8
	1:8	2.75	2.63	104.5
	1:16	1.49	1.32	113.3
	1:32	0.71	0.66	107.9
S2	-	8.92	-	-
	1:2	4.55	4.46	102.0
	1:4	2.24	2.23	100.4
	1:8	1.23	1.12	110.3
	1:16	0.58	0.56	104.0
	1:32	0.28	0.28	100.4
S3	-	8.20	-	-
	1:2	4.19	4.10	102.2
	1:4	2.02	2.05	98.54
	1:8	1.08	1.03	105.4
	1:16	0.61	0.51	119.0
	1:32	0.26	0.26	101.5
S4	-	17.75	-	-
	1:2	9.07	8.88	102.2
	1:4	4.44	4.44	100.1
	1:8	2.22	2.22	100.1
	1:16	1.18	1.11	106.4
	1:32	0.61	0.55	110.0
S5	-	22.02	-	-
	1:2	11.60	11.01	105.4
	1:4	5.51	5.51	100.1
	1:8	2.82	2.75	102.5
	1:16	1.47	1.38	106.8
	1:32	0.67	0.69	97.37

Recovery test

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

Serum	Endogen. conc. (ng/mL)	Added conc. (ng/mL)	Expected conc. (ng/mL)	Measured conc. (ng/mL)	Ratio (%) Measured/ Expected
S1	1.09	0.64	1.73	1.67	96.59
	1.09	1.30	2.39	2.06	86.25
	1.06	3.81	4.87	3.92	80.54
S2	1.23	0.65	1.88	1.71	91.02
	1.20	1.37	2.58	2.25	87.33
	1.22	3.36	4.58	3.71	80.99
S3	0.15	0.13	0.28	0.25	89.04
	0.15	0.17	0.32	0.26	82.22
	0.15	0.47	0.62	0.50	80.63
S4	0.48	0.36	0.84	0.70	83.34
	0.48	0.82	1.29	1.05	81.16
	0.48	2.15	2.63	2.11	80.16
S5	2.48	1.38	3.86	3.66	94.92
	2.44	2.69	5.13	4.17	81.31
	2.35	6.37	8.72	7.16	82.14

^{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

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

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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

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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 500X — Wash Solution 500x / Wash Solution 500x / Solution de lavage 500x / Waschlösung 500x / Soluzione di lavaggio 500x / Solución de lavado 500x / Solução de lavagem 500x / Tvättvätska 500x / Διάλυμα Πλύσης 500x / 清洗液 500x / Plovimo tirpalas 500x / Mosóoldat 500x / Roztwór przemywający 500x / Promývací roztok 500x / Premývací roztok 500x / 세척 용액 500x / Yıkama Çözeltisi 500x / Промывочный раствор 500x / Разтвор за промиване 500x / 沖洗液 500x

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