BECKMAN COULTER

CE 2797

CEA IRMA KIT

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

REVISION HISTORY

Previous version:	Current version:
IFU-IM2204-02	IFU-IM2204-03
-	Adding Bulgarian and Croatian to the IFU.

REF IM2204

FOR PROFESSIONAL USE ONLY

INTENDED PURPOSE

CEA IRMA KIT is an in vitro diagnostic manual medical device intended to be used by healthcare professionals for the quantitative measurement of carcinoembryonic antigen (CEA) in human serum. Measurement of CEA is intended to be used for primary diagnosis, monitoring and prognosis of different types of cancer in general population [1, 2, 3].

PRINCIPLE

The immunoradiometric assay of carcinoembryonic antigen (CEA) is a sandwich-type assay. Mouse monoclonal antibodies directed against two different epitopes of CEA 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 tubes are rinsed so as to remove unbound ^{125}I-labeled antibody. The bound radioactivity is then determined in a gamma counter. The CEA concentrations in the samples are obtained by interpolation from the standard curve. The concentration of CEA 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: 150995905CEAIRMAHL.

GHS HAZARD CLASSIFICATION

Wash Solution (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 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 < -20°C, 6 months maximum), 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.

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 33 mL vial (ready-to-use)

The vial contains 640 kBq, at the date of manufacture, of ^{125}I-labeled immunoglobulins in buffer containing bovine serum albumin, sodium azide (<0.1%) and a dye.

Calibrators: five 0.5 mL vials and one 6 mL vial of «zero» calibrator (ready-to-use)

The calibrator vials contain from 0 to approximately 325 ng/mL of CEA 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 international standard WHO 1st IRP 73/601.

Control samples: two vials (lyophilized)

The vials contain CEA lyophilized in human serum with sodium azide (<0.1%). The concentration range is indicated on a supplement. The control samples are traceable to the international standard WHO 1st IRP 73/601.

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 (30 µL).
- Semi-automatic pipette (300 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 label. Wait for 10 min following reconstitution and mix gently to avoid foaming before dispensing. Store the reconstituted solutions aliquoted at < -18°C, until the expiry date of the kit.

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: 30 µL of calibrator, control or sample and 300 µL of tracer. Vortex gently 1-2 seconds.	Incubate 2 hours at 18-25°C with shaking (≥ 280 rpm).	Aspirate carefully the contents of tubes (except the 2 tubes «total cpm»). Wash twice 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.

**. According to experience an incubation time of 60 min at room temperature is sufficient to perform the test automatically. This should be checked in individual cases.

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: 241,704 cpm				
Calibrators	**CEA (ng/mL)**	**cpm (n=3)**	**B/T (%)**	**cpm_{cal} – cpm_{cal0}**
0	0	83	-	-
1	1.00	867	0.32	784
2	4.80	4,054	1.64	3,971
3	19.5	14,906	6.13	14,823
4	105	62,488	25.8	62,405
5	340	140,721	58.2	140,638

· *(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.

To convert concentrations from ng/mL to mIU/L, multiply results by 19.

EXPECTED VALUES

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

Number of samples	Average	SD	95th percentile	99th percentile
	ng/mL			
500	0.98	0.85	< 2.5	< 4.6

To evaluate the clinical utility, the serum samples of patients with three types of carcinoma in the case of primary diagnosis and three types of carcinoma in the case of secondary diagnosis respectively, were assayed:

Colorectal carcinoma (n = 112 for primary diagnosis and n = 109 for secondary diagnosis, malignant tumor of colon, rectosigmoid junction and rectum).

Malignant tumor of breast (n = 121 for primary diagnosis and n = 107 for secondary diagnosis).

Malignant tumor of lungs (n = 48 for primary diagnosis and n = 102 for secondary diagnosis).

The cut off values and clinical sensitivity at 95% clinical specificity were established for above-mentioned type of carcinomas on bases of results obtained with the CEA IRMA KIT:

	Cut off (ng/mL)		Sensitivity (%)	
	prim. diag.	sec. diag.	prim. diag.	sec. diag.
Colorectal carcinoma	2.50	3.91	64.3	93.6
Breast carcinoma	2.49	2.50	29.8	80.2
Lung carcinoma	2.50	3.74	56.3	54.9

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: 0.19 ng/mL

Functional sensitivity: 0.38 ng/mL

Specificity

The antibody used in the immunoassay is highly specific for CEA. No cross reactivities were obtained with other related molecules including NCA.

Precision

Intra-assay

Samples were assayed 25 times in the same series. The coefficients of variation were found below or equal to 4.3%.

Inter-assay

Samples were assayed in duplicate in 10 different series. The coefficients of variation were found below or equal to 6.2%.

Accuracy

Dilution test

High-concentration samples were serially diluted with the zero calibrator. The recovery percentages obtained were between 95.4% and 116%.

Recovery test

Low-concentration samples were spiked with known quantities of CEA. The recovery percentages obtained were between 91.5% and 102%.

Measurement range (from analytical sensitivity to the highest calibrator): 0.19 to approximately 325 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 [4, 5, 6].

In the case of patients treated with high concentrations of biotin (5 - 10 mg/day), blood samples must be taken at least 8 hours after the last administration of biotin [7].

"Hook effect": no hook effect was observed until 10,000 ng/mL.

APPENDIX

PERFORMANCE CHARACTERISTICS

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

Interference

Serum samples containing CEA concentrations (low and high) were spiked with multiple concentrations of the substances listed below and assayed using CEA IRMA KIT. 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	150.6 ng/mL
Conjugated bilirubin	482.4 µg/mL
Hemoglobin	10,146 µg/mL
Triglycerides	14.24 mg/mL
Unconjugated bilirubin	402.2 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.

Precision

Intra-assay

Serum	S1	S2	S3
Number of determinations	25	25	25
Mean value, ng/mL	19.22	88.79	109.9
C.V., %	3.93	4.27	3.16

Inter-assay

Serum	S1	S2	S3
Number of determinations	10	10	10
Mean value, ng/mL	2.31	12.48	204.6
C.V., %	6.17	4.82	2.54

Accuracy

Dilution test

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

Serum	Dilution factor	Measured	Expected	Ratio (%) Measured/ Expected
		ng/mL		
S1	-	24.17	-	-
	1:2	13.92	12.09	115.2
	1:4	6.99	6.04	115.7
	1:8	3.44	3.02	113.9
	1:16	1.73	1.51	114.5
	1:32	0.84	0.76	111.2
S2	-	74.5	-	-
	1:2	38.57	37.25	103.5
	1:4	18.89	18.63	101.4
	1:8	9.75	9.31	104.7
	1:16	4.49	4.66	96.43
	1:32	2.39	2.33	102.7
S3	-	99.08	-	-
	1:2	52.91	49.54	106.8
	1:4	26.43	24.77	106.7
	1:8	12.68	12.39	102.4
	1:16	6.08	6.19	98.18
	1:32	3.15	3.1	101.7
S4	-	>389.0	-	-
	1:2	254.19	-	-
	1:4	129.53	127.1	101.9
	1:8	63.12	63.55	99.33
	1:16	31.57	31.77	99.36
	1:32	15.16	15.89	95.42
S5	-	18.29	-	-
	1:2	9.12	9.15	99.73
	1:4	4.73	4.57	103.4
	1:8	2.36	2.29	103.2
	1:16	1.25	1.14	109.3
	1:32	0.66	0.57	115.5

Recovery test

Samples were spiked with known quantities of CEA 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	11.53	9.90	21.42	21.00	98.02
	11.17	19.18	30.35	30.86	101.7
	10.83	27.90	38.72	37.72	97.41
S2	12.19	9.90	22.09	22.29	100.9
	11.81	19.18	30.99	28.87	93.15
	11.45	27.90	39.35	36.01	91.51
S3	64.05	9.90	73.94	72.65	98.25
	62.04	19.18	81.22	80.54	99.16
	60.16	27.90	88.06	89.06	101.1
S4	42.76	9.90	52.66	53.47	101.5
	41.43	19.18	60.61	61.36	101.2
	40.17	27.90	68.07	68.84	101.1
S5	15.22	9.90	25.12	24.63	98.04
	14.75	19.18	33.93	31.63	93.23
	14.30	27.90	42.20	40.31	95.53

^{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

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

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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

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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

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