BECKMAN COULTER

CE 2797

Cytokeratin 19 Fragment IRMA KIT

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

REVISION HISTORY

Previous version: IFU-A56888-01	**Current version:** IFU-A56888-02
Standard curve *(Example of standard curve, do not use for calculation)*	*(Example of standard curve, do not use for calculation. Use the concentration of calibrators indicated on each vial label. The concentrations are lot specific, check carefully.)*
Radioactivity table in the chapter APPENDIX.	Better specification of Iodine 125 characteristics table at the end of the chapter Appendix.
—	Adding Ukrainian to the IFU.

REF A56888

FOR PROFESSIONAL USE ONLY

INTENDED PURPOSE

Cytokeratin 19 Fragment IRMA KIT is an in vitro diagnostic manual medical device intended to be used by healthcare professionals for the quantitative measurement of cytokeratin 19 fragment in human serum. Measurement of cytokeratin 19 fragment is intended to be used in the primary diagnosis, monitoring, prognosis and prediction in patients with the different types of cancers in general population [1, 2].

PRINCIPLE

The immunoradiometric assay of cytokeratin 19 fragment (corresponding to determination of CYFRA 21-1™)[1] is a sandwich-type assay. Mouse monoclonal antibodies directed against two different epitopes of cytokeratin 19 fragment 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 cytokeratin 19 fragment concentrations in the samples are obtained by interpolation from the standard curve. The concentration of cytokeratin 19 fragment 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: 150995905A56888UR

GHS HAZARD CLASSIFICATION

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 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: 1 x 50 (ready-to-use)

^{125}I-Tracer: one 3 mL vial (ready-to-use)

The vial contains 360 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 vials (lyophilized) **and one 3 mL vial of «zero» calibrator** (ready-to-use)

The calibrator vials contain from 0 to approximately 110 ng/mL of cytokeratin 19 fragment in buffer containing bovine serum albumin and sodium azide (<0.1%). The exact concentration is indicated on each vial label. Calibrators are traceable to an internal reference standard.

Control samples: two vials (lyophilized)

The vials contain cytokeratin 19 fragment lyophilized in human serum. The concentration range is indicated on a supplement. The control samples are traceable to an internal reference standard.

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 (100 µL).
- Semi-automatic pipette (50 µL, 2 mL).
- Vortex type mixer.
- Aspiration system.
- Gamma counter set for ^{125}I.

PROCEDURE

Preparation of reagents

Let all the reagents come to room temperature.

Reconstitution of calibrators and 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 at 2-8°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: 100 µL of calibrator, control or sample and 50 µL of tracer. Vortex gently 1-2 seconds.	Incubate 20 hours (± 2 hours) at 2-8°C without shaking.	Aspirate carefully the contents of tubes (except the 2 tubes «total cpm»).** Add 2 mL of wash solution and aspirate carefully. Count bound cpm (B) and total cpm (T) for 1 minute.

* Add 50 µL of tracer to each of 2 additional tubes to obtain total cpm.

** **Pay special attention to careful aspiration of the tube contents.**

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: 213,361 cpm				
Calibrators	**Cytokeratin 19 fragment (ng/mL)**	**cpm (n=3)**	**B/T (%)**	**$cpm_{cal} - cpm_{cal0}$**
0	0	179	-	-
1	1.45	2,412	1.05	2,233
2	4.00	6,367	2.90	6,188
3	15.0	20,241	9.40	20,062
4	48.0	53,230	24.9	53,051
5	124	106,481	49.8	106,302

(Example of standard curve, do not use for calculation. Use the concentration of calibrators indicated on each vial label. The concentrations are lot specific, check carefully.)

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 cytokeratin 19 fragment concentrations in 111 sera from healthy individuals were determined using the Cytokeratin 19 Fragment IRMA KIT, A56888. The average concentration was 0.92 ng/mL, 95% of samples showed cytokeratin 19 fragment level below 2.36 ng/mL and 99% of samples below 2.94 ng/mL.

Values higher than 3.3 ng/mL are considered to be pathological.

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): 0.53 ng/mL

The LoD of the assay is 0.53 ng/mL, 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 192 blank and 168 low level samples; and Limit of Blank (LoB) of 0.04 ng/mL.

Specificity

The antibodies used in this kit exhibit no cross-reaction with cytokeratin 8 and cytokeratin 18.

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 6.13% for serum samples. For within-laboratory precision the coefficients of variation were found below or equal to 9.09% for serum samples.

Accuracy

Linearity

The assay demonstrated to be linear from 1.18 to 160.0 ng/mL using serum samples (determined consistent with guidelines in CLSI document EP06-A [5]).

Dilution test

High-concentration samples were serially diluted with zero calibrator. The recovery percentages obtained were between 81.1% and 119%.

Recovery test

Low-concentration samples were spiked with known quantities of cytokeratin 19 fragment. The recovery percentages were between 80.7% and 102%.

Measurement range (from LoD to the highest calibrator): 0.53 to approximately 110 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 [6, 7, 8].

"Hook effect": no hook effect was observed until 1,700 ng/mL.

TRADEMARKS

1 CYFRA 21-1 is a trade mark of Roche company or of its subsidiaries or affiliates

APPENDIX

PERFORMANCE CHARACTERISTICS

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

Interference

Serum samples containing cytokeratin 19 fragment concentrations (low and high) were spiked with multiple concentrations of the substances listed below and assayed using Cytokeratin 19 Fragment IRMA KIT. Values were calculated as described in CLSI EP07, 3rd ed. [9]. 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	36.58 µg/mL
Ascorbic acid	73.92 µg/mL
Biotin	1,545 ng/mL
Conjugated bilirubin	451.8 µg/mL
Hemoglobin	10,569 µg/mL
Heparin	6,971 ng/mL
Cholesterol	0.69 mg/mL
Ibuprofen	231.5 µg/mL
Prednisone	137.1 ng/mL
Prednisolone	1,372 ng/mL
Rheumatoid factor	44.09 IU/mL
Triglycerides	2.74 mg/mL
Unconjugated bilirubin	377.2 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

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 (ng/mL)	Repeatability		Within-laboratory precision	
		SD (ng/mL)	C.V. (%)	SD (ng/mL)	C.V. (%)
S1	2.04	0.12	5.79	0.19	9.09
S2	3.03	0.19	6.13	0.23	7.50
S3	11.38	0.34	3.00	0.53	4.63
S4	28.96	1.17	4.04	1.55	5.37
S5	74.00	3.08	4.16	5.09	6.88

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	-	26.92	-	-
	1:2	14.20	13.46	105.5
	1:4	5.64	6.73	83.80
	1:8	2.73	3.37	81.13
	1:16	1.39	1.68	82.62
	1:32	0.89	0.84	105.8
S2	-	26.80	-	-
	1:2	14.80	13.40	110.4
	1:4	6.80	6.70	101.5
	1:8	2.94	3.35	87.76
	1:16	1.59	1.68	94.93
	1:32	0.85	0.84	101.5
S3	-	23.07	-	-
	1:2	12.19	11.54	105.7
	1:4	5.94	5.77	103.0
	1:8	2.43	2.88	84.27
	1:16	1.26	1.44	87.39
	1:32	0.77	0.72	106.8
S4	-	44.89	-	-
	1:2	23.01	22.45	102.5
	1:4	12.64	11.51	109.9
	1:8	5.14	5.75	89.35
	1:16	2.52	2.88	87.61
	1:32	1.43	1.44	99.44
S5	-	29.76	-	-
	1:2	15.87	14.88	106.7
	1:4	7.41	7.44	99.60
	1:8	3.20	3.72	86.02
	1:16	1.81	1.86	97.31
	1:32	1.11	0.93	119.4

Recovery test

Samples were spiked with known quantities of cytokeratin 19 fragment 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	2.51	1.06	3.57	3.10	86.79
	2.44	2.07	4.51	4.12	91.32
	2.46	5.73	8.19	7.07	86.36
S2	2.71	1.50	4.21	3.40	80.73
	2.61	2.89	5.50	4.84	88.00
	2.63	8.61	11.24	10.21	90.85
S3	3.37	1.93	5.29	5.37	101.5
	3.22	3.55	6.76	6.27	92.70
	3.22	11.16	14.38	13.01	90.47
S4	0.48	1.93	2.41	2.10	87.04
	0.46	3.55	4.01	3.67	91.54
	0.46	11.36	11.83	10.75	90.89
S5	4.48	1.93	6.40	5.50	85.87
	4.28	3.55	7.83	6.59	84.19
	4.28	11.36	15.65	13.59	86.86

Method Comparison

The A56888, Cytokeratin 19 Fragment IRMA KIT was compared to a commercially available diagnostic CYFRA 21-1 IRMA assay. The results of the testing of samples are shown in the following table.

Number of samples	Intercept	Slope	Correlation Coefficient
42	0.9 ng/mL	1.14	0.981

^{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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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

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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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