BECKMAN COULTER

CE 2797

β2-Microglobulin RIA KIT

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

REVISION HISTORY

Previous version: IFU-IM1113-01	**Current version:** IFU-IM1113-02
Assay procedure —	Adding missing translations to the table header.

REF IM1113

FOR PROFESSIONAL USE ONLY

INTENDED PURPOSE

β2-Microglobulin RIA KIT is an in vitro diagnostic manual medical device intended to be used by healthcare professionals for the quantitative measurement of β2-microglobulin in human serum, plasma and urine. Measurement of β2-microglobulin is intended to be used for the prognosis of multiple myeloma and for diagnosis and monitoring of renal tubular disorders in general population [1, 2, 3, 4, 5, 6].

PRINCIPLE

The radioimmunoassay of β2-microglobulin is a competition assay. Samples and calibrators are incubated with ^{125}I-labeled β2-microglobulin, as a tracer, in monoclonal antibody-coated tubes. After incubation, the contents of the tubes are aspirated so as to remove unbound ^{125}I-labeled tracer. The bound radioactivity is then determined in a gamma counter. The β2-microglobulin concentrations in the samples are obtained by interpolation from the standard curve. The concentration of β2-microglobulin 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.

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: 150995905IM11134U.

GHS HAZARD CLASSIFICATION

Tracer — 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.
P405	Store locked up.
P501	Dispose of contents/container in accordance with local/national regulations

Boric Acid 1 - 2%

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

SPECIMEN COLLECTION, PROCESSING, STORAGE AND DILUTION

Serum or EDTA plasma or urine are the recommended sample types.

Serum and plasma

- Allow serum samples to clot completely before centrifugation.
- Serum and plasma samples may be stored at 2-8°C, if the assay is 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 or assayed using smaller sample volume, 20 µL.

Serum and EDTA plasma values for 15 samples (serum values ranging from 1.18 to 1.91 mg/L) were compared using the β2-Microglobulin RIA KIT. Results are as follows:

[EDTA-plasma] = 0.9927[serum] - 0.1426

R = 0.9557

Urine

- Collect urine in glass or plastic vessels. Add borate (10-20 mM) for storage.
- Urine samples may be stored at 2-8°C, if the assay is performed within 24 hours. For longer storage keep frozen (at < -20°C, 1 year 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.
- If samples have concentrations lower than 0.25 mg/L they should be assayed using 100 or 200 µL sample volume.

Note: At acid pH (below 5), β2-microglobulin is denatured and can no longer be assayed.

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.

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

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

The vial contains 148 kBq, at the date of manufacture, of ^{125}I-labeled β2-microglobulin in buffer with bovine serum albumin, sodium azide (<0.1%) and a dye.

Calibrators: five 0.5 mL vials and one 2 mL vial of «zero» calibrator (ready-to-use)

The calibrator vials contain from 0 to approximately 30 mg/L of β2-microglobulin 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 IS 1985. 1 IU corresponds to 14 ng.

Control sample: one vial (lyophilized)

The vial contains β2-microglobulin lyophilized in human serum with sodium azide (<0.1%). The concentration range is indicated on a supplement. The control sample is traceable to the international standard WHO, 1st IS 1985.

MATERIALS REQUIRED, BUT NOT PROVIDED

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

- Precision micropipette (50 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 sample

The content of the vial reconstitute with the volume of distilled water indicated on the vial label. Wait for 10 min following reconstitution and mix gently to avoid foaming before dispensing. Store the reconstituted solution at 2-8°C for 3 days or aliquoted at <-18°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 500 µL of tracer.* Vortex gently 1-2 seconds.	Incubate 90 minutes at 18-25°C with shaking (≥ 280 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.

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 *cubic regression* 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: 51,671 cpm				
Calibrators	**β2-Microglobulin (mg/L)**	**cpm (n=3)**	**B/T (%)**	**B/B$_0$ (%)**
0	0	42,192	81.6	100.0
1	0.29	34,240	66.3	81.2
2	0.76	20,614	39.9	48.9
3	1.90	10,463	20.2	24.8
4	7.60	3,520	6.81	8.34
5	28.5	1,384	2.68	3.28

· *(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.

EXPECTED VALUES

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

Plasma and serum:

1.0 to 2.4 mg/L (95% of the normal population); mean 1.20 mg/L. The serum level increases slightly with age but it is not dependent on sex.

Urine:

Up to 0.37 mg/L.

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): 0.13 mg/L

The LoD of the assay is 0.13 mg/L, determined consistent with guidelines in CLSI document EP17-A2 [7] based on the proportions of false positives (α) less than 5% and false negatives (β) less than 5%; using determinations, with 120 blank and 168 low level samples; and Limit of Blank (LoB) of 0.05 mg/L.

Specificity

No cross-reactivity with human IgG was detected in the assay.

Precision

Repeatability and within-laboratory precision

The precision of the assay was determined consistent with guidelines in CLSI document EP05-A3 [8]. For repeatability the coefficients of variation were found below or equal to 7.81% for serum samples. For within-laboratory precision the coefficients of variation were found below or equal to 10.62% for serum samples.

Accuracy

Linearity

The assay demonstrated to be linear from 0.23 to 34.55 mg/L using serum samples (determined consistent with guidelines in CLSI document EP06-A [9]).

Dilution test

High-concentration samples were serially diluted with the zero calibrator. The recovery percentages obtained were between 85.3% and 119% for serum and between 81.0% and 116% for urine.

Recovery test

Samples were spiked with known quantities of β2-microglobulin. The recovery percentages were obtained between 97.6% and 119% for serum and between 80.7% and 97.3% for urine.

Measurement range (from LoD to the highest calibrator): 0.13 to approximately 30 mg/L.

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 [10, 11, 12].

APPENDIX

PERFORMANCE CHARACTERISTICS

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

Interference

Serum samples containing β2-microglobulin concentrations (low and high) were spiked with multiple concentrations of the substances listed below and assayed using β2-Microglobulin RIA KIT. Values were calculated as described in CLSI EP07, 3rd ed. [13]. 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	23.65 µg/mL
Ascorbic acid	59.23 µg/mL
Biotin	1,272 ng/mL
Conjugated bilirubin	402.9 µg/mL
Hemoglobin	4,774 µg/mL
Heparin	6,912 ng/mL
Cholesterol	3.51 mg/mL
Ibuprofen	371.2 µg/mL
Prednisone	85.73 ng/mL
Prednisolone	1,025 ng/mL
Rheumatoid factor	17.18 IU/mL
Triglycerides	12.17 mg/mL
Unconjugated bilirubin	242.4 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.

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 (mg/L)	Repeatability		Within-laboratory precision	
		SD (mg/L)	C.V. (%)	SD (mg/L)	C.V. (%)
S1	0.70	0.03	4.12	0.04	5.10
S2	1.20	0.05	4.10	0.07	5.49
S3	2.10	0.09	4.13	0.12	5.88
S4	6.53	0.43	6.65	0.59	9.05
S5	13.75	0.88	6.39	1.26	9.16
S6	20.51	1.60	7.81	2.18	10.62

EDTA plasma	Mean (mg/L)	Repeatability		Within-laboratory precision	
		SD (mg/L)	C.V. (%)	SD (mg/L)	C.V. (%)
P1	1.25	0.05	3.95	0.08	6.13
P2	1.78	0.08	4.41	0.11	6.36
P3	3.02	0.13	4.29	0.20	6.77
P4	7.33	0.41	5.66	0.66	8.95
P5	15.00	1.14	7.59	1.59	10.57
P6	26.78	3.42	12.77	3.77	14.08

Urine	Mean (mg/L)	Repeatability		Within-laboratory precision	
		SD (mg/L)	C.V. (%)	SD (mg/L)	C.V. (%)
U1	0.33	0.02	5.27	0.04	11.98
U2	0.80	0.04	5.59	0.11	13.64
U3	1.56	0.08	5.31	0.23	14.88
U4	4.83	0.25	5.24	0.64	13.26
U5	9.84	0.68	6.91	1.31	13.29
U6	18.03	1.16	6.43	1.99	11.01

Accuracy

Linearity

The assay demonstrated to be linear from 0.30 to 39.00 mg/L using EDTA plasma samples (determined consistent with guidelines in CLSI document EP06-A [9]).

The assay demonstrated to be linear from 0.29 to 40.42 mg/L using urine samples (determined consistent with guidelines in CLSI document EP06-A [9]).

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
		mg/L		
S1	-	7.02	-	-
	1:2	3.32	3.51	94.59
	1:4	1.75	1.76	99.72
	1:8	0.85	0.88	96.87
	1:16	0.44	0.44	100.3
S2	-	25.92	-	-
	1:2	11.05	12.96	85.26
	1:4	6.42	6.48	99.07
	1:8	3.33	3.24	102.8
	1:16	1.68	1.62	103.7
	1:32	0.80	0.81	98.77
S3	-	9.16	-	-
	1:2	4.78	4.58	104.4
	1:4	2.59	2.29	113.1
	1:8	1.36	1.15	118.8
	1:16	0.65	0.57	113.5
	1:32	0.32	0.29	111.8
S4	-	6.65	-	-
	1:2	3.42	3.33	102.9
	1:4	1.65	1.66	99.25
	1:8	0.78	0.83	93.83
	1:16	0.40	0.42	96.24
	1:32	0.24	0.21	115.5
S5	-	19.26	-	-
	1:2	8.82	9.63	91.59
	1:4	4.71	4.82	97.82
	1:8	2.36	2.41	98.03
	1:16	1.13	1.20	93.87
	1:32	0.54	0.60	89.72

EDTA plasma	Dilution factor	Measured	Expected	Ratio (%) Measured/ Expected
		mg/L		
P1	-	4.46	-	-
	1:2	2.31	2.23	103.6
	1:4	1.13	1.12	101.3
	1:8	0.52	0.56	93.27
	1:16	0.28	0.28	100.4
P2	-	4.42	-	-
	1:2	2.34	2.21	105.9
	1:4	1.18	1.11	106.8
	1:8	0.56	0.55	101.4
	1:16	0.32	0.28	115.8
P3	-	12.25	-	-
	1:2	6.94	6.13	113.3
	1:4	3.61	3.06	117.9
	1:8	1.82	1.53	118.9
	1:16	0.90	0.77	117.6
	1:32	0.43	0.38	112.3
P4	-	12.73	-	-
	1:2	6.35	6.37	99.76
	1:4	3.29	3.18	103.4
	1:8	1.60	1.59	100.6
	1:16	0.74	0.80	93.01
	1:32	0.33	0.40	82.95
P5	-	20.53	-	-
	1:2	10.41	10.27	101.4
	1:4	5.24	5.13	102.1
	1:8	2.44	2.57	95.08
	1:16	1.20	1.28	93.52
	1:32	0.59	0.64	91.96

Urine	Dilution factor	Measured	Expected	Ratio (%) Measured/ Expected
		mg/L		
U1	-	6.64	-	-
	1:2	3.49	3.32	105.1
	1:4	1.68	1.66	101.2
	1:8	0.76	0.83	91.57
	1:16	0.39	0.42	93.98
	1:32	0.24	0.21	115.7
U2	-	8.94	-	-
	1:2	4.59	4.47	102.7
	1:4	2.18	2.24	97.54
	1:8	1.02	1.12	91.28
	1:16	0.48	0.56	85.91
	1:32	0.27	0.28	96.64
U3	-	14.99	-	-
	1:2	7.05	7.50	94.06
	1:4	3.42	3.75	91.26
	1:8	1.56	1.87	83.26
	1:16	0.76	0.94	81.12
	1:32	0.39	0.47	83.26
U4	-	17.06	-	-
	1:2	8.79	8.53	103.0
	1:4	4.18	4.27	98.01
	1:8	2.04	2.13	95.66
	1:16	0.92	1.07	86.28
	1:32	0.44	0.53	82.53
U5	-	20.55	-	-
	1:2	11.21	10.28	109.1
	1:4	5.18	5.14	100.8
	1:8	2.54	2.57	98.88
	1:16	1.19	1.28	92.65
	1:32	0.52	0.64	80.97

Recovery test

Samples were spiked with known quantities of β2-microglobulin and assayed according to the assay procedure of the kit.

Serum	Endogen. conc.	Added conc.	Expected conc.	Measured conc.	Ratio (%) Measured/ Expected
	mg/L				
S1	7.37	1.99	9.36	9.47	101.1
	7.26	7.84	15.11	17.97	118.9
	7.13	15.38	22.51	26.66	118.4
S2	2.30	0.78	3.09	3.18	103.0
	2.34	1.99	4.33	4.58	105.8
	2.32	5.91	8.23	9.21	112.0
S3	7.84	1.99	9.83	9.59	97.55
	7.73	7.84	15.57	16.94	108.8
	7.61	13.53	21.14	24.77	117.2
S4	3.86	1.40	5.25	5.46	104.0
	3.83	3.96	7.79	8.32	106.8
	3.78	9.76	13.53	15.08	111.4
S5	2.84	1.20	4.04	4.21	104.3
	2.82	3.96	6.78	7.01	103.4
	2.79	7.84	10.64	11.63	109.3

EDTA plasma	Endogen. conc.	Added conc.	Expected conc.	Measured conc.	Ratio (%) Measured/ Expected
	mg/L				
P1	1.29	0.69	1.98	1.94	98.09
	1.26	1.33	2.59	2.36	91.14
	1.22	1.95	3.17	2.84	89.64
P2	0.73	0.69	1.41	1.28	90.51
	0.71	1.33	2.04	1.87	91.59
	0.69	1.95	2.64	2.19	83.11
P3	2.31	0.69	3.00	2.86	95.41
	2.25	1.33	3.58	3.36	93.83
	2.19	1.95	4.13	4.00	96.78
P4	4.93	0.69	5.62	5.51	98.03
	4.80	1.33	6.13	6.18	100.8
	4.67	1.95	6.61	6.48	97.97
P5	2.99	0.69	3.68	3.60	97.89
	2.91	1.33	4.24	4.02	94.76
	2.83	1.95	4.78	4.33	90.66

Urine	Endogen. conc.	Added conc.	Expected conc.	Measured conc.	Ratio (%) Measured/ Expected
	mg/L				
U1	0.69	0.69	1.38	1.11	80.70
	0.67	1.33	2.00	1.64	81.84
	0.65	1.95	2.60	2.22	85.44
U2	0.85	0.69	1.53	1.25	81.65
	0.82	1.33	2.16	1.89	87.70
	0.80	1.95	2.75	2.22	80.86
U3	2.22	0.69	2.91	2.66	91.40
	2.16	1.33	3.50	3.40	97.25
	2.10	1.95	4.05	3.59	88.64
U4	3.39	0.69	4.08	3.30	80.96
	3.30	1.33	4.63	3.74	80.79
	3.21	1.95	5.15	4.29	83.25
U5	6.79	0.69	7.48	6.78	90.69
	6.60	1.33	7.94	6.84	86.20
	6.42	1.95	8.37	7.39	88.30

^{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

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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

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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

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

REFERENCES

1. National Kidney Foundation. K/DOQI clinical practice guidelines for chronic kidney disease: evaluation, classification, and stratification. Am J Kidney Dis. 2002;39: S1-266.
2. Zeng X, Hossain D, Bostwick DG, Herrera GA, Ballester B, et al. (2014) Urinary β2-Microglobulin is a Sensitive Indicator for Renal Tubular Injury. SAJ Case Rep 1: 103. doi: 10.18875/2375- 7043.1.103.
3. Kevin T Barton, Aadil Kakajiwala, Dennis J Dietzen, Charles W Goss, Hongjie Gu, Vikas R Dharnidharka, Using the newer Kidney Disease: Improving Global Outcomes criteria, beta-2- microglobulin levels associate with severity of acute kidney injury, Clinical Kidney Journal, Volume 11, Issue 6, December 2018, Pages 797–802.
4. Mikhael J, Ismaila N, Cheung MC, Costello C, Dhodapkar MV, Kumar S, Lacy M, Lipe B, Little RF, Nikonova A, Omel J, Peswani N, Prica A, Raje N, Seth R, Vesole DH, Walker I, Whitley A, Wildes TM, Wong SW, Martin T. Treatment of Multiple Myeloma: ASCO and CCO Joint Clinical Practice Guideline. J Clin Oncol. 2019 May 10;37(14):1228-1263. doi: 10.1200/JCO.18.02096. Epub 2019 Apr 1. Erratum in: J Clin Oncol. 2020 Jul 20;38(21):2469. PMID: 30932732.
5. Moreau P, San Miguel J, Sonneveld P, Mateos MV, Zamagni E, Avet-Loiseau H, Hajek R, Dimopoulos MA, Ludwig H, Einsele H, Zweegman S, Facon T, Cavo M, Terpos E, Goldschmidt H, Attal M, Buske C; ESMO Guidelines Committee. Multiple myeloma: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2017 Jul 1;28(suppl_4):iv52-iv61. doi: 10.1093/annonc/mdx096. PMID: 28453614.
6. Kumar SK, Callander NS, Adekola K, Anderson L, Baljevic M, Campagnaro E, Castillo JJ, Chandler JC, Costello C, Efebera Y, Faiman M, Garfall A, Godby K, Hillengass J, Holmberg L, Htut M, Huff CA, Kang Y, Hultcrantz M, Larson S, Liedtke M, Martin T, Omel J, Shain K, Sborov D, Stockerl-Goldstein K, Weber D, Keller J, Kumar R. Multiple Myeloma, Version 3.2021, NCCN Clinical Practice Guidelines in Oncology. J Natl Compr Canc Netw. 2020 Dec 2;18(12):1685-1717. doi: 10.6004/jnccn.2020.0057. PMID: 33285522.
7. Approved Guideline - Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures, EP17-A2. June 2012. Clinical and Laboratory Standards Institute.
8. Approved Guideline – Evaluation of Precision of Quantitative Measurement Procedures, EP05-A3. October 2014. Clinical and Laboratory Standards Institute.
9. Approved Guideline - Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach, EP6-A. April 2003. Clinical and Laboratory Standards Institute.
10. J Bjerner et al. - Immunometric Assay Interference - Incidence and Prevention; Clin Chem 48;4; 613-621, 2002
11. L J Kricka - Interferences in Immunoassay - Still a Threat; Clin Chem 46, No. 8, 2000
12. A. Dasgupta: Biotin and Other Interferences in Immunoassays – A Conchise Guide. Elsevier, St. Louis, 2019
13. Approved Guideline - Interference Testing in Clinical Chemistry, EP07 3rd Edition. April 2018. Clinical and Laboratory Standards Institute.

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