BECKMAN COULTER

CE 2797

Insulin(e) IRMA KIT

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

REVISION HISTORY

Previous version: IFU-IM3210-01	**Current version:** IFU-IM3210-02
—	Adding Dutch to the IFU.
Radioactivity table in the chapter APPENDIX.	Better specification of Iodine 125 characteristics table at the end of the chapter Appendix.

REF IM3210

INTENDED PURPOSE

Insulin(e) IRMA KIT is an in vitro diagnostic manual medical device intended to be used by healthcare professionals for the quantitative measurement of insulin in human serum and plasma. Measurement of insulin is intended to be used as an aid in diagnosis of insulinoma in general population [1, 2, 3].

PRINCIPLE

The immunoradiometric assay of insulin is a sandwich-type assay. Mouse monoclonal antibodies directed against two different epitopes of insulin and hence not competing are used. This assay may be employed for the measurement of:

- immunoreactive insulin (free insulin + insulin bound to anti-insulin antibodies) directly in serum or plasma,
- free insulin after pre-treatment of samples with precipitation reagent (see MATERIALS REQUIRED BUT NOT PROVIDED).

Samples (pre-treated or not with precipitation reagent) or calibrators are incubated in tubes coated with the first monoclonal antibody in the presence of the second monoclonal antibody which is 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 insulin concentrations in the samples are obtained by interpolation from the standard curve. The concentration of insulin 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.

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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: 150995905IM321059.

GHS HAZARD CLASSIFICATION

Calibrators	WARNING	
		
	H317	May cause an allergic skin reaction.
	H412	Harmful to aquatic life with long lasting effects.
	P273	Avoid release to the environment.
	P280	Wear protective gloves, protective clothing and eye/face protection.
	P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
	P362+P364	Take off contaminated clothing and wash it before use.
		reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) < 0.05%
Wash Solution U (20x)	DANGER	
		
	H360	May damage fertility or the unborn child.
	P201	Obtain special instructions before use.
	P280	Wear protective gloves, protective clothing and eye/face protection.
	P308+P313	IF exposed or concerned: Get medical advice/attention.
		Boric Acid 0.1 - 0.3%
		Sodium Borate Decahydrate 0.1 - 0.3%

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

SPECIMEN COLLECTION, PROCESSING, STORAGE AND DILUTION

- Serum or EDTA plasma are the recommended sample types.
- Allow serum samples to clot completely before centrifugation.
- Serum and plasma samples may be stored at 2-8°C, if the assay is to be performed within 24 hours. For longer storage keep frozen (at < -20°C, 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.

  Serum and EDTA plasma values for 20 samples (serum values ranging from 5.30 to 72.34 µIU/mL) were compared using the IM3210 Insulin(e) IRMA KIT. Results are as follows:

  [EDTA-plasma] = 1.0576 [serum] - 1.2088

  R = 0.9958

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 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.

Note: Occasional presence of clotted particles in the tracer does not affect assay performance. They may be dissolved by gentle shaking.

Calibrators: five 1 mL vials and one 2 mL vial of «zero» calibrator (ready-to-use)

The calibrator vials contain from 0 to approximately 300 µIU/mL of insulin 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 66/304 (1 µIU/mL = 43.3 ng/L = 7.46 pmol/L).

Control samples: two vials (lyophilized)

The vials contain insulin 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 66/304.

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:

For immunoreactive insulin determination

- Precision micropipette (50 µL).
- Repeating pipettes (100 µL and 2 mL).
- Vortex type mixer.
- Horizontal or orbital shaker.
- Aspiration system.
- Gamma counter set for ^{125}I.

For the determination of free insulin (facultative):

- Precision micropipette (100 µL and 400 µL).
- Repeating pipette (400 µL).
- Polypropylene or glass tubes.
- Centrifuge with cooling system (3000 g).
- Precipitation reagent: one 50 mL bottle (ready-to-use)

  Supplied upon request: REF. A09775

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 at 2-8°C for one day and at < -18°C until the expiry date of the kit. Repeated freezing and thawing do not affect the determination if not repeated more than four times.

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.

Preparation of samples and controls for the determination of free insulin

- Add 400 µL of precipitation reagent (see MATERIALS REQUIRED BUT NOT PROVIDED) to 400 µL of control or unknown sample in polypropylene or glass tube.

  Do not add precipitation reagent to the calibrators.

  Shake on vortex-type mixer and then centrifuge for at least 15 minutes at 3000 g and 4°C. The supernatant contains free insulin only.

Assay procedure

Step 1 Additions*	Step 2 Incubation	Step 3 Counting
For immunoreactive insulin determination To coated tubes add successively: 50 µL of calibrator, control or sample and 100 µL of tracer. Vortex gently 1-2 seconds.	Incubate 2 hours at 18-25°C with shaking (≥ 280 rpm).	Aspirate carefully the content of tubes (except the 2 tubes «total cpm»). Wash twice with 2 mL of wash solution. Aspirate. Count bound cpm (B) and total cpm (T) for 1 minute.
For free insulin determination To coated tubes add successively: 50 µL of calibrator or 100 µL of supernatant for controls and samples and 100 µL of tracer. Vortex gently 1-2 seconds.		

*. 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: 201,392 cpm				
Calibrators	**Insulin (µIU/mL)**	**cpm (n=3)**	**B/T (%)**	**cpm_{cal} - cpm_{cal0}**
0	0	59	-	-
1	3.20	501	0.22	442
2	10.5	1,615	0.77	1,556
3	31.5	5,612	2.76	5,553
4	105	20,406	10.1	20,347
5	315	61,940	30.7	61,881

· *(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.

The concentrations of free insulin are read off the same standard curve as the other samples. Do not multiply them by the dilution factor brought by the pre-treatment step since it is compensated by higher supernatant volume used in the assay.

EXPECTED VALUES

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

Fasting healthy individuals:

N	Mean	Median	Min-Max	2.5^{th} - 97.5^{th} percentile
	(µIU/mL)			
71	6.0	5.2	0.93 - 26.5	1.21 - 14.5

Insulin concentrations during the Oral glucose tolerance test (OGTT) of blood donors:

Time (min)	Insulin concentration (µIU/mL) Average ± SD
0	8.6 ± 4.1
15	42.3 ± 17.0
30	54.7 ± 29.0
60	43.8 ± 18.4
120	17.4 ± 11.6

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

Analytical sensitivity: 0.49 µIU/mL

Functional sensitivity: 1.35 µIU/mL

Specificity

The antibodies used in this kit exhibit extremely low cross reactivities with human proinsulin, C-peptide, Des-31,32 proinsulin, Lispro (Humalog) and 55% cross-reactivity with Des-64,65 proinsuline.

Precision

Intra-assay

Serum samples were assayed in 20 replicates in the same series. The coefficients of variation were found below or equal to 3.99% (free insulin 3.56%).

Inter-assay

Serum samples were assayed in duplicate in 16 different series. Coefficients of variation were found below or equal to 4.80% (free insulin 10.84%).

Accuracy

Dilution test

High-concentration serum samples were serially diluted in zero calibrator. The recovery percentages were obtained between 89.2% and 119%.

Recovery test

Low-concentration serum samples were spiked with known quantities of insulin. The recovery percentages were obtained between 94.3% and 117%.

Measurement range (from analytical sensitivity to the highest calibrator): 0.49 to approximately 300 µIU/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].

APPENDIX

PERFORMANCE CHARACTERISTICS

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

Interference

Serum samples containing insulin concentrations (low and high) were spiked with multiple concentrations of the substances listed below and assayed using Insulin(e) IRMA KIT. Values were calculated as described in CLSI EP07, 3rd ed. [7]. 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	446.4 ng/mL
Conjugated bilirubin	432.1 µg/mL
Hemoglobin	8,618 µg/mL
Triglycerides	22.21 mg/mL
Unconjugated bilirubin	593.5 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 Total insulin (n = 20)	S1	S2	S3
Mean value (µIU/mL)	13.0	53.6	110.6
C.V. (%)	3.26	3.99	2.76

Serum Free insulin (n = 25)	S1	S2	S3
Mean value (µIU/mL)	6.83	19.38	53.05
C.V. (%)	3.56	3.06	3.37

EDTA plasma (n = 25)	P1	P2	P3
Mean value (µIU/mL)	6.93	26.84	73.82
C.V. (%)	2.68	2.14	1.74

Inter-assay

Serum Total insulin (n = 16)	S1	S2	S3
Mean value (µIU/mL)	5.00	42.00	82.70
C.V. (%)	4.80	3.66	3.58

Serum Free insulin (n = 10)	S1	S2	S3
Mean value (µIU/mL)	2.03	30.64	84.54
C.V. (%)	10.84	3.35	5.08

EDTA plasma (n = 10)	P1	P2	P3
Mean value (µIU/mL)	3.90	32.44	154.4
C.V. (%)	7.31	4.28	7.40

Accuracy

Dilution test

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

Dilution is not applicable for the determination of free insulin.

Serum	Dilution factor	Measured (µIU/mL)	Expected (µIU/mL)	Ratio (%) Measured/ Expected
S1	-	108.8	-	-
	1:2	57.0	54.4	104.6
	1:4	28.3	27.2	103.9
	1:8	13.2	13.6	97.2
	1:16	6.06	6.8	89.2
S2	-	115.2	-	-
	1:2	61.5	57.5	106.9
	1:4	29.4	28.8	102.1
	1:8	14.8	14.4	102.9
	1:16	6.27	7.20	95.8
S3	-	81.3	-	-
	1:2	40.9	40.7	100.7
	1:4	21.5	20.3	105.6
	1:8	10.3	10.2	101.4
	1:16	4.71	5.10	92.3
S4	-	21.6	-	-
	1:2	10.8	10.8	100.0
	1:4	6.35	5.40	118.5
	1:8	2.89	2.70	106.9
	1:16	1.57	1.40	116.2
S5	-	71.5	-	-
	1:2	35.2	35.8	98.3
	1:4	17.3	17.9	96.9
	1:8	8.70	8.90	97.8
	1:16	4.20	4.47	94.0

EDTA plasma	Dilution	Measured (µIU/mL)	Expected (µIU/mL)	Ratio (%) Measured/ Expected
P1	-	90.13	-	-
	1:2	46.49	45.07	103.2
	1:4	24.77	22.53	109.9
	1:8	12.41	11.27	110.2
	1:16	5.87	5.63	104.2
	1:32	2.94	2.82	104.4
P2	-	139.8	-	-
	1:2	74.14	69.92	106.0
	1:4	35.51	34.96	101.6
	1:8	17.53	17.48	100.3
	1:16	8.71	8.74	99.66
	1:32	4.08	4.37	93.36
P3	-	159.3	-	-
	1:2	80.95	79.64	101.7
	1:4	42.01	39.82	105.5
	1:8	21.21	19.91	106.5
	1:16	10.87	9.95	109.2
	1:32	5.17	4.98	103.9
P4	-	78.84	-	-
	1:2	39.04	39.42	99.04
	1:4	20.14	19.52	103.2
	1:8	10.23	9.76	104.8
	1:16	5.41	4.88	110.9
	1:32	2.46	2.44	100.8
P5	-	155.2	-	-
	1:2	82.10	77.62	105.8
	1:4	42.25	38.81	108.9
	1:8	21.41	19.40	110.3
	1:16	10.51	9.70	108.3
	1:32	5.22	4.85	107.6

Recovery test

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

Recovery is not applicable for the determination of free insulin.

Serum	Endogen. conc.	Added conc.	Expected conc.	Measured conc.	Ratio (%) Measured/ Expected
	(µIU/mL)				
S1	16.0	40.5	56.5	63.4	117.0
		80.5	96.5	105.8	111.5
		119.0	135.0	154.1	116.2
S2	14.2	40.5	54.7	52.4	94.3
		80.5	94.7	90.7	95.0
		119.0	133.0	132.9	99.9
S3	5.8	40.5	46.3	47.6	103.2
		80.5	86.3	88.9	103.2
		119.0	124.8	132.2	106.3
S4	29.8	40.5	70.3	72.1	104.4
		80.5	110.3	106.6	95.4
		119.0	148.8	153.4	104.0
S5	45.3	40.5	85.86	88.6	106.9
		80.5	130.8	128.5	103.3
		119.0	164.3	172.4	106.9

EDTA plasma	Endogen. conc.	Added conc.	Expected conc.	Measured conc.	Ratio (%) Measured/ Expected
	(µIU/mL)				
P1	3.66	1.43	5.09	4.87	95.7
	3.56	3.91	7.47	6.97	93.3
	3.42	7.48	10.90	9.68	88.8
P2	14.74	4.72	19.46	18.57	95.4
	14.27	13.73	28.00	27.03	96.5
	13.63	26.21	39.84	36.83	92.4
P3	25.44	7.10	32.54	31.61	97.1
	24.84	13.86	38.70	39.06	101.0
	23.71	26.45	50.16	49.62	98.9
P4	33.12	7.10	40.22	39.43	98.0
	32.33	13.86	46.19	45.60	98.7
	30.86	26.45	57.32	54.93	95.8
P5	86.46	7.10	93.56	92.87	99.3
	84.40	13.86	98.26	95.61	97.3
	80.56	26.45	107.0	104.7	97.8

^{125}I Characteristics

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

^{125}I	E (MeV)	%
γ	0.035	6.50
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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SDS — Safety Data Sheet / Fiche technique santé-sécurité / Sicherheitsdatenblatt / Scheda dati di sicurezza / Hoja de datos de seguridad / Ficha de Dados de Segurança / Säkerhetsdatablad / Φύλλο Δεδομένων Ασφάλειας / 安全数据单 / Saugos duomenų lapas / Biztonsági adatlap / Karta Charakterystyki Bezpieczeństwa / Bezpečnostní list / Bezpečnostný list / 안전보건자료 / Güvenlik Bilgi Formu / Паспорт безопасности / Информационен Лист За Безопасност / 安全性資料表

Consult Instructions for Use / Consultez le mode d'emploi / Siehe Gebrauchsanweisung / Consultare le istruzioni per l'uso / Consulte las Instrucciones de uso / Instruções de utilização / Konsultera bruksanvisning / Συμβουλευτείτε τις οδηγίες χρήσης / 请参阅使用说明 / Skaitykite naudojimo instrukciją / Olvassa el a használati utasítást / Zapoznać się z instrukcją użycia / Postupujte podle návodu k použití / Prečítajte si návod na použitie / 사용 안내 문의 / Kullanma Talimatına Başvurun / Обратитесь к инструкциям / Вижте Инструкциите за употреба / 請參閱使用說明

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

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

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

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

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

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

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

Ag 125I / Ab 125I — Tracer / Traceur / Tracer / Marcato / Trazador / Marcador / Tracer / Ανιχνευτής / 追踪剂 / Atsekamoji medžiaga / Nyomjelző / Znacznik / Radioindikátor / Indikátor (tracer) / 트레이서 / Tracer´lar / метка / Индикатор / 追蹤劑

CAL / CAL 0 — Calibrator / Calibrateur / Kalibrator / Calibratore / Calibrador / Calibrador / Kalibrator / Βαθμονομητής / 校准品 / Kalibravimo medžiaga / Kalibrátor / Kalibrator / kalibrátor / Kalibrátor / 보정 물질 / Kalibratör / Калибратор / Калибратор / 校正液

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

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

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

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

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