BECKMAN COULTER

CE 2797

IRMA IGF-I

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

REVISION HISTORY

Previous version: IFU-A15729-06	Current version: IFU-A15729-07
MATERIALS PROVIDED **Calibrators: six vials** (lyophilized) The calibrator vials contain from 0 to approximately 1,600 ng/mL of IGF-I in a buffer with bovine serum albumin and a preservative. The exact concentration is indicated on each vial label. The calibrators are traceable to the international reference standard, WHO 02/254. **Control sample: one vial** (lyophilized) The vial contains IGF-I lyophilized in a buffer with bovine serum albumin. The concentration range is indicated on a supplement. The control sample is traceable to the international reference standard, WHO 02/254.	**Calibrators: six vials** (lyophilized) The calibrator vials contain from 0 to approximately 1,600 ng/mL of IGF-I in a buffer with bovine serum albumin and a preservative. The calibrators are traceable to the international reference standard, WHO 02/254. The exact concentration is indicated on the Certificate of Analysis provided with the kit and on the Beckman Coulter website (beckmancoulter.com/techdocs). **Control sample: one vial** (lyophilized) The vial contains IGF-I lyophilized in a buffer with bovine serum albumin. The control sample is traceable to the international reference standard, WHO 02/254. The concentration range is indicated on the Certificate of Analysis provided with the kit and on the Beckman Coulter website (beckmancoulter.com/techdocs).
Standard curve *(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.)*	Example of standard curve is given on the Certificate of Analysis provided with the kit and on the Beckman Coulter website (beckmancoulter.com/techdocs). The measured data are indicative only, do not use them for calculation of your results.

REF A15729

FOR PROFESSIONAL USE ONLY

INTENDED PURPOSE

IRMA IGF-I is an in vitro diagnostic manual medical device intended to be used by healthcare professionals for the quantitative measurement of insulin-like growth factor I (IGF-I) in human serum and plasma. Measurement of insulin-like growth factor I is intended to be used in diagnosis and monitoring treatment of acromegaly and GH deficiency in general population [1, 2, 3, 4, 5, 6, 7].

PRINCIPLE

The immunoradiometric assay of Insulin-like Growth Factor I (IGF-I) is a sandwich-type assay. Mouse monoclonal antibodies directed against two different epitopes of IGF-I and hence not competing are used. In order to release IGF-I from its binding proteins, a prior dissociation step is necessary. 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 IGF-I concentrations in the samples are obtained by interpolation from the standard curve. The concentration of IGF-I 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

All patient specimens should be handled as potentially infectious and waste should be discarded according to the country rules.

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.
		Sodium borate 1 - 3%
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 < -18°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 in the dissociation buffer.

Serum and EDTA plasma values for 25 samples (serum values ranging from 54.13 to 237.6 ng/mL) were compared using the A15729 IRMA IGF-I. Results are as follows:

[EDTA-plasma] = 0.899 [serum] + 16.57

R = 0.9504

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 them 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 370 kBq, at the date of manufacture, of ^{125}I-labeled immunoglobulins in liquid form, containing bovine serum albumin, sodium azide (<0.1%) and a dye. Avoid direct exposure to light.

Calibrators: six vials (lyophilized)

The calibrator vials contain from 0 to approximately 1,600 ng/mL of IGF-I in a buffer with bovine serum albumin and a preservative. The calibrators are traceable to the international reference standard, WHO 02/254.

The exact concentration is indicated on the Certificate of Analysis provided with the kit and on the Beckman Coulter website (beckmancoulter.com/techdocs).

Control sample: one vial (lyophilized)

The vial contains IGF-I lyophilized in a buffer with bovine serum albumin. The control sample is traceable to the international reference standard, WHO 02/254.

The concentration range is indicated on the Certificate of Analysis provided with the kit and on the Beckman Coulter website (beckmancoulter.com/techdocs).

Dissociation buffer: two 25 mL vials (ready-to-use)

The vial contains bovine serum albumin.

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 (50 µL).
- Semi-automatic pipette (300 µL, 1 mL and 2 mL).
- Vortex type mixer.
- Horizontal or orbital shaker.
- Aspiration system.
- Plastic tubes.
- Gamma counter set for ^{125}I.

PROCEDURE

Preparation of reagents

Let all the reagents come to room temperature.

Reconstitution of calibrators and control sample

The content of the vials is reconstituted with the volume of distilled water indicated on the label. Wait for 30 min following reconstitution and mix gently to avoid foaming before dispensing. Store the reconstituted solutions at 2-8°C for one week or aliquoted at < -18°C for a longer time, 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.

Treatment of samples and control sample

Do not treat calibrators.

- To plastic tubes, add successively 50 µL of sample and 1 mL of dissociation buffer (these conditions allow to treat 50 samples; divide volumes by two to treat 100 samples, i.e. 25 µL of serum and 500 µL of buffer).
- Mix with a vortex-type shaker.
- Treated samples may be kept for 48h at 2-8°C; for longer storage keep at < -18°C (for up to 90 days).

Assay procedure

Step 1 Additions*	Step 2 Incubation	Step 3 Counting
To antibody coated tubes, add successively **in this order**: 300 µL of tracer, 50 µL of calibrator, control or sample. Vortex gently 1-2 seconds.	Incubate 60 minutes at 18-25°C with shaking (≥180 rpm).	Aspirate carefully the content 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.

RESULTS

Results are obtained from the standard curve by interpolation. The curve serves for the determination of analyte concentrations in samples measured at the same time as the calibrators.

Standard curve

Example of standard curve is given on the Certificate of Analysis provided with the kit and on the Beckman Coulter website (beckmancoulter.com/techdocs). The measured data are indicative only, do not use them for calculation of your results.

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.

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.

Adults

Age (years)	n	IGF-I (ng/mL)				
		Min.	5th percentile	Median	95th percentile	Max.
20-30	51	219	232	288	385	644
30-40	44	140	177	245	382	405
40-50	43	64	124	199	290	336
50-60	18	71	71	147	263	284
60-70	20	94	94	141	269	269
70-80	20	72	76	117	160	167

Children

Stage of puberty		n	IGF-I (ng/mL)		
	(years)		Mean	Min.	Max.
P1	0-4	5	114	49	171
	>4	27	250	76	499
P2		6	303	247	396
P3		7	414	249	642
P4-P5		7	400	271	550

Children constitutionally small

These children have a height that is lower by two standard deviations or more than average with GH concentration greater than 20 mIU/L after stimulation, and a regular rate of growth.

Stage of puberty		n	IGF-I (ng/mL)		
	(years)		Mean	Min.	Max.
P1	0-4	13	114	98	180
	5-7	25	115	98	156
	8-9	21	129	76	186
	10-11	24	151	76	234
	>12	27	198	131	278
P2		20	258	163	502
P3		14	351	185	617
P4		9	423	272	540

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 APPENDIX)

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

Sensitivity

Analytical sensitivity: 4.55 ng/mL

Functional sensitivity: 9.26 ng/mL

Specificity

The antibodies used in the immunoassay are highly specific for IGF-I. Extremely low cross reactivities were obtained against several molecules (insulin, proinsulin, IGF II, GH).

Precision

Intra-assay

Serum samples were assayed 25 times in the same series. The coefficients of variation were found below or equal to 5.6%.

Inter-assay

Serum samples were assayed in duplicate in 10 different series. Coefficients of variation were found below or equal to 8.3%.

Accuracy

Dilution test

High-concentration serum samples were serially diluted with the dissociation buffer. The recovery percentages obtained were between 80.8% and 110%.

Recovery test

Low-concentration serum samples were spiked with known quantities of IGF-I. The recovery percentages obtained were between 86.4% and 110%.

Measurement range (from analytical sensitivity to the highest calibrator): 4.55 to approximately 1,600 ng/mL.

LIMITATIONS

Failure to follow these instructions for use (IFU) may significantly affect results.

Results should be interpreted in the light of the total clinical presentation of the patient, including clinical history, data from additional tests and other appropriate information.

Do not use hemolyzed, lipemic or icteric samples. For more details, see Appendix, § Interference.

In immunoassays, the possibility exists for interference by heterophile antibodies in the patient sample. Patients who have been regularly exposed to animals or have received immunotherapy or diagnostic procedures utilizing immunoglobulins or immunoglobulin fragments may produce antibodies, e.g. HAMA, that interfere with immunoassays. Immunoassays may be also affected by presence of anti-avidin or anti-streptavidin antibodies, as well as by the presence of autoantibodies directed against the determined analyte. Such interfering antibodies may cause erroneous results. Carefully evaluate the results of patients suspected of having these antibodies [8, 9, 10].

“Hook effect“: no hook effect was observed until 7,000 ng/mL.

APPENDIX

PERFORMANCE CHARACTERISTICS

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

Interference

Serum samples containing IGF-I concentrations (low and high) were spiked with multiple concentrations of the substances listed below and assayed using IRMA IGF-I kit. Values were calculated as described in CLSI EP07, 3rd ed. [11]. 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	2,090 ng/mL
Conjugated bilirubin	536.1 µg/mL
Hemoglobin	9,523 µg/mL
Triglycerides	18.86 mg/mL
Unconjugated bilirubin	469.1 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.

Specificity

The specificity of the assay was determined by measuring the apparent IGF-I value given by high concentrations of related compounds in the absence (cross-reactivity) or presence of IGF-I.

Cross-reactivity

Related molecules	Concentration	IGF-I concentration measured	
	nM	ng/mL	nM
GH	40	0	0
Insulin	20	0	0
Proinsulin	40	0	0
IGF-II	650	0	0

Spiking	IGF-I concentration Expected		IGF-I concentration Measured	
	ng/mL	nM	ng/mL	nM
GH (40 nM) + IGF-I	270	35.3	274	35.6
Insulin (20 nM) + IGF-I	270	35.3	273	35.7
Proinsulin (40 nM) + IGF-I	270	35.3	266	34.8
IGF-II (670 nM) + IGF-I	294	35.3	278	36.1

Precision

Intra-assay

Serum	S1	S2	S3
Number of determinations	25	25	25
Mean value (ng/mL)	39.64	360.8	1,354
C.V., (%)	5.64	1.31	4.94

EDTA plasma	P1	P2	P3
Number of determinations	25	25	25
Mean value (ng/mL)	163.3	573.5	1,468
C.V., (%)	1.35	1.95	5.23

Inter-assay

Serum	S1	S2	S3
Number of determinations	10	10	10
Mean value (ng/mL)	38.02	94.56	930.9
C.V., (%)	8.29	3.66	4.79

EDTA plasma	P1	P2	P3
Number of determinations	10	10	10
Mean value (ng/mL)	59.74	87.91	956.1
C.V., (%)	5.98	5.90	4.66

Accuracy

Dilution test

Samples were diluted in dissociation buffer and assayed according to the assay procedure of the kit.

Serum	Dilution factor	Measured (ng/mL)	Expected (ng/mL)	Ratio (%) Measured/ Expected
S1	-	647.9	-	-
	1:2	337.6	324.0	104.2
	1:4	146.4	162.0	90.39
	1:8	70.64	80.99	87.22
	1:16	32.71	40.50	80.77
S2	-	709.4	-	-
	1:2	374.0	354.7	105.4
	1:4	170.4	177.3	96.06
	1:8	78.08	88.67	88.06
	1:16	39.33	44.33	88.71
S3	-	797.3	-	-
	1:2	437.6	398.7	109.8
	1:4	197.6	199.3	99.15
	1:8	89.35	99.66	89.65
	1:16	47.70	49.83	95.72
S4	-	767.2	-	-
	1:2	412.6	383.6	107.6
	1:4	189.0	191.8	98.55
	1:8	91.93	95.90	95.86
	1:16	40.63	47.95	84.74
S5	-	993.2	-	-
	1:2	502.3	496.6	101.1
	1:4	235.6	248.3	94.87
	1:8	110.3	124.1	88.86
	1:16	53.72	62.07	86.54
S6	-	983.7	-	-
	1:2	515.5	491.9	104.8
	1:4	251.8	245.9	102.4
	1:8	116.3	123.0	94.59
	1:16	55.70	61.48	90.59

EDTA plasma	Dilution factor	Measured	Expected	Ratio (%) Measured/ Expected
		(ng/mL)		
P1	-	718.1	-	-
	1:2	394.6	359.0	109.9
	1:4	192.6	179.5	107.3
	1:8	87.85	89.76	97.87
	1:16	40.14	44.88	89.44
P2	-	759.1	-	-
	1:2	406.1	379.5	107.0
	1:4	204.3	189.8	107.7
	1:8	94.03	94.89	99.10
	1:16	44.98	47.44	94.81
P3	-	877.0	-	-
	1:2	446.0	438.5	101.7
	1:4	216.5	219.3	98.72
	1:8	106.4	109.6	97.02
	1:16	49.44	54.81	90.20
P4	-	958.1	-	-
	1:2	442.5	479.1	92.37
	1:4	236.7	239.5	98.80
	1:8	111.6	119.8	93.19
	1:16	52.69	59.88	87.99
P5	-	921.6	-	-
	1:2	475.6	460.8	103.2
	1:4	229.5	230.4	99.61
	1:8	111.7	115.2	97.00
	1:16	54.46	57.60	94.55
P6	-	1,170	-	-
	1:2	577.6	585.0	98.73
	1:4	291.2	292.5	99.55
	1:8	136.5	146.2	93.34
	1:16	63.54	73.12	86.90

Recovery test

Samples were spiked with known quantities of IGF-I 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	158.8	111.8	254.5	259.2	102.0
	165.8	268.1	404.6	408.8	101.0
	162.6	525.9	607.7	639.3	105.2
S2	148.8	103.7	252.5	231.2	91.58
	155.0	235.2	390.2	350.0	89.70
	152.4	462.4	614.7	531.2	86.41
S3	191.5	127.8	319.3	351.3	110.0
	200.9	333.5	534.4	560.0	104.8
	197.0	588.8	785.8	809.6	103.0

EDTA plasma	Endogen. conc.	Added conc.	Expected conc.	Measured conc.	Ratio (%) Measured/ Expected
	(ng/mL)				
P1	78.88	44.68	123.6	120.5	97.50
	75.21	127.8	203.0	171.5	84.47
	79.66	202.1	281.7	291.9	103.6
P2	117.9	49.03	166.9	149.6	89.62
	112.2	135.7	247.9	207.1	83.56
	119.2	218.6	337.8	339.5	100.5
P3	80.09	61.95	142.0	136.1	95.83
	75.35	166.5	241.9	212.9	88.00
	81.17	284.5	365.7	411.8	112.6

^{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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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

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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 ^{125}I
Ab ^{125}I

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

BUF

Buffer / Tampon / Puffer / Tampone / Tampón / Tampão / Buffert / Ρυθμιστικό Διάλυμα / 缓冲液 / Buferinis tirpalas/ Puffer / Bufor / Pufr / Tlmivý roztok / 완충액 / Tampon / Буфер / Буфер / 緩衝劑

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