BECKMAN COULTER

CE 2797

LH IRMA KIT

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

REVISION HISTORY

Previous version: IFU-IM1381-3302-01	**Current version:** IFU-IM1381-3302-02
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 IM1381, IM3302

FOR PROFESSIONAL USE ONLY

INTENDED PURPOSE

LH IRMA KIT is an in vitro diagnostic manual medical device intended to be used by healthcare professionals for the quantitative measurement of luteinizing hormone (LH) in human serum and plasma. Measurement of LH is intended to be used for the assessment of fertility status and sexual development. It is used in differential diagnosis of primary and secondary hypogonadism in both males and females. In females, it is used also in differential diagnosis of amenorrhea, PCOS and other causes of infertility. It is also used as an aid in diagnosis of precocious and delayed puberty in children [1, 2, 3, 4, 5, 6, 7].

PRINCIPLE

The immunoradiometric assay of LH is a sandwich-type assay. Mouse monoclonal antibodies directed against two different epitopes of LH 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 LH concentrations in the samples are obtained by interpolation from the standard curve. The concentration of LH 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.

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 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 (< -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.

Serum and EDTA plasma values for 16 samples (serum values ranging from 2.26 to 40.70 IU/L) were compared using the IM1381 LH IRMA KIT. Results are as follows:

[EDTA-plasma] = 1.0846 [serum] - 0.107

R = 0.9993

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.

Kit for determination of LH: 100 tubes (REF. IM1381)

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

^{125}I-Tracer: one 5.5 mL vial (ready-to-use)

The vial contains 370 kBq, at the date of manufacture, of ^{125}I-labeled immunoglobulins in buffer with bovine serum albumin, sodium azide (<0.1%), and a dye.

Calibrators: six vials (lyophilized)

The calibrator vials contain from 0 to approximately 180 IU/L of LH in horse serum with sodium azide (<0.1%). The exact concentration is indicated on each vial label. The calibrators are traceable to the international standard, WHO 2nd IS 80/552.

Control sample: one vial (lyophilized)

The vial contains human LH 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 2nd IS 80/552.

Wash solution U (20X): one 50 mL vial

Concentrated solution has to be diluted before use. It may be ordered separately, too (REF. A54825).

Kit for determination of LH: 400 tubes (REF. IM3302)

Tubes: 8 x 50 (ready-to-use)

^{125}I-Tracer: four 5.5 mL vials (ready-to-use)

Calibrators: six vials (lyophilized)

Control sample: one vial (lyophilized)

Wash solution U (20X): two 50 mL vials

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.
- 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 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 calibrators aliquoted at < -18°C until the expiry date of the kit. Store the reconstituted control samples 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.

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 90 minutes at 18-25°C with shaking (≥350 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 50 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: 117,064 cpm				
Calibrators	**LH (IU/L)**	**cpm (n=3)**	**B/T (%)**	**$cpm_{cal} - cpm_{cal0}$**
0	0	101	-	-
1	0.47	282	0.15	181
2	2.40	1,170	0.91	1,069
3	14.7	6,310	5.30	6,209
4	60.0	22,674	19.3	22,573
5	170	49,663	42.3	49,562

(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.

Group	N	Min.	Max.	Median	2.5th percentile	97.5th percentile
		IU/L				
Men	98	0.81	9.05	3.32	1.04	8.02
Women						
Follicular phase	351	0.77	80.3	6.65	2.81	20.4
Preovulatory peak	70	11.9	112	40.7	13.9	96.2
Luteal phase	309	0.39	38.5	7.17	1.04	24.9
Postmenopausal	48	9.03	70.6	29.5	10.5	58.8

· ***(For more details, see APPENDIX)***

Children	LH (IU/L)			
	Girls		Boys	
	Min.	Max.	Min.	Max.
Pre-pubertal		<0.19		<0.6
Stage of puberty PII		<0.6		<2.4
PIII, PIV, PV	0.32	2.7	0.24	5.9

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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: 0.16 IU/L

Functional sensitivity: 0.48 IU/L

Specificity

The antibody used in the immunoassay is highly specific for LH. Extremely low cross reactivities were obtained against several related molecules (hTSH, hFSH, hCG).

Precision

Intra-assay

Serum samples were assayed 25 times in the same series. The coefficients of variation were found below or equal to 7.33%.

Inter-assay

Serum samples were assayed in duplicate in 10 different series. The coefficients of variation were found below or equal to 8.42%.

Accuracy

Dilution test

High-concentration serum samples were serially diluted with the zero calibrator. The recovery percentages obtained were between 80.7% and 102%.

Recovery test

Low-concentration serum samples were spiked with known quantities of LH. The recovery percentages obtained were between 103% and 119%.

Measurement range (from analytical sensitivity to the highest calibrator): 0.16 to approximately 180 IU/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 [8, 9, 10].

In the case of patients treated with high concentrations of biotin (5 - 10 mg/day), blood samples must be taken at least 8 hours after the last administration of biotin [11].

APPENDIX

PERFORMANCE CHARACTERISTICS

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

Interference

Serum samples containing LH concentrations (low and high) were spiked with multiple concentrations of the substances listed below and assayed using LH IRMA KIT. Values were calculated as described in CLSI EP07, 3rd ed. [12]. 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	64.79 ng/mL
Conjugated bilirubin	553.3 µg/mL
Hemoglobin	7,201 µg/mL
Triglycerides	23.50 mg/mL
Unconjugated bilirubin	341.4 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.

Specificity

The specifity of the assay is determined by measuring the “apparent LH” response given by high concentrations of related hormones.

Hormone	Concentration (IU/L)	Apparent LH (IU/L)	
		Measured	Expected
hTSH	0.045	0.37	0
hTSH + hLH	0.045 + 20	21.67	20
hFSH	162	1.05	0
hFSH+hLH	162 + 20	22.02	20
hCG	29,750	< 0.5	0
hCG + hLH	29,750 + 24	26.8	24

Precision

Intra-assay

Sample	Serum			EDTA plasma		
	S1	S2	S3	P1	P2	P3
N	25	25	25	25	25	25
Mean value, IU/L	1.13	11.62	71.57	1.41	10.26	64.71
C.V., %	7.33	2.49	2.58	4.36	3.15	1.48

Inter-assay

Sample	Serum			EDTA plasma		
	S1	S2	S3	P1	P2	P3
N	10	10	10	10	10	10
Mean value, IU/L	0.67	19.30	144.3	0.75	18.94	147.1
C.V., %	7.11	5.81	8.42	7.92	6.07	8.47

Accuracy

Dilution test

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

Serum	Dilution factor	LH (IU/L)		Ratio (%) Measured/ Expected
		Measured	Expected	
S1	-	18.77	-	-
	1:2	8.74	9.39	93.13
	1:4	4.39	4.69	93.55
	1:8	2.22	2.35	94.62
	1:16	1.20	1.17	102.3
	1:32	0.48	0.59	81.83
S2	-	49.50	-	-
	1:2	23.34	24.75	94.30
	1:4	11.75	12.38	94.95
	1:8	5.34	6.19	86.30
	1:16	2.76	3.09	89.21
	1:32	1.27	1.55	82.10
S3	-	67.19	-	-
	1:2	31.76	33.60	94.54
	1:4	15.85	16.80	94.36
	1:8	8.16	8.40	97.16
	1:16	4.21	4.20	100.3
	1:32	1.83	2.10	87.16
S4	-	136.7	-	-
	1:2	62.34	68.37	91.18
	1:4	29.24	34.19	85.53
	1:8	14.60	17.09	85.42
	1:16	7.24	8.55	84.72
	1:32	3.45	4.27	80.74
S5	-	102.3	-	-
	1:2	45.92	51.17	89.75
	1:4	22.11	25.58	86.43
	1:8	11.43	12.79	89.36
	1:16	5.75	6.40	89.91
	1:32	2.71	3.20	84.75

EDTA plasma	Dilution factor	LH (IU/L)		Ratio (%) Measured/ Expected
		Measured	Expected	
P1	-	19.89	-	-
	1:2	9.75	9.95	98.04
	1:4	5.03	4.97	101.2
	1:8	2.47	2.49	99.35
	1:16	1.16	1.24	93.31
	1:32	0.54	0.62	86.88
P2	-	53.58	-	-
	1:2	25.35	26.79	94.62
	1:4	12.90	13.40	96.30
	1:8	6.35	6.70	94.81
	1:16	3.24	3.35	96.75
	1:32	1.42	1.67	84.81
P3	-	64.34	-	-
	1:2	30.94	32.17	96.18
	1:4	15.79	16.09	98.17
	1:8	8.04	8.04	100.0
	1:16	3.89	4.02	96.74
	1:32	1.69	2.01	84.05
P4	-	147.8	-	-
	1:2	69.46	73.88	94.02
	1:4	33.23	36.94	89.96
	1:8	16.03	18.47	86.79
	1:16	8.05	9.24	87.17
	1:32	4.08	4.62	88.36
P5	-	121.9	-	-
	1:2	58.35	60.96	95.73
	1:4	28.26	30.48	92.72
	1:8	14.76	15.24	96.86
	1:16	7.50	7.62	98.43
	1:32	3.65	3.81	95.81

Recovery test

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

Serum	LH (IU/L)				Ratio (%) Measured/ Expected
	Endogen. conc.	Added conc.	Expected conc.	Measured conc.	
S1	2.84	1.04	3.89	4.34	111.7
	2.81	3.16	5.97	6.25	104.7
	2.76	6.21	8.97	9.49	105.8
S2	4.81	1.66	6.48	7.13	110.1
	4.72	4.90	9.62	10.09	104.9
	4.60	9.53	14.13	15.70	111.1
S3	18.39	6.54	24.92	25.89	103.9
	18.84	20.13	38.97	44.54	114.3
	18.59	39.72	58.31	66.33	113.7
S4	1.17	0.33	1.50	1.58	105.3
	1.12	0.99	2.10	2.16	102.7
	1.15	2.23	3.38	4.01	118.5
S5	7.94	2.76	10.70	11.20	104.7
	7.70	8.02	15.72	16.58	105.5
	7.39	14.74	22.13	22.94	103.6

EDTA plasma	LH (IU/L)				Ratio (%) Measured/ Expected
	Endogen. conc.	Added conc.	Expected conc.	Measured conc.	
P1	0.73	0.35	1.08	1.19	110.4
	0.73	0.84	1.56	1.57	100.5
	0.72	1.73	2.46	2.09	85.12
P2	1.52	0.56	2.07	2.37	114.3
	1.50	1.73	3.24	3.54	109.3
	1.49	3.36	4.85	5.37	110.6
P3	2.74	0.97	3.72	4.37	117.5
	2.71	2.96	5.67	6.55	115.5
	2.67	5.82	8.49	9.42	111.0
P4	5.57	2.01	7.57	8.20	108.3
	5.44	5.95	11.39	12.09	106.2
	5.26	11.45	16.71	18.46	110.5
P5	17.94	6.47	24.41	24.90	102.0
	18.39	19.54	37.93	41.19	108.6
	18.14	39.15	57.29	63.18	110.3

Expected values

Values of LH in fertile females, detailed discrimination by menstrual cycle sub-phases.

Group	N	Min.	Max.	Median	2.5th percentile	97.5th percentile
		IU/L				
Follicular phase						
Early	107	0.77	16.9	5.89	2.06	12.1
Middle	141	1.27	17.9	6.22	3.07	15.0
Late	103	1.76	80.3	9.25	4.15	29.8
Preovulatory peak	70	11.9	112	40.7	13.9	96.2
Luteal phase						
Early	109	1.70	38.5	10.1	3.98	29.3
Middle	163	0.39	18.3	6.13	0.71	13.9
Late	37	0.86	14.5	5.27	0.89	12.0

^{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 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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