BECKMAN COULTER

CE 2797

Ferritin IRMA KIT

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

REVISION HISTORY

Previous version: PI-IM3492-03	**Current version:** IFU-IM3492-01
—	IVDR requirements incorporated
Chapter INTENDED USE removed	Chapter INTENDED PURPOSE added
—	Chapter APPENDIX: Interference data added
—	CLSI guidelines incorporated

REF IM3492

FOR PROFESSIONAL USE ONLY

INTENDED PURPOSE

Ferritin IRMA KIT is an in vitro diagnostic manual medical device intended to be used by healthcare professionals for the quantitative measurement of ferritin in human serum and EDTA plasma. Measurement of ferritin is intended to be used for the aid in diagnosis of anemia and hemochromatosis (iron overload) in general population [1, 2, 3].

PRINCIPLE

The immunoradiometric assay of ferritin is a sandwich-type assay. Mouse monoclonal antibodies directed against two different epitopes of ferritin and hence not competing are used. The 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 ferritin concentrations in the samples are obtained by interpolation from the standard curve. The concentration of ferritin 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.

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

Tracer / Calibrators / Controls	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), for up to 1 year, 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 zero calibrator.

Serum and EDTA plasma values for 15 samples (serum values ranging from 7.77 to 206.04 ng/mL) were compared using the IM3492 Ferritin IRMA KIT. Results are as follows:

[EDTA-plasma] = 0.9236[serum] + 4.1765

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 dilution 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 325 kBq, at the date of manufacture, of ^{125}I-labeled immunoglobulins in buffer with ProClin 300, bovine serum albumin and a dye.

Calibrators: five 0.5 mL vials and one 5 mL vial of «zero» calibrator (ready-to-use)

The calibrator vials contain from 0 to approximately 1,200 ng/mL of ferritin in buffer with ProClin 300 with bovine serum albumin.The exact concentration is indicated on each vial label. The calibrators are traceable to the international standard 3rd IS NIBSC (recombinant ferritin) 94/572.

Control samples: two 1 mL vials (ready-to-use)

The vials contain ferritin in human serum with ProClin 300. The concentration range is indicated on a supplement. The control samples are traceable to the international standard 3rd IS NIBSC (recombinant ferritin) 94/572.

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 (20 µL).
- Semi-automatic pipette (500 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.

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: 20 µL of calibrator, control or sample and 500 µL of tracer. Vortex gently 1-2 seconds.	Incubate 1 hour at 18-25°C with shaking (≥ 280 rpm).	Aspirate carefully the contents of tubes (except the 2 tubes «total cpm»). Wash with 2 mL of wash solution and aspirate twice. 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 *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: 107,924 cpm				
Calibrators	**Ferritin (ng/mL)**	**cpm (n=3)**	**B/T (%)**	**$cpm_{cal} - cpm_{cal0}$**
0	0	59	-	-
1	4.50	529	0.44	470
2	17.0	2,040	1.84	1,981
3	85.0	9,392	8.65	9,333
4	455	44,022	40.7	43,963
5	1100	70,607	65.4	70,548

(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.

EXPECTED VALUES

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

	N	Conc. range at 95% confidence level	Median
Men	343	38 to 457 ng/mL	128 ng/mL
Pre-menopausal women	211	7.4 to 73 ng/mL	23.1 ng/mL
Menopausal women	139	14 to 165 ng/mL	62.1 ng/mL

Children

The following values obtained with 426 healthy children are indicative only.

	N	Conc. range at 95% confidence level	Median
Children 0-6 months	45	1.0 – 434 ng/mL	91 ng/mL
Children 0.5-15 years	340	2.0 – 135 ng/mL	17.5 ng/mL
Boys 15-18 years	28	16 – 90 ng/mL	36 ng/mL
Girls 15-18 years	13	5.0 – 127 ng/mL	15 ng/mL

Ferritin concentrations are age-dependent. They are also influenced by the lack of iron caused by menstrual bleeding in women.

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

Limit of Detection (LoD): 1.64 ng/mL

The LoD of the assay is 1.64 ng/mL, determined consistent with guidelines in CLSI document EP17-A2 [4] based on the proportions of false positives (α) less than 5% and false negatives (β) less than 5%; using determinations, with 120 blank and 120 low level samples; and Limit of Blank (LoB) of 0.63 ng/mL.

Specificity

Cross-reaction of ferritin from various tissues:

spleen ferritin	100%
liver ferritin	35%
heart ferritin	2.2%
placental ferritin	227%

Precision

Repeatability and within-laboratory precision

The precision of the assay was determined consistent with guidelines in CLSI document EP05-A3 [5]. For repeatability the coefficients of variation were found below or equal to 5.03% for serum samples. For within laboratory precision the coefficients of variation were found below or equal to 8.54% for serum samples.

Accuracy

Linearity

The assay demonstrated to be linear from 2.43 to 1,189 ng/mL using serum samples (determined consistent with guidelines in CLSI document EP06-A [6]).

Dilution test

High-concentration serum samples were serially diluted with zero calibrator. The recovery percentages obtained were between 89.6% and 120%.

Recovery test

Low-concentration serum samples were spiked with known quantities of ferritin. The recovery percentages obtained were between 89.3% and 115%.

Measurement range (from LoD to the highest calibrator): 1.64 to approximately 1,200 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.

For assays employing antibodies, 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. Such interfering antibodies may cause erroneous results. Carefully evaluate the results of patients suspected of having these antibodies [7,8].

It is recommended to complete pipetting in 20 minutes.

“Hook effect“: no hook effect was observed until 25,000 ng/mL.

APPENDIX

PERFORMANCE CHARACTERISTICS

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

Interference

Serum samples containing ferritin concentrations (low and high) were spiked with multiple concentrations of the substances listed below and assayed using Ferritin IRMA KIT. Values were calculated as described in CLSI EP07, 3rd ed. [9]. Interference was determined by testing controls (no interfering substance added) and matched test samples (with interfering substance added). No interference (defined as a shift in dose > 15 %) was found for addition of interferent up to concentration stated in the table below.

Interferent	Test concentration
Acetylsalicylic acid	46.90 µg/mL
Ascorbic acid	59.58 µg/mL
Biotin	1,197 ng/mL
Conjugated bilirubin	423.1 µg/mL
Hemoglobin	10,334 µg/mL
Heparin	7,520 ng/mL
Cholesterol	5.51 mg/mL
Ibuprofen	274.6 µg/mL
Prednisone	142.7 ng/mL
Prednisolone	1,320 ng/mL
Rheumatoid factor	39.98 IU/mL
Triglycerides	21.55 mg/mL
Unconjugated bilirubin	399.6 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

Cross-reaction of ferritin from various tissues:

spleen ferritin	100%
liver ferritin	35%
heart ferritin	2.2%
placental ferritin	227%

Precision

Repeatability and within-laboratory precision

Samples were assayed for 20 days, 2 runs per day, in triplicates per run. Assays were performed by two lab technicians, by two reagent lots. There were 120 individual measurements per sample with no invalid results.

Serum	Mean (ng/mL)	Repeatability		Within-laboratory precision	
		SD (ng/mL)	C.V. (%)	SD (ng/mL)	C.V. (%)
S1	858.0	37.57	4.38	50.52	5.89
S2	366.6	13.52	3.69	24.55	6.70
S3	154.6	4.35	2.81	9.37	6.06
S4	63.08	2.80	4.44	4.86	7.70
S5	30.21	1.09	3.62	1.94	6.41
S6	11.14	0.56	5.03	0.95	8.54

EDTA plasma	Mean (ng/mL)	Repeatability		Within-laboratory precision	
		SD (ng/mL)	C.V. (%)	SD (ng/mL)	C.V. (%)
P1	640.5	29.21	4.56	66.21	10.34
P2	311.8	12.82	4.11	21.67	6.95
P3	52.70	2.17	4.11	3.44	6.52
P4	38.48	1.66	4.30	2.95	7.67
P5	14.79	0.76	5.15	1.60	10.81
P6	9.64	0.63	6.56	1.08	11.22

Accuracy

Linearity

The assay demonstrated to be linear from 3.29 to 1,204 ng/mL using EDTA plasma samples (determined consistent with guidelines in CLSI document EP06-A [6]).

Dilution test

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

Serum	Dilution factor	Measured (ng/mL)	Expected (ng/mL)	Ratio (%) Measured/ Expected
S1	-	724.7	-	-
	1:2	333.4	362.4	92.01
	1:4	166.9	181.2	92.09
	1:8	81.20	90.59	89.64
	1:16	43.05	45.29	95.05
	1:32	21.55	22.65	95.16
S2	-	1,080	-	-
	1:2	549.0	540.1	101.6
	1:4	267.1	270.1	98.91
	1:8	140.0	135.0	103.7
	1:16	72.70	67.51	107.7
	1:32	37.15	33.76	110.1
S3	-	1,287	-	-
	1:2	709.8	643.4	110.3
	1:4	352.3	321.7	109.5
	1:8	167.6	160.8	104.2
	1:16	76.40	80.42	95.00
	1:32	45.55	40.21	113.3
S4	1:2	973.8	-	-
	1:4	465.8	486.9	95.67
	1:8	244.6	243.4	100.5
	1:16	132.8	121.7	109.1
	1:32	72.90	60.86	119.8
S5	1:4	825.3	-	-
	1:8	403.2	412.6	97.72
	1:16	201.5	206.3	97.67
	1:32	105.2	103.2	101.9

EDTA plasma	Dilution factor	Measured (ng/mL)	Expected (ng/mL)	Ratio (%) Measured/ Expected
P1	-	207.0	-	-
	1:2	105.3	103.5	101.7
	1:4	55.99	51.75	108.2
	1:8	29.63	25.87	114.5
	1:16	15.30	12.94	118.3
	1:32	7.18	6.47	111.0
P2	-	268.3	-	-
	1:2	142.1	134.2	105.9
	1:4	74.57	67.08	111.2
	1:8	39.07	33.54	116.5
	1:16	17.85	16.77	106.4
	1:32	8.87	8.38	105.8
P3	-	305.8	-	-
	1:2	155.3	152.9	101.6
	1:4	78.20	76.44	102.3
	1:8	43.79	38.22	114.6
	1:16	22.29	19.11	116.6
	1:32	10.49	9.56	109.8
P4	-	381.3	-	-
	1:2	188.2	190.6	98.73
	1:4	100.2	94.11	106.4
	1:8	52.66	47.06	111.9
	1:16	26.15	23.53	111.1
	1:32	13.81	11.76	117.4
P5	-	515.5	-	-
	1:2	258.7	257.7	100.4
	1:4	134.9	128.9	104.7
	1:8	68.84	64.44	106.8
	1:16	32.07	32.22	99.54
	1:32	16.68	16.11	103.5

Recovery test

Samples were spiked with known quantities of ferritin 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	42.76	25.61	68.37	69.31	101.4
	41.74	50.00	91.74	87.68	95.57
	39.85	95.45	135.3	120.9	89.34
S2	17.53	8.92	26.45	26.67	100.8
	17.28	15.39	32.66	36.62	112.1
	17.19	40.38	57.58	60.55	105.2
S3	7.38	2.68	10.06	10.92	108.6
	7.10	6.02	13.12	14.30	109.0
	7.27	19.59	26.87	28.45	105.9
S4	8.23	5.21	13.43	14.86	110.6
	8.47	13.25	21.72	24.04	110.7
	8.07	33.70	41.78	47.98	114.8
S5	40.05	17.50	57.55	60.39	104.9
	38.56	33.70	72.27	76.63	106.0
	37.86	95.45	133.3	129.1	96.83

EDTA plasma	Endogen. conc.	Added conc.	Expected conc.	Measured conc.	Ratio (%) Measured/ Expected
	(ng/mL)				
P1	15.73	12.56	28.29	26.27	92.87
	15.35	24.52	39.88	36.27	90.96
	15.00	35.93	50.93	41.79	82.06
P2	20.69	12.56	33.25	32.16	96.71
	20.20	24.52	44.72	41.60	93.02
	19.73	35.93	55.66	49.09	88.20
P3	20.00	24.52	44.52	45.41	102.0
	19.09	46.82	65.91	69.96	106.1
	19.09	107.3	126.4	125.6	99.41
P4	52.70	24.52	77.23	74.19	96.07
	50.31	46.82	97.13	90.84	93.53
	50.31	107.3	157.6	127.6	80.95
P5	112.4	56.19	168.6	152.6	90.49
	109.8	82.33	192.1	163.1	84.90
	107.3	107.3	214.6	183.0	85.30

^{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

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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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