BECKMAN COULTER

CE 2797

SHBG IRMA KIT

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

REVISION HISTORY

Previous version: IFU-IM3532-01	**Current version:** IFU-IM3532-02
PROCEDURE Add 100 µL of tracer to 2 additional tubes to obtain total cpm.	Add 1 mL of tracer to 2 additional tubes to obtain total cpm.
Radioactivity table in the chapter APPENDIX. —	Better specification of Iodine 125 characteristics table at the end of the chapter Appendix.

REF IM3532

FOR PROFESSIONAL USE ONLY

INTENDED PURPOSE

SHBG IRMA KIT is an in vitro diagnostic manual medical device intended to be used by healthcare professionals for the quantitative measurement of sex hormone-binding globulin (SHBG) in human serum. Measurement of SHBG is intended to be used as an aid in diagnosis and monitoring of androgen excess and insufficiency states in general population and as an aid in monitoring patients on sex-steroid and anti-androgen therapy [1, 2, 3].

PRINCIPLE

The immunoradiometric assay of SHBG is a two-step sandwich-type assay. Mouse monoclonal antibodies directed against two different epitopes of SHBG and hence not competing are used. Samples or calibrators are first incubated in tubes coated with the first monoclonal antibody. After the first incubation, the contents of the tubes are rinsed and the presence of SHBG in the sample is revealed by incubation with a second, ^{125}I-labeled monoclonal antibody. 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 SHBG concentrations in the samples are obtained by interpolation from the standard curve. The concentration of SHBG in the samples is directly proportional to the radioactivity.

It is also possible to follow an alternative one step protocol with diluted samples.

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

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 is the recommended sample type.
- Allow serum samples to clot completely before centrifugation.
- Serum samples may be stored at 2-8°C, if the assay is to be performed within 3 days. For longer storage keep frozen (< -20°C, 8 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 in the diluent.

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 110 mL vial (ready-to-use)

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

Diluent (SHBG-Buffer): one 110 mL vial (ready-to-use)

The phosphate buffer solution contains bovine serum albumin, sodium azide (<0.1%), and a dye.

Calibrators: six 0.5 mL vials (ready-to-use)

The calibrator vials contain from 0 to approximately 300 nM of SHBG in buffer. The exact concentration is indicated on each vial label. The calibrators are traceable to the international standard, WHO 2nd IS 08/266.

Control samples: two vials (lyophilized)

The vials contain SHBG lyophilized in bovine serum and sodium azide (<0.1%). The concentration range is indicated on a supplement. The control samples are traceable to the international standard, WHO 2nd IS 08/266.

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

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

Vials for diluted calibrators: 5 vials with rubber stoppers.

MATERIALS REQUIRED, BUT NOT PROVIDED

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

- Precision micropipette (20 and 200 µL).
- Dispensers (1 mL and 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 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 < -18°C until the expiry date of the kit. Repeated freezing and thawing do not affect the determination, if it is not repeated more than twice.

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 1st incubation
To coated tubes, add successively: 20 µL calibrator, control or sample and 1 mL of diluent. Vortex gently 1-2 seconds.	Incubate 1 hour at 18-25°C with shaking (≥ 280 rpm). Aspirate carefully the content of each tube. Wash with 2 mL of wash solution. Aspirate.

Step 3 2nd incubation*	Step 4 Counting
Add to the tubes: 1 mL of tracer. Vortex gently 1-2 seconds. Incubate 1 hour at 18-25°C with shaking (≥ 280 rpm).	Aspirate carefully the content of tubes (except the 2 tubes «total cpm»). Wash with 2 mL of wash solution. Aspirate. Count bound cpm (B) and total cpm (T) for 1 minute.

*Add 1 mL of tracer to 2 additional tubes to obtain total cpm.

Possible modification – one step assay with diluted samples

Dilution of calibrators, control samples and samples

Dilute ten times calibrators, control samples, and samples with diluent (e. g. add 20 µL of sample in 180 µL of diluent) and mix. The samples with concentration above 300 nM must be diluted more than ten times.

Note: For the preparation of diluted calibrators, glass vials are supplied with the kit. The expiry date of the kit should be noted on the vial labels.

Diluted calibrators can be kept at <–18°C until the expiry date of the kit. Freezing and thawing do not affect the determination, if it is not repeated more than twice.

Modified assay procedure

Step 1 Additions*	Step 2 Incubation	Step 3 Counting
To coated tubes, add successively: 20 µL of pre-diluted calibrator, control or sample and 1 mL of tracer. Vortex gently 1-2 seconds.	Incubate 2 hours 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. Aspirate. Count bound cpm (B) and total cpm (T) for 1 minute.

*Add 1 mL 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: 117,103 cpm				
Calibrators	**SHBG (nM)**	**cpm (n=3)**	**B/T (%)**	**$cpm_{cal} - cpm_{cal0}$**
0	0.00	29	-	-
1	2.85	2,708	2.29	2,679
2	9.50	8,785	7.48	8,756
3	28.0	22,243	19.0	22,214
4	95.0	50,623	43.2	50,954
5	250	62,967	53.7	62,938

(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.

Group	N	SHBG (nM)				
		Min.	**Max.**	**Median**	**2.5th percentile**	**97.5th percentile**
All males	100	6.60	100	27.5	9.30	71.3
All females	375	10.7	109	49.1	17.2	96.4
Children (0 - 13 years)	80	34.8	164	98.3	41.5	150

Under estrogen treatment, increased levels of SHBG are found. The increase is drug and dose dependent.

Values in pregnancy may increase significantly up to values 500 nM [4].

(For more details, see APPENDIX)

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: 0.1 nM (0.41 nM for modified, one step protocol)

Functional sensitivity: 0.41 nM

Specificity

Human serum proteins (human albumin, α1-antitrypsin, orosomucoid, haptoglobin, plasminogen, fibrinogen, transferrin, IgG, IgA) in concentrations greatly exceeding physiological levels were added to samples, assayed and no interference was found.

Precision

Intra-assay

Samples were assayed in 26 replicates in the same series. The coefficients of variation were found below or equal to 6.1% for two step assay and below or equal to 5.6% for one step assay.

Inter-assay

Samples were assayed in duplicate in 10 different series (two step assay) or in 12 series (one step assay). Coefficients of variation were found below or equal to 8.6% for two step assay and to 8.3% for one step assay.

Accuracy

Dilution test

High-concentration samples were serially diluted in diluent. The recovery percentages were obtained between 91.6% and 111% for two step assay and between 88.6% and 111% for one step assay.

Recovery test

Low-concentration samples were spiked with known quantities of SHBG. The recovery percentages were obtained between 94.6% and 118% for two step assay and between 93.2% and 104% for one step assay.

Measurement range (from analytical sensitivity to the highest calibrator): 0.1 to approximately 300 nM.

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 [5, 6, 7].

“Hook effect“: there is no hook effect, when the two-step procedure is used [4].

One step IRMA: **“Hook effect“:** no hook effect was observed until 1,000 nM.

APPENDIX

PERFORMANCE CHARACTERISTICS

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

Interference

Serum samples containing SHBG concentrations (low and high) were spiked with multiple concentrations of the substances listed below and assayed using SHBG IRMA KIT. Values were calculated as described in CLSI EP07, 3rd ed. [8]. 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	1,792 ng/mL
Conjugated bilirubin	431.0 µg/mL
Hemoglobin	10,309 µg/mL
Triglycerides	18.00 mg/mL
Unconjugated bilirubin	573.0 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

Two step assay

Serum	S1	S2	S3
Number of determinations	26	26	26
Mean value, nM	25.1	37.1	63.6
C.V., %	6.10	2.16	5.74

One step assay

Serum	S1	S2	S3
Number of determinations	26	26	26
Mean value, nM	48.3	81.8	143
C.V., %	5.14	5.61	4.76

Inter-assay

Two step assay

Serum	S1	S2	S3	S4	S5	S6	S7
Number of determinations	10	10	10	10	10	10	10
Mean value, nM	13.5	92.7	61.3	22.9	93.4	41.7	119
C.V., %	5.46	5.39	8.31	7.85	8.55	8.24	5.37

One step assay

Serum	S1	S2	S3	S4	S5	S6	S7
Number of determinations	12	12	12	12	12	12	12
Mean value, nM	13.5	96.1	60.3	22.8	94.3	41.8	122
C.V., %	6.05	5.15	7.06	8.27	5.44	6.99	4.25

Accuracy

Dilution test

Samples were diluted in diluent and assayed according to both assay procedures of the kit.

Two step assay

Serum	Dilution factor	Measured (nM)	Expected (nM)	Ratio (%) Measured/ Expected
S1	-	154	-	-
	1:2	76.0	77.0	98.7
	1:4	37.9	38.5	98.4
	1:8	18.9	19.3	97.9
	1:16	9.44	9.63	98.0
	1:32	4.80	4.81	99.8
S2	-	123	-	-
	1:2	59.3	64.3	96.8
	1:4	32.0	30.6	105
	1:8	17.0	13.3	111
	1:16	8.00	7.65	105
	1:32	3.74	3.83	97.7
S3	-	144	-	-
	1:2	66.1	72.0	91.8
	1:4	37.9	36.0	105
	1:8	19.4	18.0	108
	1:16	8.36	9.00	92.9
	1:32	4.13	4.50	91.8
	1:64	2.07	2.25	91.6
S4	-	309	-	-
	1:2	153	155	99.0
	1:4	73.0	77.3	94.4
	1:8	39.4	38.7	102
	1:16	20.1	19.4	104
	1:32	9.92	9.68	102
	1:64	5.15	4.84	106

One step assay

Serum	Dilution factor	Measured (nM)	Expected (nM)	Ratio (%) Measured/ Expected
S1	-	157	-	-
	1:2	76.7	78.5	97.7
	1:4	36.3	39.2	92.6
	1:8	18.1	19.6	92.3
	1:16	8.86	9.81	88.6
	1:32	4.61	4.90	93.9
S2	-	124	-	-
	1:2	56.6	61.9	91.4
	1:4	28.8	31.0	93.1
	1:8	14.7	15.5	94.8
	1:16	7.57	7.75	97.7
	1:32	4.22	3.79	111
S3	-	319	-	-
	1:2	159	160	100
	1:4	78.6	79.7	98.6
	1:8	38.5	39.8	96.7
	1:16	19.4	19.9	97.5
	1:32	10.0	9.96	100
	1:64	4.98	4.98	100

Recovery test

Samples were spiked with known quantities of SHBG and assayed according to both assay procedures of the kit.

Two step assay

Serum	Endogen. conc.	Added conc.	Expected conc.	Measured conc.	Ratio (%) Measured/ Expected
	(nM)				
S1	6.96	5.0	12.0	12.4	103
		15.0	22.0	23.4	107
		50.0	57.0	62.0	109
		150	157	185	118
S2	20.0	5.0	25.0	23.6	94.6
		15.0	35.0	34.6	99.0
		50.0	70.0	70.6	101
		150	170	184	108
S3	36.0	5.0	41.0	43.6	107
		15.0	51.0	50.1	98.4
		50.0	86.0	93.5	109
		150	186	209	112

One step assay

Serum	Endogen. conc.	Added conc.	Expected conc.	Measured conc.	Ratio (%) Measured/ Expected
	(nM)				
S1	6.75	5.0	11.7	11.3	96.6
		15.0	21.7	21.4	98.6
		50.0	56.7	57.4	101
		150	157	164	104
S2	18.9	5.0	23.9	24.4	102
		15.0	33.9	32.9	97.1
		50.0	68.9	69.7	101
		150	169	169	100
S3	65.7	5.0	70.7	65.9	93.2
		15.0	80.7	76.1	94.2
		50.0	116	113	97.7
		150	216	209	96.9

Expected values

Group	N	Min.	Max.	Median	2.5th percentile	97.5th percentile
		(nM)				
Men						
All ages (20 - 68 years)	**100**	**6.60**	**100**	**27.5**	**9.30**	**71.3**
20 - 30 years	25	7.56	38.6	22.9	7.88	38.2
31 - 40 years	25	6.60	70.1	31.5	9.35	61.3
41 - 50 years	25	10.6	57.3	29.6	13.8	54.5
Over 51 years	25	11.2	100	33.1	14.4	95.0
Women						
All ages	**375**	**10.7**	**109**	**49.1**	**17.2**	**96.4**
All results reproductive age	326	10.7	105	49.0	16.6	95.5
Follicular phase	158	13.1	104	45.4	14.6	89.7
Preovulatory peak	35	10.7	99.0	53.2	27.6	92.3
Luteal phase	133	17.4	105	55.7	18.4	98.3
Postmenopausal	49	18.7	109	49.8	20.2	95.4
Children						
All ages (0 - 13 years)	**80**	**34.8**	**164**	**98.3**	**41.5**	**150**
Boys (0 - 11 months)	15	78.8	164	124	81.7	158
Girls (0 - 11 months)	20	34.8	150	86.5	44.1	150
Boys (1 - 13 years)	25	35.0	154	87.3	39.0	139
Girls (1 - 13 years)	20	45.4	132	87.7	45.5	131

^{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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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

VIAL CAL

Vial for calibrators / Flacon pour les calibrateurs / Fläschchen für Kalibratoren / Fiala per calibratori / Vial para calibradores / Frasco para calibradores / Flaska för kalibratorer / Φιαλίδιο για βαθμονομητές / 定标品瓶 / Buteliukas kalibratoriams / Kalibrátornak való üveg / Fiolka na kalibratory / Lahvička na kalibrátory / Fľaštička na kalibrátory / 교정물질용 바이알 / Kalibratör flakonu / Флакон для калибраторов / Фалкони за калибратори / 校準品小瓶

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