BECKMAN COULTER

CE 2797

Estrone RIA

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

REVISION HISTORY

Previous version: IFU-DSL8700-01	Current version: IFU-DSL8700-02
—	Adding Dutch to the IFU.
Radioactivity table in the chapter APPENDIX.	Better specification of Iodine 125 characteristics table at the end of the chapter Appendix.

REF DSL8700

FOR PROFESSIONAL USE ONLY

INTENDED PURPOSE

Estrone RIA is an in vitro diagnostic manual medical device intended to be used by healthcare professionals for the quantitative measurement of estrone in human serum and plasma. Measurement of estrone is intended to be used for the assessment of fertility status and sexual development. It is used in monitoring hormone replacement therapy in postmenopausal women. It can be also useful as an aid in diagnosis of precocious and delayed puberty in girls and as an aid in diagnosis of disorders of sex steroid metabolism (e.g. aromatase deficiency and 17α-hydroxylase deficiency) in general population [1, 2].

PRINCIPLE

The radioimmunoassay of estrone [3-hydroxy-1,3,5 (10)-estratrien-17-one] is a competition assay. Samples and calibrators are incubated with ^{125}I-labeled estrone, as a tracer, in monoclonal antibody-coated tubes. After incubation, the contents of the tubes are aspirated so as to remove unbound ^{125}I-labeled tracer. The bound radioactivity is then determined in a gamma counter. The estrone concentrations in the samples are obtained by interpolation from the standard curve. The concentration of estrone in the samples is indirectly 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

Not classified as hazardous

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 or 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, 1 year maximum. It is recommended to prepare aliquots 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 30 samples (serum samples ranging from 13.8 to 264.9 pg/mL) were compared using the DSL8700 Estrone RIA. Results are as follows:

[EDTA plasma] = 0.9025 [serum] + 5.366; r = 0.9711

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 opening are indicated in paragraph Procedure.

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

^{125}I-Tracer: one 11 mL vial (ready-to-use)

At the time of manufacture, the vial contains 185 kBq of ^{125}I-labeled estrone in buffer with proteins (BSA) and sodium azide (<0.1%) and a dye.

Calibrators: five 2 mL vials and one 4 mL vial of «zero» calibrator (ready-to-use)

The calibrator vials contain from 0 to approximately 2,000 pg/mL (0 to approximately 7,400 pmol/L) of estrone in human serum (estrone free) and sodium azide (<0.1%). The exact concentration is indicated on each vial label. The calibrators are traceable to a certified reference material (Cerilliant).

Control samples: two 2 mL vials (ready-to-use)

The vials contain estrone in human serum with sodium azide (<0.1%). The concentration range is indicated on a supplement. The control samples are traceable to a certified reference material (Cerilliant).

MATERIALS REQUIRED, BUT NOT PROVIDED

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

- Precision micropipette (50 µL, 200 µL).
- Semi-automatic pipette (100 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 and mix them thoroughly by gentle inversion before use.

Calibrators and control samples

Once opened, store at 2-8°C for up to 3 weeks, or at < -20°C until expiration date of kit. Avoid repeated freezing and thawing of reagents.

Assay procedure

Step 1 Additions*	Step 2 Incubation	Step 3 Counting
To coated tubes add successively: 50 µL of calibrator, control or sample and 100 µL 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»).** Count bound cpm (B) and total cpm (T) for 1 minute.

*. Add 100 µL of tracer to 2 additional tubes to obtain «total cpm».

**. Alternatively. If aspiration system is not available, add into each tube 2 mL of distilled water and decant. Repeat addition and decantation once more.

Alternative procedure

The conditions of incubation can be altered in a following way:

Step 1 Additions*	Step 2 Incubation	Step 3 Counting
To coated tubes add successively: 200 µL of calibrator, control or sample and 100 µL of tracer. Vortex gently 1-2 seconds.	Incubate 2 hours at 18-25°C with shaking (≥280 rpm).	Add 2 mL of distilled water into each tube (except the 2 tubes «total cpm»). Decant. Add 2 mL of distilled water and decant once more. Count bound cpm (B) and total cpm (T) for 1 minute.

*. Add 100 µL of tracer to 2 additional tubes to obtain «total cpm».

RESULTS

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

Standard curve

The results in the quality control department were calculated using *spline* curve fit with logit of *B/T or* B/B_0 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: 66,264 cpm				
Calibrators	**Estrone (pg/mL)**	**cpm (n=3)**	**B/T (%)**	**B/B_0 (%)**
0	0	31,263	47.2	100.0
1	18	29,313	44.2	93.8
2	90	21,928	33.1	70.1
3	290	12,660	19.1	40.5
4	800	7,307	11.0	23.4
5	2,100	4,136	6.51	13.8

· *(Example of standard curve, do not use for calculation).*

Samples

For each sample, locate ratio B/T or B/B_0 on the vertical axis and read off the corresponding analyte concentration on the horizontal axis.

To convert concentrations from pg/mL to pmol/L, multiply results by 3.7.

EXPECTED VALUES

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

Sample population	n	Median	Min.	Max.	2.5th percentile	97.5th percentile
		pg/mL				
1st trimester	50	860.0	155.0	3,077	246.7	2,774
2nd trimester	50	1,874	408.3	6,215	569.4	5,781
Postmenopausal with ERT	30	147.8	50.94	487.5	51.34	455.2
Postmenopausal without ERT	32	62.60	30.92	99.82	35.64	96.64
Contraceptives	20	71.60	48.03	342.4	48.12	231.4
Follicular Phase	95	74.23	36.13	156.5	38.92	131.7
Luteal Phase	82	93.45	47.29	198.1	54.10	179.3
Pre-Ovulatory	19	141.8	57.92	255.9	70.26	246.8
Men	30	60.91	34.11	127.1	38.87	101.7

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

In the US, contact the Beckman Coulter technical support at 1-800-854-3633; or by email at: immunoassay@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

Limit of Detection (LoD): 10.0 pg/mL

The LoD of the assay is 10.0 pg/mL, determined consistent with guidelines in CLSI document EP17-A2 [3] based on the proportions of false positives (α) less than 5% and false negatives (β) less than 5%; using determinations, with 128 blank and 120 low level samples; and Limit of Blank (LoB) of 2.1 pg/mL.

Specificity

The antibody used in the immunoassay is highly specific for estrone. Low cross reactivities were obtained with following compounds (Estrone-sulfate, 17β-estradiol, 16α-hydroxyestrone etc.).

Precision

Repeatability and within-laboratory precision

The precision of the assay was determined consistent with guidelines in CLSI document EP05-A3 [4]. For repeatability the coefficients of variation were found below or equal to 11.5% for serum samples. For within laboratory precision the coefficients of variation were found below or equal to 19.1% for serum samples.

Accuracy

Linearity

The assay demonstrated to be linear from 2.38 to 2,611 pg/mL using serum samples (determined consistent with guidelines in CLSI document EP06-A [5]).

Dilution test

High-concentration serum samples were serially diluted with zero calibrator. The recovery percentages ranged from 81.6% to 98.4%.

Recovery test

Low-concentration serum samples were spiked with known quantities of estrone. The recovery percentages ranged from 91.1% to 114.4%.

Measurement range (from LoD to the highest calibrator): 10.0 to approximately 2,000 pg/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 [6, 7, 8].

It is recommended to finish pipetation within 30 minutes.

APPENDIX

PERFORMANCE CHARACTERISTICS

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

Summary and explanation of the test

Estrone [3-hydroxy-1,3,5(10)-estratrien-17-one: E1] is one of the three major naturally-occurring estrogens. Other natural estrogens include estradiol and estriol. Estrone is produced primarily from androstenedione originating from either the adrenal cortex or gonads [9,10]. In premenopausal adult women, more than 50% of estrone is secreted by the ovary. In prepubertal children, men and postmenopausal women, the major portion of estrone is derived from peripheral tissue conversion of androstenedione. Interconversion of estrone and estradiol also occurs in peripheral tissues. During pregnancy, large amounts of estrone are synthesized in the placenta from dehydroepiandrosterone sulfate (DHEA-S) which originates from the maternal circulation and from the fetal adrenal gland. Bioassay data indicates that the estrogenic action of estrone is considerably less than that of estradiol [10].

However, the physiologic role of endogenous estrone is not well defined. Estrone is a primary estrogenic component of several pharmaceutical preparations, including those containing conjugated and esterified estrogens. Circulating levels of estrone are high during fetal life in both sexes, decrease to very low levels within the first few days of life, remain relatively low during childhood, and increase steadily during puberty [11,12,13]. Postnatal circulating levels in girls are higher than for boys.

In premenopausal women, estrone levels generally parallel those of estradiol, rising gradually during the follicular phase, peaking just prior to ovulation, with a secondary and smaller increase during the luteal phase [10,11]. After menopause, estrone levels do not decline as dramatically as estradiol levels, possibly due to increased conversion of androstenedione to estrone [11]. Measurement of estrone may be complicated by assay interference due to the presence of other estrogens and related compounds in the sample.

Interference

Serum samples containing estrone concentrations (low and high) were spiked with multiple concentrations of the substances listed below and assayed using Estrone RIA. Values were calculated as described in CLSI EP07, 3rd ed. [14]. 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	40.68 µg/mL
Ascorbic acid	58.36 µg/mL
Biotin	1,551 ng/mL
Conjugated bilirubin	195.9 µg/mL
Hemoglobin	1,851 µg/mL
Heparin	7,199 ng/mL
Cholesterol	4.30 mg/mL
Ibuprofen	123.4 µg/mL
Prednisone	127.7 ng/mL
Prednisolone	1,277 ng/mL
Rheumatoid factor	34.20 IU/mL
Triglycerides	12.25 mg/mL
Unconjugated bilirubin	470.1 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 percent cross-reactivity is expressed as the ratio of the estrone concentration to the concentration of the reacting compound at 50% binding of the zero calibrator.

Compound	% Cross-reactivity
Estrone	100
Estrone-3-glucuronide	2.17
Epiestriol	1.26
16α-hydroxyestrone	1.19
17β-Estradiol	0.56
Estriol	0.35
Estrone sulfate	0.11
17α-OH progesterone	ND
DHEA-S	ND
Androsterone	ND
Testosterone	ND
Dexamethasone	ND
Progesterone	ND
Androstenedione	ND
DHEA	ND
Corticosterone	ND
Cortisone	ND
Cortisol	ND
Danazol	ND
5α-androstane-3β, 17β-diol	ND
17β-estradiol-3-sulfate	ND
17β-estradiol-3-D-glucuronide	ND
Estriol-16α-D-glucuronide	ND
Estriol-3-sulfate	ND
Digoxin	ND

· *ND = Non-Detectable (< 0.1%)*

Repeatability and within-laboratory precision

Samples were assayed for 20 days, 2 runs per day, 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 (pg/mL)	Repeatability		Within-laboratory precision	
		SD (pg/mL)	C.V. (%)	SD (pg/mL)	C.V. (%)
S1	52.93	6.11	11.54	10.09	19.07
S2	123.1	7.32	5.94	14.16	11.50
S3	311.9	21.30	6.83	30.13	9.66
S4	418.8	23.74	5.67	57.13	13.64
S5	976.0	92.10	9.44	160.3	16.43
S6	1,674	169.5	10.12	307.6	18.37

EDTA plasma	Mean (pg/mL)	Repeatability		Within-laboratory precision	
		SD (pg/mL)	C.V. (%)	SD (pg/mL)	C.V. (%)
P1	62.32	5.91	9.48	12.16	19.51
P2	58.05	5.66	9.76	9.53	16.42
P3	458.1	23.55	5.14	55.99	12.22
P4	362.8	24.88	6.86	38.75	10.68
P5	1,304	121.2	9.30	224.8	17.24
P6	1,257	127.5	10.14	191.0	15.19

Accuracy

Linearity

The assay demonstrated to be linear from 4.73 to 2,179 pg/mL using EDTA-plasma samples (determined consistent with guidelines in CLSI document EP06-A [5]).

Dilution test

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

Serum	Dilution factor	Measured (pg/mL)	Expected (pg/mL)	Ratio (%) Measured/ Expected
S1	-	1,680	-	-
	1:2	685.6	840.0	81.61
	1:4	353.1	420.0	84.08
	1:8	171.6	210.0	81.71
	1:16	95.51	105.0	90.96
S2	-	869.3	-	-
	1:2	402.0	434.7	92.49
	1:4	198.1	217.3	91.16
	1:8	95.43	108.7	87.82
	1:16	48.96	54.33	90.11
S3	-	652.5	-	-
	1:2	303.3	326.2	92.97
	1:4	158.4	163.1	97.10
	1:8	76.76	81.56	94.12
	1:16	40.13	40.78	98.41

EDTA plasma	Dilution factor	Measured (pg/mL)	Expected (pg/mL)	Ratio (%) Measured/ Expected
P1	-	1,648	-	-
	1:2	805.3	823.9	97.74
	1:4	381.3	412.0	92.56
	1:8	206.8	206.0	100.4
	1:16	107.4	103.0	104.3
P2	-	1,779	-	-
	1:2	812.6	889.6	91.34
	1:4	379.4	444.8	85.30
	1:8	204.7	222.4	92.03
	1:16	89.33	111.2	80.33
P3	-	1,721	-	-
	1:2	718.8	860.4	83.54
	1:4	374.3	430.2	87.00
	1:8	189.7	215.1	88.17
	1:16	96.21	107.6	89.45

Recovery test

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

Serum	Endogen. conc. (pg/mL)	Added conc. (pg/mL)	Expected conc. (pg/mL)	Measured conc. (pg/mL)	Ratio (%) Measured/ Expected
S1	48.02	18.24	66.26	67.18	101.4
	46.80	38.09	84.89	81.43	95.92
	44.67	72.73	117.4	124.4	106.0
S2	132.1	18.24	150.3	143.6	95.53
	128.7	38.09	166.8	151.9	91.05
	122.9	72.73	195.6	205.5	105.0
S3	69.85	18.24	88.09	100.7	114.4
	68.08	38.09	106.2	111.9	105.3
	64.98	72.73	137.7	140.2	101.8

EDTA plasma	Endogen. conc. (pg/mL)	Added conc. (pg/mL)	Expected conc. (pg/mL)	Measured conc. (pg/mL)	Ratio (%) Measured/ Expected
P1	33.45	18.24	51.69	54.02	104.5
	32.60	38.09	70.69	67.72	95.80
	31.12	72.71	103.8	101.4	97.65
P2	42.03	18.24	60.27	58.64	97.30
	40.96	38.09	79.05	66.75	84.44
	39.10	72.71	111.8	91.18	81.55
P3	85.85	18.24	104.1	92.15	88.53
	83.67	38.09	121.8	102.6	84.23
	79.86	72.71	152.6	132.9	87.13

^{125}I Characteristics

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

^{125}I	E (MeV)	%
γ	0.035	6.50
K_α X-ray	0.027	112.5
K_β X-ray	0.031	25.4

Symbols Key

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

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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

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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

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