BECKMAN COULTER

CE 2797

RIA Aldosterone

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

REVISION HISTORY

Previous version: IFU-IM1664-01	**Current version:** IFU-IM1664-02
-	The new language Hungarian was added.
Radioactivity table in the chapter APPENDIX.	Better specification of Iodine 125 characteristics table at the end of the chapter Appendix.

REF IM1664

FOR PROFESSIONAL USE ONLY

INTENDED PURPOSE

RIA Aldosterone is an in vitro diagnostic manual medical device intended to be used by healthcare professionals for the quantitative measurement of aldosterone in human serum, plasma or urine. Measurement of aldosterone is intended to be used as an aid in diagnosis and differential diagnosis of primary and secondary hyperaldosteronism and hypoaldosteronism in general population [1, 2].

PRINCIPLE

The radioimmunoassay of aldosterone is a competition assay. Samples and calibrators are incubated with ^{125}I-labeled aldosterone, as a tracer, in polyclonal 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 aldosterone concentrations in the samples are obtained by interpolation from the standard curve. The concentration of aldosterone 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.

Protection against ionizing radiation

The purchase, possession, utilization, and transfer of radioactive material is 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.

Material 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 or urine are the recommended sample types.

Diuretics, antihypertensive drugs, cyclic progestogens, estrogens, and licorice should be terminated for at least two weeks, and preferably four weeks, prior to testing. Sample donors should be on a normal sodium diet for 2-4 weeks (approximately 135 mEq or 3 g of sodium per day).

Serum and plasma

- It is necessary to specify the patient's position during specimen collection. A supine sample should be drawn in the early morning before the subject arises, if feasible. If an upright sample is indicated, the subject should be upright for ≥2 hours prior to sampling.
- 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, 2 years maximum), after aliquoting so as to avoid repeated freezing and thawing. Thawing of sample should be performed at room temperature.
- If samples have concentrations grater than the highest calibrator, they must be diluted with Diluent S (see MATERIALS REQUIRED BUT NOT PROVIDED).

Serum and EDTA plasma values for 58 samples (serum samples ranging from 37.82 to 387.6 pg/mL) were compared using the IM1664 RIA Aldosterone. Results are as follows:

[EDTA-plasma] = 1.1335 [serum] + 17.159,

R = 0.9693

Urine

Sampling of urine

- Collect 24-hour urine in flask.
- Determine volume.
- If necessary, store aliquoted at < -20°C (up to 1 month). Thawing of sample should be performed at room temperature.

  NOTE: Specimens should be stored at 2-8°C during collection period and total volume collected should be recorded.

Urine hydrolysis

The aldosterone is assayed after acid hydrolysis as follows:

1. Mix in glass tube 100 µL of urine with 1 mL of 0.1N HCl.
2. Stopper tubes and incubate for 18-22 h at 30 ± 2°C in the dark.

Dilution of urine

Urine samples with a too high concentration of aldosterone may be diluted by one half in distilled water, before acid hydrolysis treatment.

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 are indicated in paragraph Procedure.

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

^{125}I-Tracer: one 55 mL vial (ready-to-use)

The vial contains 165 kBq, at the date of manufacture, of ^{125}I-labeled aldosterone in buffer containing proteins and a dye.

Calibrators: six vials (lyophilized)

The calibrator vials contain from 0 to approximately 2,000 pg/mL (0 to approximately 5.55 nM) of lyophilized aldosterone in human serum with sodium azide (<0.1%). The exact concentration is indicated on each vial label. The calibrators are traceable to a certified reference material (Cerilliant).

Control sample: one vial (lyophilized)

The vial contains aldosterone lyophilized in human serum with sodium azide (<0.1%). The expected values are in the concentration range indicated on a supplement. The control sample is 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 (10 µL, 50 µL).

- Semi-automatic pipette (500 µL).
- Vortex type mixer.
- Horizontal or orbital shaker.
- Aspiration system.
- Gamma counter set for ^{125}I.

For the determination of aldosterone in urine

Solution U: one vial (ready-to-use)

Supplied upon request: REF. IM1736

- The Solution U needs to be assayed first in order to determine its aldosterone endogenous concentration. This concentration needs to be subtracted from the patient sample.

For the dilution of serum and plasma samples

Diluent S: one vial (lyophilized)

Supplied upon request: REF. IM2445

- The diluent needs to be assayed first in order to determine its aldosterone endogenous concentration. This concentration needs to be subtracted from the patient sample aldosterone concentration before multiplication by the dilution factor. Results are meaningful if the concentration recovered is at least twice that of the concentration measured when assaying the diluent only.

PROCEDURE

Preparation of reagents

Let all the reagents come to room temperature.

Reconstitution of calibrators and control sample

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

Assay procedure for serum or plasma

Step 1 Additions*	Step 2 Incubation	Step 3 Counting
To coated tubes add successively: 50 µL of calibrator, control or sample 500 µL of tracer. Vortex gently 1-2 seconds.	Incubate 3 hours 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 500 µL of tracer to 2 additional tubes to obtain total cpm.

Assay procedure for urine

The Solution U needs to be assayed first in order to determine its aldosterone endogenous concentration. This concentration needs to be subtracted from the patient sample.

Step 1 Additions*	Step 2 Incubation	Step 3 Counting
To coated tubes add successively: 50 µL of calibrator, control or 50 µL of Solution U and 10 µL of urine sample 500 µL of tracer. Vortex gently 1-2 seconds.	Incubate 3 hours 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 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 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: 59,339 cpm				
Calibrators	**Aldosterone (pg/mL)**	**cpm (n = 3)**	**B/B_0 (%)**	**B/T (%)**
0	0	23,613	100.0	39.8
1	30.0	20,788	88.0	35.0
2	100	17,846	75.6	30.1
3	290	13,034	55.2	22.0
4	825	9,000	38.1	15.2
5	2,500	5,650	23.9	9.52

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

Serum and plasma 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.

Urine samples

Proceed as shown in previous section for serum and plasma samples. In order to obtain the quantity of aldosterone of the entire 24-hour urine, convert the concentration of pg/mL into µg/24h according to the following formula:

$$Y = X \times 0.056 \times V$$

where

Y = urinary aldosterone (µg/24h)

X = urinary aldosterone (pg/mL)

V = 24h urine volume in liter.

To convert concentrations from pg/mL to pmol/L, multiply results by 2.774.

EXPECTED VALUES

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

Serum

Blood for supine values was collected after whole night rest in bed and blood for upright values was collected in a morning after at least two hours spent in upright position.

Adults		**Aldosterone (pg/mL)**				
	n	**Mean**	**Min-Max**		**2.5^{th} - 97.5^{th} percentile**	
Supine	29	120.1	37.82	233.0	41.71	208.9
Upright	69	159.6	53.81	387.6	67.40	335.1

Detail information about expected values for children (sorted according to age) can be found in the data sheet "APPENDIX".

24-hour urine

	Aldosterone (µg/24h)		
n	**Mean**	**Min-Max**	**2.5^{th} - 97.5^{th} percentile**
29	6.87	0.35 - 32.42	0.58 - 25.86

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: 14.8 pg/mL

Functional sensitivity: 26.2 pg/mL

Specificity

The antibody used in the immunoassay is highly specific for aldosterone. Extremely low cross reactivities were obtained against other naturally occurring steroids (cortisone, corticosterone, DHEAs, etc...).

Precision

Intra-assay

Samples were assayed 25 times in the same series. The coefficients of variation were found below or equal to 11.9% for serum samples.

Inter-assay

Samples were assayed in duplicate in 10 different series. Coefficients of variation were found below or equal to 10.2% for serum samples.

Accuracy

Dilution test

High-concentration serum samples were serially diluted into Diluent S. The recovery percentages obtained were between 83.1% and 110%.

Recovery test

Low-concentration serum samples were spiked with known quantities of aldosterone. The recovery percentages obtained were between 97.7% and 115%.

Measurement range (from analytical sensitivity to the highest calibrator): 14.8 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 [3, 4, 5].

APPENDIX

PERFORMANCE CHARACTERISTICS

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

Interference

Serum samples containing aldosterone concentrations (low and high) were spiked with multiple concentrations of the substances listed below and assayed using RIA Aldosterone. Values were calculated as described in CLSI EP07, 3rd ed. [6]. 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	1,806 ng/mL
Conjugated bilirubin	41.05 µg/mL
Hemoglobin	1,579 µg/mL
Triglycerides	16.21 mg/mL
Unconjugated bilirubin	465.8 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 cross-reactivity has been measured against various compounds in this assay. The percent cross-reactivity is expressed as the ratio of the aldosterone concentration to the concentration of the reacting compound at 50% binding of the aldosterone zero calibrator.

Steroid	Cross-reactivity (%)
Aldosterone	100
18 OH-Corticosterone	0.02
Cortisol	< 0.005
Corticosterone	0.02
11-Desoxycorticosterone	0.06
Cortisone	< 0.005
Androstenedione	< 0.005
17αOH-Progesterone	< 0.005
DHEAs	< 0.005
Fludrocortisone	ND
3α,5β-Tetrahydroaldosterone	1.66

ND – not detectable

Precision

Intra-assay

Serum samples	S1	S2	S3
Number of determinations	25	25	25
Mean value, pg/mL	108.2	801.7	2,402
C.V., %	7.08	11.92	7.64

EDTA - plasma samples	P1	P2	P3
Number of determinations	25	25	25
Mean value, pg/mL	103.3	238.4	291.5
C.V., %	7.44	8.05	4.42

Urine samples	U1	U2	U3
Number of determinations	25	25	25
Mean value, µg/L	2.32	9.69	19.44
C.V., %	13.52	5.20	9.22

Inter-assay

Serum samples	S1	S2	S3	S4	S5
Number of determinations	10	10	10	10	10
Mean value, pg/mL	98.40	112.4	1,026	1,301	2,467
C.V., %	8.18	9.60	10.15	9.44	8.79

EDTA - plasma samples	P1	P2	P3	P4	P5
Number of determinations	10	10	10	10	10
Mean value, pg/mL	127.1	152.9	180.1	847.2	1,659
C.V., %	13.48	9.35	8.48	9.46	7.70

Urine samples	U1	U2	U3	U4	U5
Number of determinations	10	10	10	10	10
Mean value, µg/L	3.05	9.08	16.42	22.94	54.96
C.V., %	12.14	5.50	4.08	8.82	14.54

Accuracy

Dilution test

Serum or EDTA-plasma samples were diluted into Diluent S and assayed according to the assay procedure of the kit.

Serum	Dilution factor	Aldosterone (pg/mL)		Ratio (%) Measured/ Expected
		Measured	Expected	
S1	-	1,545	-	-
	1:2	705.9	806.8	87.49
	1:4	390.3	420.5	92.80
	1:8	189.1	227.4	83.14
S2	-	1,096	-	-
	1:2	509.3	582.5	87.43
	1:4	293.2	308.4	95.08
	1:8	188.6	171.3	110.1
S3	-	2,351	-	-
	1:2	1,144	1,210	94.54
	1:4	519,2	621.9	83.48
	1:8	299.6	328.1	91.31

EDTA - plasma	Dilution factor	Aldosterone (pg/mL)		Ratio (%) Measured/ Expected
		Measured	Expected	
P1	-	1,044	-	-
	1:2	525.6	542.3	96.92
	1:4	325.0	281.2	115.5
	1:8	180.8	150.7	119.9
P2	-	917.5	-	-
	1:2	426.7	478.9	89.10
	1:4	244.1	249.5	97.81
	1:8	156.0	134.8	115.7
P3	-	440.8	-	-
	1:2	259.7	240.6	107.9
	1:4	143.6	130.3	110.2
	1:8	88.35	75.24	117.4

Urine samples were diluted before hydrolysis by distilled water and assayed according to the assay procedure of the kit.

Urine	Dilution factor	Aldosterone (µg/L)		Ratio (%) Measured/ Expected
		Measured	Expected	
U1	-	58.40	-	-
	1:2	26.20	29.20	89.73
U2	-	61.52	-	-
	1:2	29.75	30.76	96.71
U3	-	48.70	-	-
	1:2	22.74	24.35	93.40

Recovery test

Serum or EDTA-plasma samples were spiked with known quantities of aldosterone and assayed according to the assay procedure of the kit.

Serum	Endogen. conc.	Added conc.	Expected conc.	Measured conc.	Ratio (%) Measured/ Expected
	(pg/mL)				
S1	111.3	60.98	172.3	198.8	115.4
	106.1	174.4	280.6	314.0	111.9
	103.7	227.3	331.0	341.7	103.2
S2	224.3	60.98	285.3	281.2	98.56
	219.0	119.0	338.0	349.2	103.3
	209.0	227.3	436.3	439.3	100.7
S3	255.7	60.98	316.7	309.4	97.71
	249.6	119.0	368.7	390.9	106.0
	238.3	227.3	465.5	530.0	113.8

EDTA - plasma	Endogen. conc.	Added conc.	Expected conc.	Measured conc.	Ratio (%) Measured/ Expected
	(pg/mL)				
P1	140.9	60.70	201.6	221.9	110.1
	137.6	118.5	256.1	281.3	109.9
	131.3	226.2	357.5	423.0	118.3
P2	146.6	60.70	207.3	210.7	101.6
	143.1	118.5	261.6	255.4	97.62
	136.6	226.2	362.8	393.0	108.3
P3	129.8	60.70	190.5	213.8	112.3
	126.7	118.5	245.2	253.2	103.3
	120.9	226.2	347.2	414.6	119.4

Urine samples were spiked with known quantities of aldosterone before hydrolysis and assayed according to the assay procedure of the kit.

Urine	Endogen. conc.	Added conc.	Expected conc.	Measured conc.	Ratio (%) Measured/ Expected
	(µg/L)				
U1	8.10	0.53	8.63	8.63	100.1
	7.91	1.03	8.93	9.43	105.5
	7.55	1.96	9.51	10.31	108.4
U2	4.36	0.53	4.89	5.41	110.7
	4.26	1.03	5.29	6.03	114.1
	4.07	1.96	6.03	7.09	117.7
U3	7.89	0.53	8.42	8.36	99.33
	7.71	1.03	8.73	9.52	109.0
	7.35	1.96	9.31	9.22	99.04

Expected data for children

Results are sorted according to age.

Children		Aldosterone (pg/mL)				
Supine	**n**	**Mean**	**Min-Max**		**2.5th - 97.5th percentile**	
0 - 3 months	17	583.4	146.3	1,378	186.5	1,340
4 - 12 months	22	405.6	111.9	1,434	117.9	1,253
7 - 15 years	19	133.1	80.18	203.6	82.06	191.2

Children		Aldosterone (pg/mL)				
Upright	**n**	**Mean**	**Min-Max**		**2.5th - 97.5th percentile**	
2 - 6 years	18	288.8	144.6	601.3	146.4	550.4
7 - 15 years	43	223.1	85.69	469.1	115.8	419.8

^{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

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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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

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