BECKMAN COULTER

CE 2797

ACTIVE® Androstenedione RIA

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

REVISION HISTORY

Previous version: IFU-DSL3800-03	**Current version:** IFU-DSL3800-04
MATERIALS PROVIDED **Calibrators: six vials** (lyophilized) The calibrator vials contain from 0 to approximately 10.0 ng/mL (0 to approximately 34.9 nmol/L) of androstenedione in human serum with sodium azide (<0.1%). The exact concentration is indicated on each vial label. The calibrators are traceable to an internal reference standard. **Control samples: two vials** (lyophilized) The vials contain androstenedione in human serum with sodium azide (<0.1%). The concentration range is indicated on a supplement. The control samples are traceable to an internal reference standard.	 **Calibrators: six vials** (lyophilized) The calibrator vials contain from 0 to approximately 10.0 ng/mL (0 to approximately 34.9 nmol/L) of androstenedione in human serum with sodium azide (<0.1%). The calibrators are traceable to an internal reference standard. The exact concentration is indicated on the Certificate of Analysis provided with the kit and on the Beckman Coulter website (beckmancoulter.com/techdocs). **Control samples: two vials** (lyophilized) The vials contain androstenedione in human serum with sodium azide (<0.1%). The control samples are traceable to an internal reference standard. The concentration range is indicated on the Certificate of Analysis provided with the kit and on the Beckman Coulter website (beckmancoulter.com/techdocs).
Standard curve *(Example of standard curve, do not use for calculation. Use the concentration of calibrators indicated on each vial label. The concentrations are lot specific, check carefully.)*	Example of standard curve is given on the Certificate of Analysis provided with the kit and on the Beckman Coulter website (beckmancoulter.com/techdocs). The measured data are indicative only, do not use them for calculation of your results.

REF DSL3800

FOR PROFESSIONAL USE ONLY

INTENDED PURPOSE

ACTIVE® Androstenedione RIA is an in vitro diagnostic manual medical device intended to be used by healthcare professionals for the quantitative measurement of androstenedione in human serum and plasma. Measurement of androstenedione is intended to be used for diagnosis and differential diagnosis of hyperandrogenism and for diagnosis and monitoring of congenital adrenal hyperplasia in general population [1, 2, 3, 4].

PRINCIPLE

The radioimmunoassay of androstenedione (ASD, 4-Androstene-3,17-dione) is a competition assay. Samples and calibrators are incubated with ^{125}I-labeled androstenedione, 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 androstenedione concentrations in the samples are obtained by interpolation from the standard curve. The concentration of androstenedione 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.
- Samples may be stored at 2-8°C, if the assay is to be performed within 24 hours. For longer storage, keep frozen (at < -18°C, 1 year maximum), after aliquoting so as to avoid repeated freezing and thawing. Thawing of sample should be performed at room temperature.
- If samples have concentrations greater than the highest calibrator, they must be diluted twice in zero calibrator. Further dilution may give erroneous results.

Serum and EDTA-plasma values for 20 samples (serum values ranging from 0.50 to 2.07 ng/mL) were compared using the DSL3800 ACTIVE® Androstenedione RIA. Results are as follows:

[EDTA-plasma] = 1.03 [serum] - 0.03

R = 0.9758

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 them into account.

Storage conditions for reagents after reconstitution are indicated in paragraph Procedure.

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

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

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

Calibrators: six vials (lyophilized)

The calibrator vials contain from 0 to approximately 10.0 ng/mL (0 to approximately 34.9 nmol/L) of androstenedione in human serum with sodium azide (<0.1%). The calibrators are traceable to an internal reference standard.

The exact concentration is indicated on the Certificate of Analysis provided with the kit and on the Beckman Coulter website (beckmancoulter.com/techdocs).

Control samples: two vials (lyophilized)

The vials contain androstenedione in human serum with sodium azide (<0.1%). The control samples are traceable to an internal reference standard.

The concentration range is indicated on the Certificate of Analysis provided with the kit and on the Beckman Coulter website (beckmancoulter.com/techdocs).

MATERIALS REQUIRED, BUT NOT PROVIDED

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

- Precision micropipette (50 µL).
- Semi-automatic pipette (500 µL).
- Temperature-controlled water bath, 37°C ± 2°C.

- A sponge rack or similar device for decantation.
- Absorbent material for blotting tubes.
- 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.

Reconstitution of calibrators and control samples

The content of the vials is reconstituted with the volume of deionized water indicated on the vial label. Wait for 10 min following reconstitution and mix gently to avoid foaming before dispensing. Store the reconstituted solutions at 2-8°C for up to 3 weeks or aliquoted at < -20°C for a longer time, until the expiry date of the kit.

Assay procedure

Step 1 Additions*	Step 2 Incubation	Step 3 Counting
To coated tubes add successively: 50 µL of calibrator, control or sample, immediately add 500 µL of tracer. Mix rack vigorously by hand.	Incubate 1 hour at 37°C in water bath.	Aspirate or decant tubes, (except «total cpm» tubes), by simultaneous inversion with a sponge rack into a radioactive waste receptacle. Strike tubes sharply and drain on absorbent material for >2 minutes and gently blot the tubes. 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 standard curve by interpolation. The curve serves for the determination of analyte concentrations in samples measured at the same time as the calibrators.

Standard curve

Example of standard curve is given on the Certificate of Analysis provided with the kit and on the Beckman Coulter website (beckmancoulter.com/techdocs). The measured data are indicative only, do not use them for calculation of your results.

The results in the quality control department were calculated using *cubic regression* 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.

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 ng/mL into nmol/L, multiply results by 3.49.

EXPECTED VALUES

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

Population	N	Median	Min-Max	2.5th - 97.5th percentile
		(ng/mL)		
Males	132	1.15	0.62 - 3.12	0.64 - 2.97
Females	99	1.09	0.24 - 3.44	0.35 - 2.78
Postmenopausal Females	50	0.86	0.22 - 2.24	0.30 - 2.07

· ***(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: 0.05 ng/mL

Functional sensitivity: 0.09 ng/mL

Specificity

The antibody used in the immunoassay is highly specific for androstenedione. Low (<1%) cross reactivities were obtained with several related molecules (androsterone, 17 OH progesterone, cortisone etc).

Precision

Intra-assay

Serum samples were assayed 25 times in the same run. The coefficients of variation were found below or equal to 7.5%.

Inter-assay

Serum samples were assayed in duplicate in 10 different runs. The coefficients of variation were found below or equal to 11.3%.

Accuracy

Dilution test

High-concentration serum samples were diluted with zero calibrator. The recovery percentages ranged from 81.6% to 99.4%.

Recovery test

Low-concentration serum samples were spiked with known quantities of androstenedione. The recovery percentages ranged from 93.0% to 111%.

Measurement range (from analytical sensitivity to the highest calibrator): 0.05 to approximately 10.0 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.

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].

APPENDIX

PERFORMANCE CHARACTERISTICS

ACTIVE is a trademark of BECKMAN COULTER Inc. and its subsidiaries.

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

Summary and explanation of the test

Androstenedione (ASD, 4-Androstene-3,17-dione), a C19 steroid, is produced in the adrenal gland and gonads. ASD is an immediate precursor to both testosterone and estrone, both of which may be subsequently converted to estradiol. Due to the presence of a 17-oxo (rather than hydroxyl) group, ASD has relatively weak androgenic activity, estimated at <20% of testosterone [8]. Although it is a weak androgen, serum ASD levels may exceed testosterone in both normal and disease states, ASD secretion and production rates exceed those of testosterone in women, and significant extra-adrenal conversion of ASD to testosterone occurs. Furthermore, the affinity of sex hormone-binding globulin for ASD is much less than for testosterone or estradiol [8, 9, 10].

The physiologic role of ASD is not well defined. Serum ASD levels are high in fetal and neonatal serum, decrease during childhood, and increase during puberty. In normal pubertal and adult men, the major portion of ASD is derived from the testis, either directly or from conversion of testosterone, while in normal adult women essentially equivalent amounts of ASD are produced by the adrenal gland and ovary [9, 10]. Increased ASD levels may play a role in the development of secondary sexual hair during adrenarche. Serum ASD levels show significant diurnal variation dependent on the secretion of ACTH. Ovarian ASD production is stimulated by luteinizing hormone, and serum ASD levels vary with the menstrual cycle [10]. Adrenal ASD production gradually declines with advanced age in both men and women. In addition, ovarian ASD production decreases after menopause [10].

Measurement of serum ASD provides a useful marker of androgen biosynthesis. Elevated ASD levels have been demonstrated in virilizing congenital adrenal hyperplasia; additionally ASD levels may have advantages over 17-hydroxy-progesterone levels in monitoring treatment of this condition, e.g. less marked diurnal variation and less suppression after brief glucocorticoid exposure [11].

Assays for ASD include gas-liquid chromatography, mass spectrometry, and immunoassay. The DSL3800 ACTIVE® Androstenedione RIA uses a specific and sensitive rabbit anti-human ASD polyclonal antiserum [12, 13, 14].

Interference

Serum samples containing androstenedione concentrations (low and high) were spiked with multiple concentrations of the substances listed below and assayed using ACTIVE® Androstenedione RIA. Values were calculated as described in CLSI EP07, 3rd ed. [15]. 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	1,656 ng/mL
Conjugated bilirubin	462.2 µg/mL
Hemoglobin	291.7 µg/mL
Triglycerides	11.35 mg/mL
Unconjugated bilirubin	372.2 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 androstenedione concentration to the concentration of the reacting compound at 50% binding of the androstenedione zero calibrator.

COMPOUND	% CROSS-REACTIVITY	COMPOUND	% CROSS-REACTIVITY
Androstenedione	100	Corticosterone	0.04
Androsterone	0.33	Cortisol	0.04
17OH-Progesterone	0.25	Estrone	0.03
Cortisone	0.16	Pregnenolone	0.02
Isoandrosterone	0.10	Cholesterol	ND
Deoxycortisone	0.09	DHEA-sulfate	ND
Etiocholanolone	0.08	Estradiol	ND
5α-Dihydrotestosterone	0.08	Estriol	ND
DHEA	0.07	17OH-Pregnenolone	ND
Progesterone	0.06		

· ND – not detectable

Precision

Intra-assay

	Serum			EDTA plasma		
Sample	**S1**	**S2**	**S3**	**P1**	**P2**	**P3**
Number of determinations	25	25	25	25	25	25
Mean value, ng/mL	0.51	0.94	8.10	0.55	0.93	7.89
C.V., %	7.46	5.42	5.06	6.14	6.57	5.94

Inter-assay

	Serum			EDTA plasma		
Sample	**S1**	**S2**	**S3**	**P1**	**P2**	**P3**
Number of determinations	10	10	10	10	10	10
Mean value, ng/mL	0.27	0.66	6.71	0.38	1.15	9.18
C.V., %	11.32	6.31	4.12	12.44	7.19	6.70

Accuracy

Dilution test

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

Serum	Dilution factor	Measured	Expected	Ratio (%) Measured/ Expected
		(ng/mL)		
S1	-	5.18	-	-
	1:1	2.33	2.59	89.96
S2	-	5.07	-	-
	1:1	2.52	2.54	99.41
S3	-	9.23	-	-
	1:1	3.93	4.62	85.16
S4	-	7.82	-	-
	1:1	3.19	3.91	81.59
S5	-	5.51	-	-
	1:1	2.25	2.76	81.67

EDTA plasma	Dilution factor	Measured	Expected	Ratio (%) Measured/ Expected
		(ng/mL)		
P1	-	4.55	-	-
	1:1	1.92	2.28	84.40
P2	-	4.70	-	-
	1:1	1.98	2.35	84.26
P3	-	9.17	-	-
	1:1	4.18	4.59	91.17
P4	-	6.50	-	-
	1:1	2.85	3.25	87.69
P5	-	6.00	-	-
	1:1	2.53	3.00	84.33

Recovery test

Samples were spiked with known quantities of androstenedione 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	1.20	0.35	1.55	1.72	110.6
	1.16	0.69	1.85	1.86	100.5
	1.13	1.00	2.13	2.30	108.1
S2	0.94	0.35	1.29	1.30	100.5
	0.91	0.69	1.60	1.59	99.57
	0.88	1.00	1.88	1.75	93.00
S3	0.30	0.34	0.64	0.64	100.2
	0.29	0.66	0.95	0.97	102.4
	0.28	0.95	1.24	1.31	106.0

EDTA plasma	Endogen. conc.	Added conc.	Expected conc.	Measured conc.	Ratio (%) Measured/ Expected
	(ng/mL)				
P1	0.21	0.34	0.55	0.60	108.8
	0.21	0.66	0.86	0.86	99.71
	0.20	0.95	1.15	1.32	114.3
P2	0.31	0.34	0.65	0.69	106.4
	0.30	0.66	0.96	1.03	107.7
	0.29	0.95	1.25	1.41	113.2
P3	0.21	0.34	0.55	0.58	105.1
	0.21	0.66	0.86	0.90	104.3
	0.20	0.95	1.15	1.25	108.3

Expected values

Population	Age range (years)	N	Median	Min - Max	2.5^{th} - 97.5^{th} percentile
			(ng/mL)		
Males	20 - 67	132	1.15	0.62 - 3.12	0.64 - 2.97
	20 - 30	31	1.51	0.24 - 2.29	0.65 - 2.20
	31 - 40	38	1.29	0.66 - 2.93	0.67 - 2.56
	41 - 50	37	1.33	0.62 - 2.74	0.74 - 2.61
	51 - 67	26	1.15	0.62 - 3.12	0.64 - 2.97
Females	19 - 62	99	1.09	0.24 - 3.44	0.35 - 2.78
	19 - 30	25	1.47	0.61 - 3.44	0.67 - 3.05
	31 - 40	25	1.12	0.47 - 2.76	0.48 - 2.55
	41 - 49	25	1.17	0.71 - 2.97	0.72 - 2.28
	51 - 62	24	0.72	0.24 - 1.44	0.26 - 1.31
Postmenopausal Females		50	0.86	0.22 - 2.24	0.30 - 2.07

^{125}I Characteristics

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

^{125}I Characteristics	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

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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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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