BECKMAN COULTER

CE 2797

Prolactin IRMA KIT

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

REVISION HISTORY

Previous version: IFU-IM2121-3303-02	**Current version:** IFU-IM2121-3303-03
Standard curve *(Example of standard curve, do not use for calculation)*	*(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.)*
—	Adding Ukrainian to the IFU.

REF IM2121, IM3303

FOR PROFESSIONAL USE ONLY

INTENDED PURPOSE

Prolactin IRMA KIT is an in vitro diagnostic manual medical device intended to be used by healthcare professionals for the quantitative measurement of prolactin in human serum and plasma. Measurement of prolactin is intended to be used as an aid in diagnosis of infertility, impotence, pituitary tumors and prolactinomas and as an aid in monitoring of prolactinomas in general population [1, 2, 3, 4].

PRINCIPLE

The immunoradiometric assay of prolactin is a sandwich-type assay. Mouse monoclonal antibodies directed against two different epitopes of prolactin and hence not competing are used. The assay determines biologically active, monomeric form of prolactin (22-23 kDa) and, at certain extent, also other forms known as big prolactin (50-60 kDa) and big-big prolactin (or macroprolactin; >150 kDa). The assay enables also facultative determination of prolactin after macroprolactin precipitation.

Samples or calibrators are incubated in tubes coated with the first monoclonal antibody in the presence of the second monoclonal antibody labeled with iodine 125. After incubation, the contents of the tubes are rinsed so as to remove unbound ^{125}I-labeled antibody. The bound radioactivity is then determined in a gamma counter. The prolactin concentrations in the samples are obtained by interpolation from the standard curve. The concentration of prolactin in the samples is directly proportional to the radioactivity.

WARNING AND PRECAUTIONS

General remarks:

- The vials with calibrators and controls should be opened as shortly as possible to avoid excessive evaporation.
- Do not mix the reagents from kits of different lots.
- A standard curve must be established with each assay.
- It is recommended to perform the assay in duplicate.
- Each tube must be used only once.

Basic rules of radiation safety

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

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.

The summary of safety and performance for this in vitro diagnostic medical device is available to the public in the European database on medical device (EUDAMED) when this database is available, and the information has been uploaded by the Notified Body. The web address of the EUDAMED public web site is: https://ec.europa.eu/tools/eudamed.

To search the information about this product in EUDAMED, use BUDI-DI: 150995905PRLIRMAZK.

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 or EDTA plasma are the recommended sample types.
- Allow serum samples to clot completely before centrifugation.
- Serum and plasma samples may be stored at 2-8°C, if the assay is to be performed within 24 hours. For longer storage keep frozen (at < -20°C, 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 into the zero calibrator.

Serum and EDTA plasma values for 20 samples (serum values ranging from 2.51 to 10.44 ng/mL) were compared using the IM2121 Prolactin IRMA KIT. Results are as follows:

[EDTA-plasma] = 1.1093[serum] - 0.0215

R = 0.9863

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.

Kit for the determination of prolactin: 100 tubes (REF. IM2121)

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

^{125}I-Tracer: one 55 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.

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

The calibrator vials contain from 0 to approximately 180 ng/mL of human prolactin in horse serum and sodium azide (<0.1%). The exact concentration is indicated on each vial label. The calibrators are traceable to the international standard WHO 4th IS 83/573.

Control samples: two vials (lyophilized)

The vials contain human prolactin lyophilized in human serum and sodium azide (<0.1%). The concentration range is indicated on a supplement. The control samples are traceable to the international standard WHO 4th IS 83/573.

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

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

Kit for determination of prolactin: 400 tubes (REF. IM3303)

Tubes: 8 x 50 (ready-to-use)

^{125}I-Tracer: four 55 mL vials (ready-to-use)

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

Control samples: two vials (lyophilized)

Wash solution U (20X): two 50 mL vials

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, 2 mL).
- Vortex type mixer.
- Horizontal or orbital shaker.
- Aspiration system.
- Gamma counter set for ^{125}I.

For macroprolactine precipitation (optional)

- Precision micropipette (400 µL).
- Semi-automatic pipette (400 µL).
- Polypropylene or glass tubes.
- Precipitation reagent (sold separately; REF. A09775).
- Centrifuge with cooling system (3000 g).

PROCEDURE

Preparation of reagents

Let all the reagents come to room temperature.

Reconstitution of calibrators and control samples

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 foarming before dispensing. Store the reconstituted solutions at 2-8°C for one week or aliquoted at < -18°C for a longer time, until the expiry date of the kit.

Preparation of the wash solution

Pour the contents of the vial into 950 mL of distilled water and homogenize. The diluted solution can be stored at 2-8°C until the expiry date of the kit.

Assay procedure

Step 1 Additions*	Step 2 Incubation	Step 3 Counting
To coated tubes add successively: 50 µL of calibrator, control or sample and 500 µL of tracer. Vortex gently 1-2 seconds.	Incubate 1 hour at 18-25°C with shaking (≥350 rpm).	Aspirate carefully the content of tubes (except the 2 tubes «total cpm»). Wash twice with 2 mL of wash solution. Count bound cpm (B) and total cpm (T) for 1 minute.

* Add 500 µL of tracer to 2 additional tubes to obtain total cpm.

RESULTS

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

Standard curve

The results in the quality control department were calculated using *spline* curve fit with log of determined radioactivity *(cpm_{cal}-cpm_{cal0})* or *B/T* **after subtraction of Blank** on the vertical axis and log of analyte concentration of the calibrators on the horizontal axis.

Other calculation methods may give slightly different results.

Total activity: 125,024 cpm				
Calibrators	**Prolactin (ng/mL)**	**cpm (n=3)**	**B/T (%)**	**$cpm_{cal} - cpm_{cal0}$**
0	0	103	-	-
1	1.90	502	0.32	399
2	9.50	2,249	1.72	2,146
3	43.0	11,812	9.37	11,709
4	86.0	23,972	19.1	23,869
5	180	39,150	31.2	39,047

(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.)

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.

To convert concentrations from ng/mL to mIU/L, multiply results by 30.3.

EXPECTED VALUES

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

Population	**N**	**Min.**	**Max.**	**Median**	**2.5th percentile**	**97.5th percentile**
		ng/mL				
Males	98	3.06	26.9	5.53	3.37	11.9
Females						
Reproductive age	207	2.64	37.2	10.9	4.07	24.4
- Follicular phase	103	2.72	29.4	10.4	3.92	23.0
- Preovulatory peak	23	6.91	27.9	12.8	7.76	24.3
- Luteal phase	81	2.64	37.2	11.6	4.05	26.2
Postmenopausal	48	2.77	14.4	5.95	3.06	11.7

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

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): 0.36 ng/mL

The LoD of the assay is 0.36 ng/mL, determined consistent with guidelines in CLSI document EP17-A2 [5] based on the proportions of false positives (α) less than 5% and false negatives (β) less than 5%; using determinations, with 120 blank and 120 low level samples; and Limit of Blank (LoB) of 0.08 ng/mL.

Specificity

The antibody used in the immunoassay is highly specific for prolactin. Extremely low cross reactivities were obtained against several related molecules (hLH, hFSH, hTSH, hCG, hGH, HPL).

Precision

Repeatability and within-laboratory precision

The precision of the assay was determined consistent with guidelines in CLSI document EP05-A3 [6]. For repeatability the coefficients of variation were found below or equal to 5.5% for serum samples. For within-laboratory precision the coefficients of variation were found below or equal to 10.7% for serum samples.

Accuracy

Linearity

The assay demonstrated to be linear from 1.55 ng/mL to 189.3 ng/mL using serum samples (determined consistent with guidelines in CLSI document EP06-A [7]).

Dilution test

High-concentration serum samples were serially diluted with the zero calibrator. The recovery percentages obtained were between 83.6% and 100%.

Recovery test

Low-concentration serum samples were spiked with known quantities of prolactin. The recovery percentages obtained were between 103.5% and 112%.

Measurement range (from LoD to the highest calibrator): 0.36 to approximately 180 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.

"Hook effect": no hook effect was observed until 15,000 ng/mL.

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 [8, 9, 10].

Rarely, the level of prolactin may be significantly increased due to the presence of high concentrations of macroprolactin. In such cases, increased prolactin concentrations may be found in individuals who lack many of clinical symptoms related to hyperprolactinemia. Determination of prolactin after macroprolactin precipitation may help to identify such cases.

PRE-TREATMENT OF SAMPLES WITH PRECIPITATION REAGENT - OPTIONAL

Add 400 µL of precipitation reagent (sold separately; cat. No. A09775) to 400 µL of unknown sample, in polypropylene or glass tube.

Shake on vortex-type mixer and leave for 30 minutes at room temperature, then centrifuge for at least 15 minutes at 3000 g and 4°C.

Supernatant is treated in the same way as unknown sample.

It is necessary to multiply the read-off concentration by 2, to reflect the dilution of the sample. Approximately 23% (range 10-42%) of monomeric prolactin is co-precipitated with precipitation reagent. When the prolactin concentration (after correction for dilution factor 2) is less than 50% of the concentration of untreated sample, there is a high probability of macroprolactin presence in the sample.

APPENDIX

PERFORMANCE CHARACTERISTICS

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

Interference

Serum samples containing prolactin concentrations (low and high) were spiked with multiple concentrations of the substances listed below and assayed using Prolactin IRMA KIT. Values were calculated as described in CLSI EP07, 3rd ed. [11]. 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
Hemoglobin	9,984 µg/mL
Conjugated bilirubin	440.7 µg/mL
Unconjugated bilirubin	469.1 µg/mL
Biotin	1,517 ng/mL
Ascorbic acid	59.41 µg/mL
Acetylsalicylic acid	36.39 µg/mL
Ibuprofen	196.3 µg/mL
Cholesterol	4.12 mg/mL
Heparin	6,619 ng/mL
Prednisone	101.0 ng/mL
Prednisolone	1,267 ng/mL
Rheumatoid factor	27.58 IU/mL
TAG	18.60 mg/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 antibody used in the immunoassay is highly specific for prolactin. Extremely low cross reactivities were obtained against several related molecules (hLH, hFSH, hTSH, hCG, hGH, HPL).

Hormone	Cross-reactivity
hLH	<0.04%
hFSH	<0.01%
hTSH	<0.01%
hCG	<0.01%
hGH	<0.1%
HPL	<0.1%

Repeatability and within-laboratory precision

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

Serum	Mean (ng/mL)	Repeatability		Within laboratory precision	
		SD (ng/mL)	C.V. (%)	SD (ng/mL)	C.V. (%)
S1	104.8	2.90	2.77	6.08	5.80
S2	51.43	1.51	2.95	3.78	7.36
S3	14.42	0.53	3.65	1.55	10.74
S4	8.11	0.32	3.97	0.54	6.69
S5	4.11	0.23	5.52	0.34	8.23

EDTA-plasma	Mean (ng/mL)	Repeatability		Within laboratory precision	
		SD (ng/mL)	C.V. (%)	SD (ng/mL)	C.V. (%)
P1	109.8	2.75	2.50	5.60	5.10
P2	57.12	1.79	3.14	3.51	6.15
P3	20.64	0.65	3.15	1.52	7.37
P4	9.36	0.35	3.70	0.68	7.22
P5	5.35	0.28	5.19	0.47	8.77

Accuracy

Linearity

The assay demonstrated to be linear from 1.43 ng/mL to 185.1 ng/mL using EDTA plasma samples (determined consistent with guidelines in CLSI document EP06-A [7]).

Dilution test

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

Serum	Dilution factor	Prolactin (ng/mL)		Ratio (%) Measured/ Expected
		Measured	Expected	
S1	-	113.8	-	-
	1:2	56.88	56.88	100.00
	1:4	27.38	28.44	96.28
	1:8	13.89	14.22	97.69
	1:16	6.82	7.11	95.93
	1:32	3.17	3.55	89.18
S2	-	121.7	-	-
	1:2	60.37	60.85	99.21
	1:4	28.76	30.43	94.53
	1:8	13.44	15.21	88.35
	1:16	6.89	7.61	90.58
	1:32	3.18	3.80	83.62
S3	-	152.5	-	-
	1:2	75.59	76.25	99.13
	1:4	36.17	38.13	94.87
	1:8	18.00	19.06	94.43
	1:16	9.09	9.53	95.37
	1:32	4.25	4.77	89.18

EDTA-plasma	Dilution factor	Prolactin (ng/mL)		Ratio (%) Measured/ Expected
		Measured	Expected	
P1	-	90.05	-	-
	1:2	41.89	45.03	93.04
	1:4	18.36	22.51	81.55
	1:8	9.01	11.26	80.04
	1:16	4.60	5.63	81.73
	1:32	2.50	2.81	88.84
P2	-	99.40	-	-
	1:2	47.81	49.71	96.18
	1:4	23.56	24.86	94.79
	1:8	12.17	12.43	97.93
	1:16	5.93	6.21	95.43
	1:32	3.19	3.11	102.7
P3	-	167.9	-	-
	1:2	87.49	83.94	104.2
	1:4	44.09	41.97	105.1
	1:8	21.19	20.98	101.0
	1:16	10.43	10.49	99.41
	1:32	5.50	5.25	104.8

Recovery test

Samples were spiked with known quantities of prolactin 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	2.95	1.14	4.09	4.36	106.5
	2.93	2.90	5.84	6.06	103.8
	2.93	5.81	8.74	9.18	105.0
S2	2.04	0.86	2.90	3.25	112.0
	1.99	1.96	3.95	4.25	107.6
	1.97	4.56	6.53	6.98	106.9
S3	5.87	2.34	8.21	9.08	110.6
	5.69	5.09	10.78	11.42	105.9
	5.62	12.30	17.92	18.55	103.5

EDTA-plasma	Endogen. conc.	Added conc.	Expected conc.	Measured conc.	Ratio (%) Measured/ Expected
	(ng/mL)				
P1	2.95	1.14	4.09	4.36	106.5
	2.93	2.90	5.84	6.06	103.8
	2.93	5.81	8.74	9.18	105.0
P2	2.04	0.86	2.90	3.25	112.0
	1.99	1.96	3.95	4.25	107.6
	1.97	4.56	6.53	6.98	106.9
P3	5.87	2.34	8.21	9.08	110.6
	5.69	5.09	10.78	11.42	105.9
	5.62	12.30	17.92	18.55	103.5

^{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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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

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SOLN WASH 20X

Wash Solution Concentrate 20X / Solution de lavage concentrée 20X / Waschlösungskonzentrat 20X / Concentrato di soluzione di lavaggio 20X / Solución de lavado concentrada 20X / Concentrado de solução de lavagem 20X / Tvättlösningskoncentrat 20X / Συμπυκνωμένο διάλυμα πλύσης 20X / 浓缩清洗液 20X / Plovimo tirpalo koncentratas 20X / 20X mosóoldat-koncentrátum / Koncentrat 20X roztworu płuczącego / Koncentrát mycího roztoku 20X / Koncentrát premývacieho roztoku 20X / 농축 세척액(20배) / Yıkama Çözeltisi Konsantresi 20X / Концентрат промывочного раствора 20X / Концентрат на разтвор за промиване 20X / 清洗溶液濃縮 20X

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