BECKMAN COULTER

CE 2797

RIA 17α-Hydroxyprogesterone

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

REVISION HISTORY

Previous version:	Current version:
IFU-IM1452-03	IFU-IM1452-04
—	Adding Ukrainian to the IFU.

REF IM1452

FOR PROFESSIONAL USE ONLY

INTENDED PURPOSE

RIA 17α-Hydroxyprogesterone is an in vitro diagnostic manual medical device intended to be used by healthcare professionals for the quantitative measurement of 17α-hydroxyprogesterone in human serum and plasma. Measurement of 17α-hydroxyprogesterone is intended to be used for differential diagnosis of hyperandrogenism and for diagnosis and monitoring of congenital adrenal hyperplasia in general population [1, 2, 3, 4].

PRINCIPLE

The radioimmunoassay of 17α-hydroxyprogesterone (17-OHP) is a competition assay. Samples, or extracts, and calibrators are incubated with ^{125}I-labeled 17-OHP as a tracer, in polyclonal antibody-coated tubes. After incubation, the contents of the tubes are rinsed so as to remove unbound ^{125}I-labeled tracer. The bound radioactivity is then determined in a gamma counter. The 17-OHP concentrations in the samples are obtained by interpolation from the standard curve. The concentration of 17-OHP 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.

Ethyl ether

Ethyl ether is a volatile and highly flammable organic solvent. Extraction and evaporation must be done in a ventilated hood. Avoid any contact with a flame and do not pipette reagents by mouth.

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 < -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 into the zero calibrator.

Serum and EDTA plasma values for 30 samples (serum values ranging from 0.24 to 1.88 ng/mL) were compared using the RIA 17α-Hydroxyprogesterone. Results are as follows:

[EDTA-plasma] = 0.9026[serum] + 0.0283,

R = 0.9747

MATERIALS PROVIDED

All reagents of the kit are stable until the expiry date indicated on the kit label, if stored at 2-8°C. Expiry dates printed on vial labels apply to the long-term storage of components by the manufacturer only, prior to assembly of the kit. Do not take into account.

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

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

^{125}I-Tracer: one 45 mL vial (ready-to-use)

The vial contains 640 kBq, at the date of manufacture, of ^{125}I-labeled 17-OHP in buffer containing proteins and a dye.

Note: Occasional presence of clotted particles in the tracer does not affect assay performance.

Calibrators: five 0.5 mL vials and one 2 mL vial of «zero» calibrator (ready-to-use)

The calibrator vials contain from 0 to approximately 50 ng/mL (0 to approximately 151 nmol/L) of 17-OHP in human serum with sodium azide (<0.1%). The exact concentration is indicated on each vial label. Calibrators are traceable to a certified reference material (Cerilliant).

The zero calibrator (5 mL) may be ordered separately, too (REF. B23373).

Control samples: two vials (lyophilized)

The vials contain 17-OHP 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).

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

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

MATERIALS REQUIRED, BUT NOT PROVIDED

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

- Precision micropipette (25 µL, 50 µL and 400 µL).
- Semi-automatic pipette (25 µL, 400 µL and 2 mL).
- Vortex type mixer.
- Horizontal or orbital shaker.
- Aspiration system.

- Gamma counter set for ^{125}I.

For the extraction step (optional):

- Precision micropipette (200 µL).
- Glass pipets (2.5 mL, 5 mL, 10 mL).
- Glass vials (from 6 mL to 15 mL).
- Glass tubes for recovery of ether phase.
- Evaporator (speedvac type) or 37°C water bath.
- Analytical grade ethyl ether.

PROCEDURE

Preparation of reagents

Let all the reagents come to room temperature.

Reconstitution of control samples

The content of the vials is reconstituted with the volume of distilled water indicated on the label. Wait for 10 min following reconstitution and mix gently to avoid foaming before dispensing. Store the reconstituted solutions at 2-8°C until the expiry date of the kit.

Preparation of wash solution

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

Extraction of samples (optional; see § Limitations)

Note: The extraction must be done in clean glass vials or tubes, pre-rinsed with ethyl ether.

Samples only are extracted before assay; do not extract calibrators.

- Bring samples to room temperature and mix well before starting extraction.
- Number one vial for each sample.
- Place 200 µL of each sample into corresponding vial.
- Add 5 mL of ethyl ether to vials. Stopper carefully.
- Vortex vials vigorously (2 x 1 minute).
- Let stay vials on the table for minimum 5 minutes.
- Take off carefully 2.5 mL of organic phase without contaminating with aqueous phase and place it into numbered glass tubes.
- Evaporate ether phase completely with either evaporator (e.g. speedvac type) or by placing tubes into 37°C water bath.

Note 1: The tubes must be firmly attached to test tubes rack, since after evaporation of the ether; they will be lighter and tend to float off.

At this stage it is possible to stopper the tubes containing the dry extracts and to store them for up to 7 days in the cold (2-8°C) prior to continuing the assay.

- Re-dissolve dry ether extracts in 200 µL of the zero calibrator. Vortex vigorously (30 sec, 2000 rpm), wait for 15 minutes, vortex again.

Note 2: If a larger volume is necessary, instead of taking off 2.5 mL of organic phase, keep vials at <-18°C until aqueous phase freezes, take off carefully 5 mL of organic phase without contaminating with aqueous phase, evaporate it and re-dissolve it in 400 µL of the zero calibrator.

Assay procedure

Step 1 Additions*	Step 2 Incubation	Step 3 Counting
To coated tubes add successively: 25 µL of calibrator, control, sample or 50 µL of extract and 400 µL of tracer. Vortex gently 1-2 seconds.	Incubate 120 minutes at 18 - 25°C with shaking (≥280 rpm).	Aspirate carefully the content of tubes (except the 2 tubes «total cpm»). Wash twice with 2 mL of wash solution. Aspirate. Count bound cpm (B) and total cpm (T) for 1 minute.

* Add 400 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: 179,362 cpm				
Calibrators	**17-OHP (ng/mL)**	**cpm (n=3)**	**B/T (%)**	**B/B_0 (%)**
0	0	55,975	31.2	100.0
1	0.12	44,882	25.0	80.2
2	0.40	31,190	17.4	55.7
3	1.90	12,557	7.00	22.4
4	12.5	2,515	1.40	4.49
5	50.0	895	0.50	1.60

(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 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 3.026.

EXPECTED VALUES

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

Adults	**N**	**Median**	**Min.**	**Max.**	**2.5th percentile**	**97.5th percentile**
		(ng/mL)				
Men	55	0.93	0.53	2.22	0.55	1.99
Women						
Follicular Phase	111	0.48	0.13	1.67	0.21	1.45
Luteal Phase	112	1.52	0.42	3.20	0.61	2.88
Preovulatory Peak	22	1.39	0.54	2.04	0.55	2.01
Contraception	30	0.37	0.17	1.48	0.18	1.47
Women after menopause	38	0.38	0.13	0.92	0.16	0.79
Pregnancy 1st trimester	45	2.03	0.78	5.75	0.93	3.82
Pregnancy 2nd trimester	44	2.23	0.60	6.86	1.23	3.70

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

Limit of detection (LoD): 0.07 ng/mL

The LoD of the assay is 0.07 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 0.04 ng/mL.

Specificity

The antibody used in the immunoassay is specific for 17α-hydroxyprogesterone.

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 10.5% for serum samples. For within laboratory precision the coefficients of variation were found below or equal to 12.8% for serum samples.

Accuracy

Linearity

The assay demonstrated to be linear from 0.12 to 50.88 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 zero calibrator. The recovery percentages ranged from 95.7% to 119%.

Recovery test

Low-concentration serum samples were spiked with known quantities of 17-OHP. The recovery percentages ranged from 100% to 119%.

Measurement range (from LoD to the highest calibrator): 0.07 to approximately 50 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 [8, 9, 10].

Very young infants (particularly less than 6 months old) have very high levels of 17OH-pregnenolone sulfate. In that particular case, extraction with ether prior to the 17-OHP assay is recommended.

In spite of low cross reactivity, one can observe falsely high levels of 17-OHP after regular administration of spironolactone. Spironolactone therapy must therefore be interrupted at least three weeks prior to the assay to ensure absence of interference.

APPENDIX

PERFORMANCE CHARACTERISTICS

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

Interference

Serum samples containing 17α-hydroxyprogesterone concetrations (low and high) were spiked with multiple concentrations of the substances below and assayed using RIA 17α-Hydroxyprogesterone. Values were calculated as described in CLSI EP07, 3rd ed. [11] and EP37, 1st ed. [12]. 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	10,191 µg/mL
Conjugated bilirubin	435.9 µg/mL
Unconjugated bilirubin	130.6 µg/mL
Biotin	1,705 ng/mL
Ascorbic acid	65.67 µg/mL
Acetylsalicylic acid	64.48 µg/mL
Ibuprofen	211.5 µg/mL
Cholesterol	8.13 mg/mL
Heparin	6,227 ng/mL
Prednisone	282.6 ng/mL
Prednisolone	1,282 ng/mL
Protein (γ-globulin)	136.8 mg/mL
Rheumatoid factor	19.76 IU/mL
Triglycerides	12.32 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 cross-reactivity has been measured against various compounds in this assay. The percent cross-reactivity is expressed as the ratio of the 17-OHP concentration to the concentration of the reacting compound at 50% binding of the 17-OHP zero calibrator.

COMPOUND	% CROSS-REACTIVITY
17α-hydroxyprogesterone	100.0
11-deoxycortisol	2.24
17α-hydroxypregnenolone sulfate	1.78
17α-hydroxypregnanolone	1.26
17α-hydroxypregnenolone	1.00
Progesterone	0.28
11-deoxycorticosterone	ND
Aldosterone	ND
Androstenedione	ND
Corticosterone	ND
Cortisone	ND
DHEA	ND
Estradiol	ND
Estriol	ND
Estrone	ND
Etiocholanolone	ND
Pregnanetriol	ND
Pregnanetriolone	ND
Pregnenolone	ND
Spironolactone	ND
Testosterone	ND

- *ND = Non-Detectable (< 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 two 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	29.03	3.05	10.50	3.73	12.84
S2	15.88	1.19	7.50	1.44	9.05
S3	11.06	0.60	5.41	0.84	7.58
S4	1.00	0.04	4.28	0.07	7.13
S5	0.20	0.02	8.38	0.02	10.30

EDTA-plasma	Mean (ng/mL)	Repeatability		Within laboratory precision	
		SD (ng/mL)	C.V. (%)	SD (ng/mL)	C.V. (%)
P1	26.02	3.36	12.91	4.41	16.94
P2	19.49	1.54	7.91	2.74	14.05
P3	8.80	0.59	6.69	0.85	9.64
P4	0.69	0.05	7.35	0.07	9.98
P5	0.25	0.02	7.54	0.03	11.19

Extract	Mean (ng/mL)	Repeatability		Within laboratory precision	
		SD (ng/mL)	C.V. (%)	SD (ng/mL)	C.V. (%)
E1	30.49	2.63	8.62	5.83	19.13
E2	16.52	1.15	6.96	2.59	15.70
E3	10.73	0.64	5.93	1.45	13.54
E4	0.74	0.04	5.65	0.08	10.18
E5	0.26	0.02	7.11	0.03	11.45

Accuracy

Linearity

The assay demonstrated to be linear from 0.15 to 62.04 ng/mL using EDTA-plasma samples (determined consistent with guidelines in CLSI document EP06-A [7]).

The assay demonstrated to be linear from 0.16 to 64.39 ng/mL using extracts (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	(ng/mL)		Ratio (%) Measured/ Expected
		Measured	Expected	
S1	-	30.00	-	-
	1:2	14.36	15.00	95.73
	1:4	7.45	7.50	99.33
	1:8	4.45	3.75	118.7
	1:16	2.22	1.88	118.4
S2	-	10.78	-	-
	1:2	5.91	5.39	109.6
	1:4	3.00	2.70	111.3
	1:8	1.48	1.35	109.8
	1:16	0.68	0.67	100.9
S3	-	5.83	-	-
	1:2	3.03	2.92	103.9
	1:4	1.61	1.46	110.5
	1:8	0.74	0.73	101.5
	1:16	0.36	0.36	98.80

EDTA-plasma	Dilution factor	(ng/mL)		Ratio (%) Measured/ Expected
		Measured	Expected	
P1	-	14.73	-	-
	1:2	7.57	7.37	102.8
	1:4	3.93	3.68	106.7
	1:8	2.08	1.84	113.0
	1:16	0.99	0.92	107.5
P2	-	15.04	-	-
	1:2	8.64	7.52	114.9
	1:4	4.29	3.76	114.1
	1:8	2.20	1.88	117.0
	1:16	1.08	0.94	114.9
P3	-	9.02	-	-
	1:2	5.01	4.51	111.1
	1:4	2.59	2.26	114.9
	1:8	1.29	1.13	114.4
	1:16	0.61	0.56	108.2

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

Extract	Dilution factor	(ng/mL)		Ratio (%) Measured/ Expected
		Measured	Expected	
E1	-	22.50	-	-
	1:2	10.86	11.25	96.53
	1:4	6.16	5.63	109.5
	1:8	3.01	2.81	107.0
	1:16	1.44	1.41	102.4
E2	-	15.26	-	-
	1:2	7.33	7.63	96.07
	1:4	3.75	3.82	98.30
	1:8	1.82	1.91	95.41
	1:16	0.88	0.95	92.27
E3	-	10.11	-	-
	1:2	4.88	5.06	96.54
	1:4	2.54	2.53	100.5
	1:8	1.29	1.26	102.1
	1:16	0.64	0.63	101.3

Recovery test

Samples were spiked with known quantities of 17-OHP 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	0.76	0.36	1.12	1.13	100.8
	0.74	0.60	1.34	1.38	103.1
	0.74	2.38	3.12	3.24	103.7
S2	1.32	0.60	1.92	2.08	108.4
	1.34	1.92	3.26	3.43	105.2
	1.29	3.70	4.99	5.95	119.2
S3	1.82	0.82	2.64	2.64	99.99
	1.88	1.92	3.80	4.44	116.9
	1.77	4.55	6.32	7.06	111.7

EDTA-plasma	Endogen. conc.	Added conc.	Expected conc.	Measured conc.	Ratio (%) Measured/ Expected
	(ng/mL)				
P1	0.45	0.25	0.70	0.78	112.1
	0.44	0.48	0.92	1.10	119.2
	0.44	1.92	2.37	2.53	107.0
P2	0.58	0.36	0.95	1.03	108.8
	0.57	0.71	1.27	1.51	118.6
	0.57	2.38	2.95	3.39	114.8
P3	1.80	0.93	2.72	2.72	99.92
	1.87	1.92	3.79	3.75	98.98
	1.76	4.55	6.31	5.57	88.29

Samples were spiked with known quantities of 17-OHP, extracted and assayed according to the assay procedure of the kit.

Extract	Endogen. conc.	Added conc.	Expected conc.	Measured conc.	Ratio (%) Measured/ Expected
	(ng/mL)				
E1	1.13	0.66	1.78	1.75	98.15
	1.10	1.61	2.72	3.09	113.8
	1.07	3.13	4.19	4.90	116.8
E2	0.76	0.66	1.42	1.54	108.6
	0.75	1.30	2.05	2.29	111.8
	0.73	2.83	3.56	4.21	118.4
E3	0.38	0.29	0.67	0.74	111.1
	0.38	0.82	1.20	1.28	106.4
	0.38	1.92	2.30	2.57	111.8

Comparison of direct and indirect (with extraction) procedure

30 serum samples were assayed by direct and indirect procedure (sample values in direct procedure ranging from 0.23 to 2.22 ng/mL) using the RIA 17α-Hydroxyprogesterone. Results are as follows:

[indirect procedure] = 0.8448[direct procedure] + 0.0088,

R = 0.9633

Expected data for children

Results are sorted according to the age and sex.

Children	N	Median	Min.	Max.	2.5th percentile	97.5th percentile
		(ng/mL)				
0-2 months (after extraction)	40	1.41	0.23	3.08	0.42	2.91
3-5 months (after extraction)	20	0.67	0.33	1.69	0.33	1.68
6-23 months	26	0.72	0.13	2.51	0.14	2.35
Boys 2-11 years	38	0.31	0.09	2.21	0.14	1.41
Girls 2-9 years	32	0.50	0.16	2.41	0.19	1.63
Boys 12-15 years	17	0.67	0.30	2.18	0.32	2.10
Girls 10-15 years	25	0.86	0.33	3.21	0.42	2.64

^{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

CONTENTS — Contents / Contenu / Inhalt / Contenuto / Contenido / Conteúdo / Περιεχόμενο / 组成 / Rinkinio sudėtis / Tartalom / Zawartość / Obsah / Obsah / 내용물 / İçindekiler / Содержание / Съдържание / 目錄

Manufactured by / Fabriqué par / Hergestellt von / Prodotto da / Fabricado por / Tillverkas av / Κατασκευαστής / 制造商 / Gamintojas / Gyártó: / Producent / Výrobce / Výrobca / 제조 / Üretici / Изготовлено / Произведено от / 製造商

Contains sufficient for <n> tests / Contenu suffisant pour "n" tests / Inhalt ausreichend für <n> Prüfungen / Contenuto sufficiente per "n" saggi / Contenido suficiente para <n> ensayos / Conteúdo suficiente para "n" ensaios / Räcker till "n" antal tester / Περιεχόμενο επαρκές για "ν" εξετάσεις / 含量足够 <n> 次测试 / Turinio pakanka < n > tyrim / <n> teszthez elegendő mennyiséget tartalmaz / Zawartość wystarcza na <n> testów / Lze použít pro <n> testů / Obsah vystačí na < n > testov / <n> 테스트에 대해 충분한 양 포함 / <n> sayıda test için yeterlidir / Содержит достаточно для количества тестов: <n> / Съдържа достатъчно за <n> теста / 內容物足夠執行 <n> 次測試

CE Mark / Marquage CE / CE-Kennzeichnung / Marchio CE / Marcado CE / Marcação CE / CE-märkning / Σήμανση CE / CE 标志 / CE ženklas / CE jelzés / Znak CE / Značka CE / Označenie CE / CE 표시 / CE İşareti / Маркировка CE / CE маркировка / CE 標識

SDS — Safety Data Sheet / Fiche technique santé-sécurité / Sicherheitsdatenblatt / Scheda dati di sicurezza / Hoja de datos de seguridad / Ficha de Dados de Segurança / Säkerhetsdatablad / Φύλλο Δεδομένων Ασφάλειας / 安全数据单 / Saugos duomenų lapas / Biztonsági adatlap / Karta Charakterystyki Bezpieczeństwa / Bezpečnostní list / Bezpečnostný list / 안전보건자료 / Güvenlik Bilgi Formu / Паспорт безопасности / Информационен Лист За Безопасност / 安全性資料表

Consult Instructions for Use / Consultez le mode d'emploi / Siehe Gebrauchsanweisung / Consultare le istruzioni per l'uso / Consulte las Instrucciones de uso / Instruções de utilização / Konsultera bruksanvisning / Συμβουλευτείτε τις οδηγίες χρήσης / 请参阅使用说明 / Skaitykite naudojimo instrukciją / Olvassa el a használati utasítást / Zapoznać się z instrukcją użycia / Postupujte podle návodu k použití / Prečítajte si návod na použitie / 사용 안내 문의 / Kullanma Talimatına Başvurun / Обратитесь к инструкциям / Вижте Инструкциите за употреба / 請參閱使用說明

Temperature range(s) / Plage(s) de température / Temperaturbereich(e) / Intervallo/i di temperatura / Intervalo(s) de temperatura / Intervalo(s) de temperatura / Temperaturintervall / Εύρος(-η) θερμοκρασίας / 温度范围 / Temperatūros diapazonas (-ai) / Hőmérséklet-tartomány(ok) / Zakres(y) temperatury / Rozsahy teplot / Rozsah(y) teploty / 온도 범위 / Sıcaklık aralıkları / Диапазон(-ы) температуры / Температурен(ни) диапазон(и) / 溫度範圍 請參閱使用說明

Caution / Précaution / Achtung / Attenzione / Precaución / Atenção / Försiktighet / Προσοχή / 注意事项 / Įspėjimas / Figyelem / Uwaga / Upozornění / Upozornenie / 주의 / Dikkat / Внимание / 注意

Expiration Date / Date D'expiration / Verfallsdatum, Verw. bis: / Data Di Scadenza / Fecha De Caducidad / Data de validade / Utgångsdatum / Ημερομηνία λήξης / 失效日期 / Galiojimo data / Lejárati idő / Data ważności / Datum exspirace / Dátum exspirácie / 만료 날짜 / Son Kullanma Tarihi / Срок годности / Срок на годност / 到期日

LOT — Lot Number / Numéro de lot / Chargennummer / Numero di lotto / Lote número / Número de lote / Satsnummer / Αριθ. παρτίδας / 批次号 / partijos numeris / Tételszám / Numer serii / Číslo šarže / 로트 번호 / Lot Numarası / Номер партии / Номер на партида / 批號

Date of Manufacture / Date de Fabrication / Herstellungsdatum / Data di Fabbricazione / Fecha de Fabricación / Data de Fabrico / Produktionsdatum / Ημερομηνία Παραγωγής / 生产日期 / Pagaminimo Data / Gyártás Dátuma / Data Produkcji / Datum Výroby / Dátum Výroby / 제조 일자 / Üretim Tarihi / Дата Производства / Дата на Производство / 製造日期

Biohazard / Risque biologique / Biogefährdung / Rischio biologico / Riesgo biológico / Risco biológico / Biologisk fara / Βιολογικός κίνδυνος / 生物危害 / Biologisk fara / Veszélyes biológiai anyag / Zagrożenie biologiczne / Biologické riziko / Biologické riziko / 생물학적 위험 / Biyolojik tehlike / Биологическая опасность / Биологична опасност / 生物危害

Radioactive / Radioactif / Radioaktiv / Radioattivo / Radiactivo / Radioactivo / Radioaktivt / Ραδιενεργό / 放射性 / Radioaktyvioji medžiaga / Radioaktív / Radioaktywny / Radioaktivní / Rádioaktívny / 방사성 / Radyoaktif / Радиоактивный / Радиоактивен / 具放射性

Ag 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

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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IMMUNOTECH s.r.o., Radiova 1122/1, 102 00 Prague 10, Czech Republic
www.beckmancoulter.com