BECKMAN COULTER

CE 2797

DHEA RIA

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

REVISION HISTORY

Previous version: IFU-DSL8900-01	Current version: IFU-DSL8900-02
MATERIALS PROVIDED **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 40 ng/mL of DHEA in buffer with bovine serum albumin and sodium azide (<0.1%). The exact concentration is indicated on each vial label. The calibrators are traceable to a certified reference material (Cerilliant) D-063. **Control samples: two 1 mL vials** (ready-to-use) The vials contain DHEA in buffer with bovine serum albumin and sodium azide (<0.1%). The control samples are traceable to a certified reference material (Cerilliant) D-063. The vials contain DHEA in buffer with bovine serum albumin and sodium azide (<0.1%). The concentration range is indicated on a supplement. The control samples are traceable to a certified reference material (Cerilliant) D-063.	**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 40 ng/mL of DHEA in buffer with bovine serum albumin and sodium azide (<0.1%). The calibrators are traceable to a certified reference material (Cerilliant) D-063. 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 1 mL vials** (ready-to-use) The vials contain DHEA in buffer with bovine serum albumin and sodium azide (<0.1%). The control samples are traceable to a certified reference material (Cerilliant) D-063. 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)*	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 DSL8900

FOR PROFESSIONAL USE ONLY

INTENDED PURPOSE

DHEA RIA is an in vitro diagnostic manual medical device intended to be used by healthcare professionals for the quantitative measurement of dehydroepiandrosterone (DHEA) in human serum and plasma. Measurement of DHEA is intended to be used for the diagnosis and differential diagnosis of hyperandrogenism and premature adrenarche and as an aid in the diagnosis of congenital adrenal hyperplasia in general population [1, 2, 3, 4].

PRINCIPLE

The radioimmunoassay of dehydroepiandrosterone (DHEA; androstenolone; 3β-hydroxy-5-androsten-17-one) is a competition assay. Samples or calibrators are incubated with ^{125}I-labeled DHEA, 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 DHEA concentrations in the samples are obtained by interpolation from the standard curve. The concentration of DHEA 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

All patient specimens should be handled as potentially infectious and waste should be discarded according to the country rules.

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.
- Frozen samples should be thawed and mixed thoroughly by gentle swirling or inversion prior to use.
- 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 30 samples (serum values ranging from 1.57 to 21.1 ng/mL) were compared using the DSL8900 DHEA RIA. Results are as follows:

[serum] = 0.9861 [plasma] + 0.1077; R = 0.9927

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 opening or dilution are indicated in paragraph Procedure.

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

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

The vial contains 350 kBq, at the date of manufacture, of ^{125}I-labeled DHEA in buffer with porcine gelatin, sodium azide (<0.1%) and a dye.

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 40 ng/mL of DHEA in buffer with bovine serum albumin and sodium azide (<0.1%). The calibrators are traceable to a certified reference material (Cerilliant) D-063.

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 1 mL vials (ready-to-use)

The vials contain DHEA in buffer with bovine serum albumin and sodium azide (<0.1%). The control samples are traceable to a certified reference material (Cerilliant) D-063.

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

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).
- Semi-automatic pipette (500 µL, 2 mL).
- Vortex type mixer.
- Horizontal or orbital shaker.
- Absorbent material for blotting tubes.
- A sponge rack or similar device for decantation.
- Aspiration system.
- Gamma counter set for ^{125}I.

For the dilution of serum and plasma samples

Diluent S: one vial (lyophilized)

Supplied upon request: REF. IM2445

- Diluent S needs to be assayed first in order to determine its DHEA endogenous concentration. This concentration needs to be subtracted from the patient sample DHEA concentration before multiplication by the dilution factor – see equation below. Results are meaningful if the concentration recovered is at least twice that of the concentration measured when assaying the diluent only.
- Sample concentration = [Concentration of DHEA from analysis – (Volume of Diluent S*Concentration of Diluent S)/(Volume of sample + Volume of Diluent S)]*Dilution factor

PROCEDURE

Preparation of reagents

Let all the reagents come to room temperature.

Calibrators and control samples

Once opened, store at < -20°C until expiration date of kit. Avoid repeated freezing and thawing of reagents.

Preparation of the wash solution

Pour the content 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: 25 µL of calibrator, control or sample and 500 µL of tracer.	Incubate 60 minutes at 18-25°C with shaking (≥ 280 rpm).	Aspirate carefully the content of tubes or decant (except «total cpm» tubes). Wash once 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 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 *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.

Samples

For each sample, locate ratio B/T or B/B$_0$ on the vertical axis and read off the corresponding analyte concentration on the horizontal axis.

To convert concentrations from ng/mL to nmol/L, multiply results by 3.46.

EXPECTED VALUES

We recommend each laboratory to establish its own reference values. The following values obtained with 243 apparently healthy subjects are indicative only.

Age (years)	N	Min.	Max.	Median	2.5th percentile	97.5th percentile
		ng/mL				
Males						
All males (19 - 74)	121	1.19	19.46	4.87	1.87	15.01
19 - 30	30	3.36	19.46	6.69	3.85	19.36
31 - 40	30	3.05	12.14	5.04	3.20	12.10
41 - 50	30	2.37	12.62	4.35	2.61	11.45
≥ 51	31	1.19	10.75	2.69	1.38	7.98
Females						
All females (19 - 69)	122	1.32	19.95	4.31	1.65	13.50
19 - 30	30	1.91	19.95	5.59	2.24	17.96
31 - 40	31	2.51	18.85	4.70	2.71	12.87
41 - 50	30	1.69	11.99	4.30	2.16	9.27
≥ 51	31	1.32	11.04	3.09	1.37	8.22

QUALITY CONTROL

Good laboratory practices require that control samples be used regularly to ensure the quality of the results obtained. These controls must be processed in exactly the same way as the patient samples, and it is recommended that their results be analyzed using appropriate statistical methods.

Failure to obtain the appropriate values for controls may indicate imprecise manipulations, improper sample handling or deterioration of reagents.

In case of packaging deterioration or if data obtained show some performance alteration, please contact your local distributor or use the following e-mail address: imunochem@beckman.com

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

According to EU regulation 2017/746, any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of EU Member State in which the user and/or patient is located.

PERFORMANCE CHARACTERISTICS

(For more details, see the data sheet "APPENDIX")

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

Sensitivity

Limit of Detection (LoD): 0.25 ng/mL

The LoD of the assay is 0.25 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 72 blank and 126 low level samples; and Limit of Blank (LoB) of 0.16 ng/mL.

Specificity

The antibody used in the immunoassay is highly specific for DHEA. Low cross reactivities were obtained with several compounds (DHEA-sulfate, isoandrosterone, androstenedione etc.).

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 9.05 % for serum samples. For within-laboratory precision the coefficients of variation were found below or equal to 17.3 % for serum samples.

Accuracy

Linearity

The assay demonstrated to be linear from 0.22 to 47.9 ng/mL using serum samples (determined consistent with guidelines in CLSI document EP06-A [7]).

Dilution test

High-concentration samples were serially diluted with Diluent S. The recovery percentages obtained were between 87.3% and 109.3% for serum samples.

Recovery test

Low-concentration samples were spiked with known quantities of DHEA. The recovery percentages obtained were between 80.5% and 113.1% for serum samples.

Measurement range (from LoD to the highest calibrator): 0.25 to approximately 40 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].

APPENDIX

PERFORMANCE CHARACTERISTICS

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

Summary and explanation of the test

Dehydroepiandrosterone (DHEA; androstenolone; 3β-hydroxy-5-androsten-17-one) is a C19 steroid produced in the adrenal cortex and, to a lesser extent, gonads [11, 12, 13]. DHEA serves as a precursor in testosterone and estrogen synthesis. Due to the presence of a 17-oxo (rather than hydroxyl) group, DHEA has relatively weak androgenic activity, which has been estimated at ~10% that of testosterone [11]. However in neonates, peripubertal children and in adult women, circulating DHEA levels may be several-fold higher than testosterone concentrations, and rapid peripheral tissue conversion to more potent androgens (androstenedione and testosterone) and estrogens may occur.

Moreover, DHEA has relatively low affinity for sex-hormone binding globulin. These factors may enhance the physiologic biopotency of DHEA. The physiologic role of DHEA has not been conclusively defined [14, 15]. A variety of in vitro effects, including antiproliferative effects in different cell lines and effects on enzyme-mediated cell metabolism, have been reported. In vivo studies suggest that DHEA may affect cholesterol and lipid metabolism, insulin sensitivity and secretion and immune function. Abnormal DHEA levels have been reported in schizophrenia [16] and obesity [17].

Therapeutic administration of DHEA has been proposed for several conditions, including obesity and cardiovascular disease [14, 15]. Serum DHEA levels are relatively high in the fetus and neonate, low during childhood, and increase during puberty [18, 19]. Increased levels of DHEA during adrenarche may contribute to the development of secondary sexual hair. Serum DHEA levels progressively decline after the third decade of life [14, 20, 21]. No consistent changes in serum DHEA levels occur during the menstrual cycle or pregnancy; however, parity may lower serum DHEA levels in premenopausal women [22]. DHEA has a rapid metabolic clearance rate as compared to its sulfated conjugate, DHEA-S. Because of this, serum DHEA levels are 100-1000 fold lower than DHEA-S levels. In addition, serum DHEA levels show significant diurnal variation which is dependent on adrenocorticotrophic hormone (ACTH) [12, 18]. Serum DHEA levels increase in response to exogenous ACTH administration [17]. Measurement of serum DHEA is a useful marker of adrenal androgen synthesis.

Abnormally low levels may occur in hypoadrenalism, and elevated levels occur in several conditions; including virilizing adrenal adenoma and carcinoma [23], 21-hydroxylase and 3β-hydroxysteroid dehydrogenase deficiencies and in some cases of female hirsutism [13]. This DHEA radioimmunoassay uses a sensitive and specific antibody with low cross-reactivity to other physiologic compounds, including DHEA-S. Unlike other methods for DHEA measurement, the DSL8900 DHEA RIA does not require prior sample extraction.

Interference

Serum samples containing DHEA concentrations (low and high) were spiked with multiple concentrations of the substances listed below and assayed using DHEA RIA. Values were calculated as described in CLSI EP07, 3rd ed. [24]. 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	1,856 ng/mL
Hemoglobin	1,338 µg/mL
Prednisone	145.6 ng/mL
Prednisolone	1,304 ng/mL
Acetylsalicylic acid	46.30 µg/mL
Ibuprofen	202.8 ng/mL
Cholesterol	4.50 mg/mL
Heparin	6,859 ng/mL
Unconjugated bilirubin	391.7 µg/mL
Conjugated bilirubin	512.9 µg/mL
Rheumatoid factor	43.5 IU/mL
Ascorbic acid	55.2 µg/mL
Triglycerides	23.6 ng/mL

In spite of hemoglobin, bilirubin (conjugated, unconjugated) and triglyceride interference data in the table, we advise to avoid using hemolyzed, lipemic or icteric samples.

Specificity

The percent cross-reactivity is expressed as the ratio of the DHEA concentration to the concentration of the reacting compound at 50% binding of the 0 ng/mL DHEA calibrator.

Compound	% Cross-reactivity
DHEA	100
Androstenediol	15.9
Isoandrosterone	3.16
Epiandrosterone	1.00
Δ4-Androstenedione	0.49
5α-Androstane-3ß,17ß-diol	0.40
DHEA glucuronide	0.32
5-α-Androstane-3,17-dione	0.10
Testosterone	0.06
5β-Androstane-3,17-dione	0.06
17α-hydroxypregnenolone	0.06
Androsterone	0.05
11β-Hydroxytestosterone	0.04
19-Hydroxyandrostenedione	0.03
5α-Dihydrotestosterone	0.03
4-Androsten-11β-ol-3,17-dione	0.03
DHEA sulfate	ND
Androsterone sulfate	ND
11-deoxycortisol	ND
Dihydroandrosterone	ND
5β-Androstan-3α-ol-17-one	ND
19-Nortestosterone	ND
Norethindrone	ND
Spironolactone	ND
4-Androsten-17β-ol-3,11-dione	ND
4-Androsten-17α-Ethynyl-17β-ol-3-one	ND
5β-Androstane-3α,17β-diol	ND
Aldosterone	ND
Corticosterone	ND
Cortisol	ND
Danazol	ND
Estriol	ND
Estrone	ND
Prednisone	ND
Triamcinolone	ND
Methyltestosterone	ND
11α-Hydroxyprogesterone	ND
5(10)Estren-17α-Ethynyl-17β-ol-3-one	ND
Estradiol	ND
Progesterone	ND
5β-Androstane-3β,17β-diol	ND
Dexamethasone	ND
Epitestosterone	ND

Precision

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	4.29	0.32	7.39	0.74	17.30
S2	2.85	0.17	5.85	0.40	13.90
S3	11.08	0.88	7.92	1.60	14.47
S4	15.09	1.37	9.05	2.21	14.67
S5	43.18	3.06	7.09	6.36	14.73

EDTA plasma	Mean, ng/mL	Repeatibility		Within laboratory precision	
		SD, ng/mL	C.V., %	SD, ng/mL	C.V., %
P1	2.00	0.15	7.55	0.35	17.63
P2	4.11	0.32	7.81	0.60	14.67
P3	7.32	0.50	6.77	0.82	11.24
P4	11.95	1.02	8.50	1.47	12.30
P5	16.25	1.43	8.82	2.57	15.79
P6	45.08	3.12	6.92	6.49	14.40

Accuracy

Linearity

The assay demonstrated to be linear from 0.21 to 48.3 ng/mL using EDTA plasma samples (determined consistent with guidelines in CLSI document EP06-A [7]).

Dilution test

Samples were diluted with Diluent S and assayed according to the assay procedure of the kit.

Serum	Dilution factor	DHEA (ng/mL)		Ratio (%) Measured/ Expected
		Measured	Expected	
S1	-	20.69	-	-
	1:2	11.08	10.35	107.1
	1:4	4.98	5.17	96.23
	1:8	2.58	2.59	99.71
S2	-	31.98	-	-
	1:2	15.46	15.99	96.65
	1:4	7.18	8.00	89.77
	1:8	3.49	4.00	87.27
S3	-	38.52	-	-
	1:2	19.29	19.26	100.1
	1:4	10.53	9.63	109.3
	1:8	4.81	4.82	99.87

EDTA plasma	Dilution factor	DHEA (ng/mL)		Ratio (%) Measured/ Expected
		Measured	Expected	
P1	-	10.12	-	-
	1:2	5.24	5.06	103.7
	1:4	2.77	2.53	109.4
	1:8	1.04	1.26	82.5
P2	-	16.38	-	-
	1:2	9.16	8.19	111.9
	1:4	4.55	4.09	111.1
	1:8	2.11	2.05	82.5
P3	-	25.00	-	-
	1:2	14.87	12.50	119.0
	1:4	7.38	6.25	118.0
	1:8	3.70	3.12	118.5

Recovery test

Samples were spiked with known quantities of DHEA 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	0.46	0.26	0.72	0.58	80.48
	0.42	0.70	1.12	0.93	83.12
	0.45	1.50	1.95	1.98	101.3
S2	5.32	2.05	7.37	7.37	100.0
	5.82	3.69	12.21	13.81	113.1
	5.69	12.78	18.47	17.37	94.03
S3	13.14	4.96	18.1	15.71	86.81
	12.72	14.13	26.85	26.24	97.71
	12.15	26.98	39.12	39.19	100.2

EDTA plasma	Endogen. conc.	Added conc.	Expected conc.	Measured conc.	Ratio (%) Measured/ Expected
	(ng/mL)				
P1	0.60	0.28	0.88	0.85	96.43
	0.61	0.83	1.44	1.27	87.95
	0.59	1.61	2.20	1.95	88.75
P2	7.01	2.90	9.91	9.96	100.5
	7.99	9.48	17.47	18.57	106.3
	7.74	18.37	26.11	27.65	105.9
P3	9.69	3.22	12.91	12.93	100.2
	11.15	12.23	23.38	21.81	93.27
	10.72	23.25	33.97	29.97	88.23

^{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

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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Σ — 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 — 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
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