BECKMAN COULTER

CE 2797

RIA DHEA sulfate

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

REVISION HISTORY

Previous version: PI-IM0729-05	**Current version:** IFU-IM0729-01
—	IVDR requirements incorporated
Chapter INTENDED USE removed	Chapter INTENDED PURPOSE added
—	Chapter APPENDIX: Interference data added
—	CLSI guidelines incorporated

REF IM0729

FOR PROFESSIONAL USE ONLY

INTENDED PURPOSE

RIA DHEA sulfate is an in vitro diagnostic manual medical device intended to be used by healthcare professionals for the quantitative measurement of dehydroepiandrosterone sulfate (DHEA-S) in human serum and plasma. Measurement of DHEA-S is intended to be used as an aid in the diagnosis and differential diagnosis of adrenocortical diseases, such as Cushing's syndrome, congenital adrenal hyperplasia or adrenal tumors in general population [1, 2, 3].

PRINCIPLE

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

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: 150995905IM072962.

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.
- 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 18 samples (serum values ranging from 48.66 to 323.7 µg/100 mL) were compared using the IM0729 RIA DHEA sulfate. Results are as follows:

[EDTA-plasma] = 0.8700[serum] + 7.4149,

R = 0.9940

MATERIALS PROVIDED

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

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

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

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

The vial contains 185 kBq, at the date of manufacture, of ^{125}I-labeled DHEA sulfate in buffer with proteins, sodium azide (<0.1%) and a dye.

Calibrators: six vials (lyophilized)

The calibrator vials contain from 0 to approximately 1000 µg/100 mL of DHEA sulfate lyophilized in human serum. The exact concentration is indicated on each vial label. The calibrators are traceable to an internal reference standard.

Control sample: one vial (lyophilized)

The vial contains DHEA sulfate lyophilized in human serum. The concentration range is indicated on a supplement. The control sample is traceable to an internal reference standard.

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).
- Vortex type mixer.
- Waterbath 37 ± 2°C.
- Aspiration system.
- Gamma counter set for ^{125}I.

PROCEDURE

Preparation of reagents

Let all the reagents come to room temperature.

Reconstitution of calibrators and control sample

The contents of the vials must be brought to room temperature before reconstitution with the volume of distilled 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 30 days or aliquoted at < -18°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: 25 µL of calibrator, control or sample and 500 µL of tracer. Vortex gently 1-2 seconds.	Cover tubes. Incubate 30 min in a water bath at 37±2°C.	Aspirate carefully the content of tubes (except the 2 tubes «total cpm»). Count bound cpm (B) and total cpm (T) for 1 minute.

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

RESULTS

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

Standard curve

The results in the quality control department were calculated using *spline* curve fit with logit of *B/T or B/B$_0$* on the vertical axis and log of analyte concentration of the calibrators on the horizontal axis.

Other calculation methods may give slightly different results.

Total activity: 70,745 cpm				
Calibrators	**DHEA sulfate (µg/100 mL)**	**cpm (n=3)**	**B/B$_0$ (%)**	**B/T (%)**
0	0	46,693	100.0	66.0
1	9.90	37,797	80.9	53.4
2	28.0	24,837	53.2	35.1
3	93.0	12,118	26.0	17.1
4	267	5,801	12.4	8.20
5	1,003	2,451	5.25	3.46

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

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 µg/100 mL into µmol/L, multiply results by **0.027**.

EXPECTED VALUES

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

Age (years)	N	Min.	Max.	Median	2.5th percentile	97.5th percentile
		DHEAs (µg/100 mL)				
Males						
All males	100	44	619	182	55	490
20 - 30	25	139	619	275	146	562
31 - 40	25	114	468	189	115	442
41 - 50	25	82	510	173	89	464
51 - 67	25	44	316	115	47	251
Females						
All females	99	15	475	126	31	288
19 - 30	25	57	475	167	61	384
31 - 40	25	51	264	154	56	255
41 - 50	25	42	307	140	55	272
51 - 62	24	15	220	72	23	207

Children		DHEAs (µg/100 mL)		
Age	**N**	**Mean**	**Standard deviation**	**Limit for the whole population**
<1 month	16	109	85	9 - 338
1-9 years	72	14	14	2 - 85
9-11 years	38	39	27	4 - 98
11-15 years	29	78	45	20 - 263
15-17 years	12	118	48	28 - 238

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): 2.51 µg/100 mL

The LoD of the assay is 2.51 µg/100 mL, determined consistent with guidelines in CLSI document EP17-A2 [4] based on the proportions of false positives (α) less than 5% and false negatives (β) less than 5%; using determinations, with 168 blank and 168 low level samples; and Limit of Blank (LoB) of 0 µg/100 mL.

Specificity

The antibody used in the immunoassay is highly specific for DHEA sulfate. Extremely low cross reactivities were obtained against other steroids (Androstenedione, Δ4-androstenedione, Cortisol, etc…) or therapeutic drugs that may be present in patient samples (Danazol, etc…).

Precision

Repeatability and within-laboratory precision

The precision of the assay was determined consistent with guidelines in CLSI document EP05-A3 [5]. For repeatability the coefficients of variation were found below or equal to 11.30% for serum samples. For within-laboratory precision the coefficients of variation were found below or equal to 12.58% for serum samples.

Accuracy

Linearity

The assay demonstrated to be linear from 9.13 to 1,081 µg/100 mL using serum samples (determined consistent with guidelines in CLSI document EP06-A [6]).

Dilution test

High-concentration serum samples were serially diluted with the zero calibrator. The recovery percentages obtained were between 93.0% and 119%.

Recovery test

Low-concentration serum samples were spiked with known quantities of DHEA sulfate. The recovery percentages obtained were between 91.9% and 103%.

Measurement range (from LoD to the highest calibrator): 2.51 to approximately 1,000 µg/100 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 [7, 8, 9].

APPENDIX

PERFORMANCE CHARACTERISTICS

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

Interference

Serum samples containing DHEA sulfate concentrations (low and high) were spiked with multiple concentrations of the substances listed below and assayed using RIA DHEA sulfate. Values were calculated as described in CLSI EP07, 3rd ed. [10]. 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
Acetylsalicylic acid	48.55 µg/mL
Ascorbic acid	70.49 µg/mL
Biotin	1,574 ng/mL
Conjugated bilirubin	334.3 µg/mL
Hemoglobin	10,929 µg/mL
Heparin	7,421 ng/mL
Cholesterol	8.30 mg/mL
Ibuprofen	406.1 µg/mL
Prednisone	127.1 ng/mL
Prednisolone	1,439 ng/mL
Rheumatoid factor	44.65 IU/mL
Triglycerides	23.42 mg/mL
Unconjugated bilirubin	379.7 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 DHEA sulfate concentration to the concentration of the reacting compound at 50% binding of the DHEA sulfate zero calibrator.

Steroid	Cross-reactivity (%)
DHEA sulfate	100
DHEA	95
DHEA glucuronide	65
Androsterone	6.80
Androsterone sulfate	5.70
Epiandrosterone	24.2
Dihydroandrosterone	0.05
Δ4-Androstenedione	1.30
5β-Androstan-3β, 17β-diol	0.09
5α-Androstan-3β, 17β-diol	0.02
Androstenediol	0.05
Testosterone	0.016
5α-Dihydrotestosterone	0.016
Epitestosterone	0.05
19-Nortestosterone	0.016
Methyltestosterone	0.016
11β-Hydroxytestosterone	<0.01
Aldosterone	<0.01
Progesterone	1.10
11α-Hydroxyprogesterone	1.00
Estrone	0.25
Estradiol	<0.01
Estriol	<0.01
19-Norethisterone	<0.01
Cortisol	<0.01
Corticosterone	0.025
Danazol	<0.01

Precision

Repeatability and within-laboratory precision

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

Serum	Mean (µg/100 mL)	Repeatability		Within laboratory precision	
		SD (µg/100 mL)	C.V. (%)	SD (µg/100 mL)	C.V. (%)
S1	19.53	2.21	11.30	2.46	12.58
S2	40.44	2.69	6.66	3.49	8.62
S3	113.9	5.52	4.85	7.31	6.42
S4	174.9	7.33	4.19	9.64	5.51
S5	580.1	33.87	5.84	58.38	10.06
S6	824.4	60.91	7.39	77.75	9.43

EDTA plasma	Mean (µg/100 mL)	Repeatability		Within laboratory precision	
		SD (µg/100 mL)	C.V. (%)	SD (µg/100 mL)	C.V. (%)
P1	8.88	0.64	7.25	1.03	11.64
P2	99.89	4.46	4.46	6.67	6.68
P3	196.7	10.33	5.25	14.29	7.27
P4	342.4	19.17	5.60	33.54	9.80
P5	608.5	38.90	6.39	64.31	10.57
P6	1,038	54.69	5.27	112.4	10.83

Accuracy

Linearity

The assay demonstrated to be linear from 5.99 to 1,059 µg/100 mL using EDTA plasma samples (determined consistent with guidelines in CLSI document EP06-A [6]).

Dilution test

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

Serum	Dilution factor	DHEA sulfate (µg/100 mL)		Ratio (%) Measured/ Expected
		Measured	Expected	
S1	-	233.0	-	-
	1:2	132.8	116.5	114.0
	1:4	60.57	58.25	104.0
	1:8	28.10	29.13	96.5
	1:16	14.75	14.56	101.3
S2	-	210.9	-	-
	1:2	109.5	105.4	103.8
	1:4	53.42	52.72	101.3
	1:8	26.51	26.36	100.6
	1:16	14.74	13.18	111.8
S3	-	140.0	-	-
	1:2	66.06	70.0	94.4
	1:4	32.53	34.99	93.0
	1:8	17.22	17.50	98.4
	1:16	10.38	8.75	118.7

EDTA plasma	Dilution factor	DHEA sulfate (µg/100 mL)		Ratio (%) Measured/ Expected
		Measured	Expected	
P1	-	148.4	-	-
	1:2	79.29	74.20	106.9
	1:4	41.79	37.09	112.7
	1:8	19.56	18.55	105.5
	1:16	10.26	9.27	110.6
P2	-	413.2	-	-
	1:2	221.3	206.6	107.1
	1:4	114.1	103.3	110.5
	1:8	55.33	51.65	107.1
	1:16	27.91	25.83	108.1
	1:32	13.39	12.91	103.7
P3	-	557.5	-	-
	1:2	269.5	278.7	96.7
	1:4	132.0	139.4	94.7
	1:8	64.94	69.69	93.2
	1:16	32.69	34.84	93.8
	1:32	15.13	17.42	86.8

Recovery test

Samples were spiked with known quantities of DHEA sulfate and assayed according to the assay procedure of the kit.

Serum	DHEA sulfate (µg/100 mL)				
	Endogen. conc.	Added conc.	Expected conc.	Measured conc.	Ratio (%) Measured/ Expected
S1	48.05	34.29	82.34	84.69	102.9
	46.55	66.44	113.0	110.9	98.14
	45.14	96.64	141.8	139.2	98.21
S2	106.7	34.29	141.0	143.2	101.6
	103.3	66.44	169.8	173.3	102.1
	100.2	96.64	196.8	191.2	97.15
S3	158.7	34.29	192.9	190.9	98.93
	153.7	66.44	220.1	202.3	91.90
	149.0	96.64	245.7	233.2	94.94

EDTA plasma	DHEA sulfate (µg/100 mL)				
	Endogen. conc.	Added conc.	Expected conc.	Measured conc.	Ratio (%) Measured/ Expected
P1	117.7	34.29	152.0	147.3	96.85
	114.1	66.44	180.5	173.0	95.82
	110.6	96.64	207.2	192.1	92.70
P2	91.80	34.29	126.1	129.3	102.6
	88.93	66.66	155.4	163.1	105.0
	86.24	96.64	182.9	189.5	103.6
P3	144.5	34.29	178.8	176.0	98.43
	140.0	66.44	206.4	201.3	97.52
	135.7	96.64	232.4	228.9	98.49

^{125}I Characteristics

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

^{125}I	E (MeV)	%
γ	0.035	
X	0.027	114
	0.032	25

Symbols Key

REF — Product Reference / Référence du produit / Produktreferenz / Riferimento prodotto / Número de referencia del producto / Referência do produto / Produktreferens / Κωδικός αναφοράς προϊόντος / 产品参考 / Gaminio nuoroda / Termékszám / Dane referencyjne produktu / Reference k produktu / Referenčné označenie výrobku / 제품 참조 자료 / Ürün Referansı / Ссылка на продукт / Референца за производ / 產品參考

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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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