

## DHEA RIA

Instruction for use in local language is available at [beckmancoulter.com/techdocs](http://beckmancoulter.com/techdocs).

### REVISION HISTORY

|   |   |
|---|---|
| <b>Previous version:</b><br>PI-DSL8900-06 | <b>Current version:</b><br>IFU-DSL8900-01 |
| —   | IVDR requirements incorporated            |
| Chapter INTENDED USE removed              | Chapter INTENDED PURPOSE added            |
| Traceability to an internal standard      | Traceability to the Cerilliant D-063      |

**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; 3 $\beta$ -hydroxy-5-androsten-17-one) is a competition assay. Samples or calibrators are incubated with <sup>125</sup>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 <sup>125</sup>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

P201

P280

P308+P313

May damage fertility or the unborn child.

Obtain special instructions before use.

Wear protective gloves, protective clothing and eye/face protection.

IF exposed or concerned: Get medical advice/attention.

Boric Acid 0.1 - 0.3%

Sodium Borate Decahydrate 0.1 - 0.3%



Safety Data Sheet is available at [beckmancoulter.com/techdocs](http://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 greater 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 into account.

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

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

**<sup>125</sup>I-Tracer: one 55 mL vial** (ready-to-use)

The vial contains 350 kBq, at the date of manufacture, of <sup>125</sup>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 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 concentration range is indicated on a supplement. The control samples are traceable to a certified reference material (Cerilliant) D-063.

**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 <sup>125</sup>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 =  $[\text{Concentration of DHEA from analysis} - (\text{Volume of Diluent S} \times \text{Concentration of Diluent S}) / (\text{Volume of sample} + \text{Volume of Diluent S})] \times \text{Dilution factor}$

## PROCEDURE

### Preparation of reagents

Let all the reagents come to room temperature.

### Calibrators and control samples

Once opened, store at  $< -20^{\circ}\text{C}$  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  $2-8^{\circ}\text{C}$  until the expiry date of the kit.

### Assay procedure

| Step 1<br>Additions*   | Step 2<br>Incubation  | Step 3<br>Counting  |
|--|---|---|
| To coated tubes add successively:<br><br>25 $\mu\text{L}$ of calibrator, control or sample and<br>500 $\mu\text{L}$ of tracer. | Incubate 60 minutes at $18-25^{\circ}\text{C}$ with<br>shaking ( $\geq 280$ rpm). | Aspirate carefully the content of tubes or<br>decant (except «total cpm» tubes).<br>Wash once with 2 mL of wash solution.<br>Count bound cpm (B) and total cpm<br>(T) for 1 minute. |

\*Add 500  $\mu\text{L}$  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  $B/T$  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: 109,109 cpm |              |           |         |                      |
|-----------------------------|--------------|-----------|---------|----------------------|
| Calibrators                 | DHEA (ng/mL) | cpm (n=2) | B/T (%) | B/B <sub>0</sub> (%) |
| 0                           | 0            | 49,496    | 45.3    | 100.0                |
| 1                           | 0.34         | 37,757    | 34.5    | 76.3                 |
| 2                           | 2.20         | 20,762    | 19.0    | 41.9                 |
| 3                           | 5.30         | 13,965    | 12.8    | 28.2                 |
| 4                           | 28.0         | 6,271     | 5.75    | 12.7                 |
| 5                           | 45.0         | 4,804     | 4.40    | 9.71                 |

(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 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 | 2.5 <sup>th</sup> percentile | 97.5 <sup>th</sup> percentile |
|------------------------------|-----|------|-------|--------|------------------------------|-------------------------------|
| ng/mL                        |     |      |       |        |                              |                               |
| Males                        |     |      |       |        |                              |                               |
| <b>All males (19 - 74)</b>   | 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                      |     |      |       |        |                              |                               |
| <b>All females (19 - 69)</b> | 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](mailto:imunochem@beckman.com)

In the US, contact the Beckman Coulter technical support at 1-800-854-3633; or by email at: [immunoassay@beckman.com](mailto: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 ( $\alpha$ ) less than 5% and false negatives ( $\beta$ ) 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].

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## 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; androstenedione; 3 $\beta$ -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 3 $\beta$ -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, 3<sup>rd</sup> 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 $\mu$ g/mL   |
| Prednisone             | 145.6 ng/mL        |
| Prednisolone           | 1,304 ng/mL        |
| Acetylsalicylic acid   | 46.30 $\mu$ g/mL   |
| Ibuprofen              | 202.8 ng/mL        |
| Cholesterol            | 4.50 mg/mL         |
| Heparin                | 6,859 ng/mL        |
| Unconjugated bilirubin | 391.7 $\mu$ g/mL   |
| Conjugated bilirubin   | 512.9 $\mu$ g/mL   |
| Rheumatoid factor      | 43.5 IU/mL         |
| Ascorbic acid          | 55.2 $\mu$ g/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               |
| $\Delta$ 4-Androstenedione                           | 0.49               |
| 5 $\alpha$ -Androstane-3 $\beta$ ,17 $\beta$ -diol   | 0.40               |
| DHEA glucuronide                                     | 0.32               |
| 5- $\alpha$ -Androstane-3,17-dione                   | 0.10               |
| Testosterone   | 0.06               |
| 5 $\beta$ -Androstane-3,17-dione                     | 0.06               |
| 17 $\alpha$ -hydroxypregnenolone                     | 0.06               |
| Androsterone   | 0.05               |
| 11 $\beta$ -Hydroxytestosterone                      | 0.04               |
| 19-Hydroxyandrostenedione                            | 0.03               |
| 5 $\alpha$ -Dihydrotestosterone                      | 0.03               |
| 4-Androsten-11 $\beta$ -ol-3,17-dione                | 0.03               |
| DHEA sulfate   | ND                 |
| Androsterone sulfate                                 | ND                 |
| 11-deoxycortisol                                     | ND                 |
| Dihydroandrosterone                                  | ND                 |
| 5 $\beta$ -Androstan-3 $\alpha$ -ol-17-one           | ND                 |
| 19-Nortestosterone                                   | ND                 |
| Norethindrone  | ND                 |
| Spironolactone                                       | ND                 |
| 4-Androsten-17 $\beta$ -ol-3,11-dione                | ND                 |
| 4-Androsten-17 $\alpha$ -Ethyne-17 $\beta$ -ol-3-one | ND                 |
| 5 $\beta$ -Androstane-3 $\alpha$ ,17 $\beta$ -diol   | ND                 |
| Aldosterone  | ND                 |
| Corticosterone                                       | ND                 |
| Cortisol   | ND                 |
| Danazol  | ND                 |
| Estriol  | ND                 |
| Estrone  | ND                 |
| Prednisone   | ND                 |
| Triamcinolone  | ND                 |
| Methyltestosterone                                   | ND                 |
| 11 $\alpha$ -Hydroxyprogesterone                     | ND                 |
| 5(10)Estr-17 $\alpha$ -Ethyne-17 $\beta$ -ol-3-one   | ND                 |
| Estradiol  | ND                 |
| Progesterone   | ND                 |
| 5 $\beta$ -Androstane-3 $\beta$ ,17 $\beta$ -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 | Repeatability |         | 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 (%)<br>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 (%)<br>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/<br>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/<br>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                           |

## <sup>125</sup>I Characteristics

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


| <sup>125</sup> 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 / Κυβικός αναφοράς προϊόντος / 产品参考 / Gaminio nuoroda / Termékszám / Dane referencyjne produktu / Reference k produktu / Referenčné označenie výrobku / 제품 참조 자료 / Úrün 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 / In 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 / Råcker till "n" antal tester / Περιεχόμενο επαρκές για "n" 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> sayida test için yeterlidir / Содержит достаточно для количества тестов: <n> / Съдържа достатъчно за <n> теста / 内容物足夠執行 <n> 次測試


**CE** CE Mark / Marquage CE / CE-Kennzeichnung / Marchio CE / Marcado CE / Marcação CE / CE-märkning / Σήμανση CE / 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 adattal / 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 / Kullanna Talimatina Başvurun / Обратитесь к инструкциям / Вижте Инструктите 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) / 温度範圍 請參閱使用說明

 Caution / Précaution / Achtung / Attenzione / Precaución / Atenção / Försiktighet / Προσοχή / 注意事项 / İspējimas / 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 expirace / Dátum expirácie / 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 Fabricazione / 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 / Radioaktiv / Ραδιενεργό / 放射性 / Radioaktyvioji medžiaga / Radioaktiv / Radioaktywny / Radioaktivní / Rádioaktívny / 방사성 / Radyoaktif / Радиоактивный / Радиоактивен / 具放射性



Tracer / Traceur / Tracer / Marcato / Trazador / Marcador / Tracer / Αιχνευτής / 追踪剂 / Atsekamoji medžiaga / Nyomjelző / Znacznik / Radioindikátor / Indikátor (tracer) / 트레이서 / Tracer'lar / метка / Индикатор / 追蹤劑



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Control / Contrôle / Kontrolle / Controllo / Control / Controllo / Kontrolle / Μάρτυρας / 质控品 / Kontrolliné / Kontroll / Kontrola / Kontrola / Kontrola / 정도관리 / Kontrol / Контроль / Контролна / 質控品



Tubes / tubes / Röhrchen / provette / tubos / Tubos de amostra / Provrör / σωληνάρια / 试管 / Mégintüveliai / Csövek / Probówki / Zkumavky / Skúmavky / 튜브 / Tüpler / пробирки / Епруветки / 試管



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