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Changes: §
Deletions: § 4

LIAISON® Androstenedione (REF 318870)

1. INTENDED USE

The DiaSorin LIAISON® Androstenedione assay is an *in vitro* diagnostic chemiluminescent immunoassay (CLIA) intended for the quantitative determination of Δ4-Androstenedione in human serum and EDTA plasma. Assay results should be used in conjunction with other clinical and laboratory data to assist the clinician in making individual patient management decisions. The assay must be performed on the LIAISON® Analyzer family*.

2. SUMMARY AND EXPLANATION OF THE TEST

Δ^4-Androstenedione, commonly referred to simply as androstenedione, and also known as androst-4-ene-3,17-dione or 17-ketotestosterone, is an endogenous androgen steroid hormone and is a precursor of cortisol, aldosterone, testosterone, and estrogen[1].

Androstenedione is converted to either testosterone or estrogen. In males, conversion of androstenedione to testosterone requires the enzyme 17β-hydroxysteroid dehydrogenase. In females, androstenedione is released into the blood by theca cells. Conversion of androstenedione to estrogen (e.g., estrone and estradiol) requires the enzyme aromatase. Androstenedione is a substrate for estrogen production in granulosa cells which produce aromatase[2].

Androstenedione is secreted predominately by the adrenal gland and production is at least partly controlled by adrenocorticotropic hormone (ACTH). It is also produced ACTH-independent in the testes and ovaries from adrenal-secreted dehydroepiandrosterone sulfate (DHEA-S)[3,4]. Androstenedione is a crucial sex-steroid precursor.

Androstenedione production during life mimics the pattern of other androgen precursors. Fetal serum concentrations increase throughout embryonal development and peak near birth at approximately young adult levels. Levels then fall rapidly during the first year of life to low prepubertal values. With the onset of adrenarche, androstenedione levels rise gradually, a process that accelerates with the onset of puberty, reaching adult levels around age 18[5].

Elevated androstenedione levels can cause symptoms or signs of hyperandrogenism or virilization in women. Symptoms of this may include excess body and facial hair growth (called hirsutism), stopping of periods (amenorrhoea), worsening acne and changes to the genitalia[6]. Men are usually asymptomatic, but through peripheral conversion of androgens to estrogens can occasionally experience mild symptoms of estrogen excess, such as gynecomastia. Most mild-to-moderate elevations in androstenedione are idiopathic. However, pronounced elevations of androstenedione may be indicative of androgen-producing adrenal or gonadal tumors[7].

3. PRINCIPLE OF THE PROCEDURE

The method for quantitative determination of Androstenedione is a direct, competitive chemiluminescence immunoassay (CLIA). During the first incubation, Δ4-Androstenedione binds to the specific antibody on the solid phase. Paramagnetic particles, assay buffer, and controls, calibrators or patient samples are combined for the intial incubation. After 10 minutes the tracer, (Androstenedione derivative linked to an isoluminol derivative) is added. After a second 10 minute incubation, the unbound material is removed with a wash cycle. Subsequently, the starter reagents are added to initiate a flash chemiluminescent reaction. The light signal is measured by a photomultiplier as relative light units (RLU) and is inversely proportional to the concentration of Δ4-Androstenedione present in calibrators, controls, or samples.

*(LIAISON® and LIAISON® XL)

4. MATERIALS PROVIDED

Reagent Integral

Magnetic Particles (2.4 mL)	SORB	Magnetic particles coated with sheep monoclonal antibody against Androstenedione in phosphate buffer containing surfactant and < 0.1% sodium azide.
Conjugate (12 mL)	CONJ	Proprietary polymer conjugated with Androstenedione and an isoluminol derivative, in MES buffer with surfactant and 0.1% ProClin® 300.
Assay Buffer (12 mL)	BUF AS	Phosphate buffer with sheep serum and 0.1% ProClin® 300 for preservative.
Number of Tests		100

ProClin is a trademark of the Dow Chemical Company (Dow) or an affiliated company of Dow.

The order of reagents reflects the layout of containers in the Reagent Integral**.**

Additional components not on the Reagent Integral

Calibrator 1 (3 mL)	CAL 1	Human hormone free serum containing Androstenedione and 0.2% ProClin® 300 and 0.01% Gentamicin sulfate.
Calibrator 2 (3 mL)	CAL 2	Human hormone free serum containing Androstenedione and 0.2% ProClin® 300 and 0.01% Gentamicin sulfate.

Standardization: The calibrator concentrations (ng/mL) are referenced to an in-house standard preparation.

All reagents are supplied ready to use.

Materials required but not provided (system related)

LIAISON® XL Analyzer	LIAISON® Analyzer
LIAISON® Wash/System Liquid (REF 319100) LIAISON® XL Waste Bags (REF X0025) LIAISON® XL Cuvettes (REF X0016) LIAISON® XL Starter Kit (REF 319200) LIAISON® XL Disposable Tips (REF X0015)	LIAISON® Wash/System Liquid REF (319100) LIAISON® Waste Bags (REF 450003) LIAISON® Module (REF 319130) LIAISON® Starter Kit (REF 319102) LIAISON® XL Starter Kit (REF 319200) LIAISON® Cleaning Kit (REF 310990) LIAISON® Light Check 12 (REF 319150)

Additional required materials:

LIAISON® Androstenedione Control Set (REF 318871)

Additional recommended material

LIAISON® Endocrinology Diluent (REF 319133)

5. WARNINGS AND PRECAUTIONS

FOR *IN VITRO* DIAGNOSTIC USE – Not for internal or external use in humans or animals.

General Safety:

- All specimens, biological reagents and materials used in the assay must be considered potentially able to transmit infectious agents. Avoid contact with skin, eyes or mucous membranes. Follow good industrial hygiene practices during testing.
- Do not eat, drink, smoke or apply cosmetics in the assay laboratory.
- Do not pipette solutions by mouth.
- Avoid direct contact with all potentially infectious materials by wearing lab coat, protective eye/face wear and disposable gloves.
- Wash hands thoroughly at the end of each assay.
- Avoid splashing or forming aerosols when handling, diluting or transferring specimens or reagents. Any reagent spill should be decontaminated with 10% bleach solution (containing 0.5% sodium hypochlorite) and disposed of as though potentially infectious.
- Waste materials should be disposed of in accordance with the prevailing regulations and guidelines of the agencies holding jurisdiction over the laboratory, and the regulations of each country.
- Do not use kits or components beyond the expiration date given on the label.

Chemical Hazard and Safety Information: Reagents in this kit are classified in accordance with US OSHA Hazard Communication Standard; individual US State Right-to-Know laws; Canadian Centre for Occupational Health and Safety Controlled Products Regulations; and applicable European Union directives (see Material Safety Data Sheet for additional information).

Reagents Containing Human Source Material:
Warning – Treat as potentially infectious. Each serum/plasma donor unit used in the preparation of this product has been tested by an U.S. FDA approved method and found non-reactive for the presence of the antibody to Human Immunodeficiency Virus 1 and 2 (HIV 1/2), the Hepatitis B surface antigen (HBsAg), and the antibody to Hepatitis C (HCV). While these methods are highly accurate, they do not guarantee that all infected units will be detected. This product may also contain other human source diseases for which there is no approved test. Because no known test method can offer complete assurance that HIV, Hepatitis B Virus (HBV) and HCV or other infectious agents are absent, all products containing human source material should be handled following universal precautions; and as applicable in accordance with good laboratory practices as described in the Centers for Disease Control and the National Institutes of Health current manual, Biosafety in Microbiological and Biomedical Laboratories (BMBL); or the World Health Organization current edition, Laboratory Biosafety Manual.

GHS/CLP:

	ProClin®	Sodium Azide
CAS No.:	55965-84-9	26628-22-8
Reagents:	CONJ CAL 1 CAL 2 BUF AS	SORB
Classification:	Skin sensitization, Category 1 Aquatic Chronic, Category 3	None required
Signal Word:	Warning	None required
Pictogram:	 GHS07 – Exclamation mark	None required
Hazard Statements:	H317 – May cause an allergic skin reaction. H412 – Harmful to aquatic life with long lasting effects.	None required
Precautionary Statements:	P261 – Avoid breathing mist or spray. P272 – Contaminated work clothing should not be allowed out of the workplace. P273 – Avoid release to the environment. P280 – Wear protective gloves and clothing, and eye protection.	None required

REAGENTS CONTAINING SODIUM AZIDE: Sodium azide may react with lead or copper plumbing to form highly explosive metal azides. On disposal, flush with a large volume of water to prevent azide build-up. For further information, refer to "Decontamination of Laboratory Sink Drains to Remove Azide Salts," in the Manual Guide-Safety Management No. CDC-22 issued by the Centers for Disease Control and Prevention, Atlanta, GA, 1976.

6. PREPARATION OF THE REAGENT INTEGRAL

Please note the following important reagent handling precautions:

6.1 Resuspension of magnetic particles

Magnetic particles must be completely resuspended before the integral is placed on the instrument. Follow the steps below to ensure complete suspension:

- Before the seal is removed, rotate the small wheel at the magnetic particle compartment until the colour of the suspension has changed to brown. Gentle and careful side-to-side mixing may assist in the suspension of the magnetic particles (avoid foam formation). Visually check the bottom of the magnetic particle vial to confirm that all settled magnetic particles have resuspended.
- Repeat as necessary until the magnetic particles are completely resuspended.
- After removal of the seal carefully wipe the surface of each septum to remove residual liquid if necessary.

6.2 Foaming of reagents

In order to ensure optimal performance of the integral, foaming of reagents should be avoided. Adhere to the recommendation below to prevent this occurrence:

- Visually inspect the reagents to ensure there is no foaming present before using the integral. If foam is present after re-suspension of the magnetic particles, place the integral on the instrument and allow the foam to dissipate. The integral is ready to use once the foam has dissipated and the integral has remained onboard and mixing.

6.3 Loading of integral into the reagent area

LIAISON® Analyzer

- Place the integral into the reagent area of the analyzer with the bar code label facing left and let it stand for 30 minutes before using. The analyzer automatically stirs and completely resuspends the magnetic particles.
- Follow the analyzer operator's manual to load the specimens and start the run.

LIAISON® XL Analyzer

- LIAISON® XL Analyzer is equipped with a built-in solid-state magnetic device which aids in the dispersal of microparticles prior to placement of a Reagent Integral into the reagent area of the analyzer. Refer to the analyzer operator's manual for details.
    a. Insert the reagent integral into the dedicated slot.
    b. Allow the reagent integral to remain in the solid-state magnetic device for at least 30 seconds (up to several minutes). Repeat as necessary.
- Place the integral into the reagent area of the analyzer with the label facing left and let it stand for 15 minutes before using. The analyzer automatically stirs and completely resuspends the magnetic particles.
- Follow the analyzer operator's manual to load the specimens and start the run.

7. STORAGE AND STABILITY OF THE REAGENT INTEGRAL

Upon receipt, the reagent integral must be stored in an upright position to facilitate re-suspension of magnetic particles. When the reagent integral is stored unopened the reagents are stable at 2-8°C up to the expiration date. Do not freeze. The reagent integral should not be used past the expiration date indicated on the kit and reagent integral labels. After removing seals reagent integral may be returned to the kit box and stored upright at 2-8°C or stored on board the Analyzer for 28 days. Undue exposure to light should be avoided.

8. SPECIMEN COLLECTION AND PREPARATION

Either human serum, EDTA plasma or serum separator tubes may be used. (Fasting samples are recommended, but not required). Blood should be collected aseptically by venipuncture. Serum samples should be allowed to clot. Centrifuge samples and separate serum from the clot or plasma from the cells as soon as possible. No additives or preservatives are required to maintain integrity of the sample. Samples having particulate matter, turbidity, lipemia, or erythrocyte debris may require clarification by filtration or centrifugation before testing. Grossly hemolyzed or lipemic samples as well as samples containing particulate matter or exhibiting obvious microbial contamination should not be tested. Check for and remove air bubbles before assaying. Samples are stable at room temperature for up to 48 hours. If the assay is performed within 14 days of sample collection, the samples should be kept at 2-8°C; otherwise they should be stored frozen (-20°C or below). If samples are stored frozen, mix thawed samples well before testing. Samples may be frozen-thawed 3 times. Self-defrosting freezers are not recommended for sample storage.

The minimum specimen volume required for a single determination is 250 µL. [100 µL specimen for testing + 150 µL dead volume (volume left at the bottom of the aliquot tube which the instrument cannot aspirate)].

9. CALIBRATORS 1 and 2

The LIAISON® Androstenedione calibrators are liquid and ready to use. Upon receipt, the calibrators must be stored at 2-8°C in an upright position. Unopened calibrators are stable at 2-8°C up to the expiry date indicated on the kit and calibrator labels. Calibrators should be equilibrated to room temperature and mixed thoroughly by gentle inversion.
Calibrate the assay as described in the Operator’s manual. Once opened, remaining liquid calibrators should be re-capped and returned to 2-8°C. Open use is 4 weeks when stored at 2-8°C. During handling, use appropriate precautions to avoid bacterial contamination of calibrators.

Transfer vial to appropriate analyzer rack.

Calibrator and reagent integral lot number are lot specific. Do not use calibrators matched with a different reagent lot in the same assay.

10. CALIBRATION

Individual LIAISON® Androstenedione reagent integrals contain specific information for calibration of the particular reagent integral lot. Test of assay specific calibrators allows the detected relative light units (RLU) values to adjust the assigned master curve. Each calibration solution allows 7 calibrations to be performed.
Recalibration in triplicate is mandatory whenever at least 1 of the following conditions occurs:

- With each new lot of reagents (Reagent Integral or Starter Reagents).
- The previous calibration was performed more than 7 days prior.
- Quality Control results are out of the acceptable range.
- The Analyzer has been serviced.

Refer to the analyzer operator’s manual for calibration instructions.

Measuring range: The LIAISON® Androstenedione assay measures between 0.24 and 10 ng/mL. The lowest reportable value is 0.24 ng/mL. Values below 0.24 ng/mL should be reported as < 0.24 ng/mL. The highest reportable value without dilution is 10 ng/mL.

Samples that read above the assay range may be diluted with the LIAISON® Endocrinology Diluent (REF 319133) and retested.
Suggested dilution: 1 part sample and 3 parts diluent.

11. ASSAY PROCEDURE

To ensure proper test performance, strictly adhere to the operating instructions of the Analyzer.

LIAISON® Analyzer: Each test parameter is identified via the bar codes on the reagent integral label. In the event that the barcode label cannot be read by the analyzer, the integral cannot be used. Do not discard the reagent integral; contact your local DiaSorin technical support for instruction.

LIAISON® XL Analyzer: Each test parameter is identified via information encoded in the Reagent Integral Radio Frequency Identification transponder (RFID Tag). In the event that the RFID Tag cannot be read by the analyzer, the integral cannot be used. Do not discard the reagent integral: contact your local DiaSorin technical support for instruction. For details, refer to the analyzer operator's manual

The analyzer operations are as follows:

LIAISON® or LIAISON® XL

1. Dispense sample, calibrator or control into reaction module.
2. Dispense magnetic particle and Assay Buffer into reaction module.
3. Incubate
4. Dispense conjugate into reaction module.
5. Incubate
6. Wash with Wash/System liquid
7. Add the Starter Reagents and measure the light emitted

12. QUALITY CONTROL

Quality control is required to be performed once per day of use, or according to the guidelines or requirements of local regulations or accredited organizations. It is recommended that the user refer to CLSI C24-A3 and 42 CFR 493.1256 (c) for guidance on appropriate quality control practices.

LIAISON® Androstenedione controls are intended to monitor for substantial reagent failure. LIAISON® controls should be run in singlicate to monitor the assay performance. If control values lie within the expected ranges provided on the certificate of analysis, the test is valid. If control values lie outside the expected ranges, the test is invalid and patient results cannot be reported. Assay calibration should be performed if a control failure is observed and controls and patient specimens must be repeated.

The performance of other controls should be evaluated for compatibility with this assay before they are used. Appropriate value ranges should be established for all quality control materials used.

The range of concentrations of each control is reported on the certificate of analysis and indicates the limits established by DiaSorin for control values that can be obtained in reliable assay runs.

13. INTERPRETATION OF RESULTS

The Analyzer automatically calculates the concentration of Androstenedione in the sample. This concentration is expressed in **ng/mL**.
To convert results to SI units: 1 ng/mL = 3.49 nmol/L

Warning – If the sample result displays "invalid RLU" and an exclamation mark (!) flag, the result obtained lies below the assay signal range. The sample must be retested. If the sample upon retest still displays "invalid RLU", call DiaSorin Technical Support.

14. LIMITATIONS OF THE PROCEDURE

1. Assay results should be utilized in conjunction with other clinical and laboratory data to assist the clinician in making individual patient management decisions.
2. A skillful technique and strict adherence to the instructions are necessary to obtain reliable results.
3. Bacterial contamination of samples may affect the test results.
4. Grossly hemolyzed, icteric or lipemic samples as well as samples containing particulate matter or exhibiting obvious microbial contamination are not recommended and should not be tested.
5. Do not heat inactivate serum or plasma
6. Patients routinely exposed to animals, animal serum products, or other immunogenic products that may elicit heterophilic antibody production against the assay's reagents can be prone to this interference and anomalous values may be observed.
7. Results for patients being treated with exemestane and/or formestane should be interpreted with caution.

Integrals may not be exchanged between analyzer types (LIAISON® and LIAISON® XL). Once an integral has been introduced to a particular analyzer type, it must always be used on that analyzer until it has been exhausted. Due to traceability issues resulting from the above statement, patient follow-ups may not be concluded between analyzer types. These must be accomplished on one particular analyzer type (either LIAISON® or LIAISON® XL).

15. EXPECTED VALUES

It is recommended that each laboratory establish its own range of expected values for the population taken into consideration.

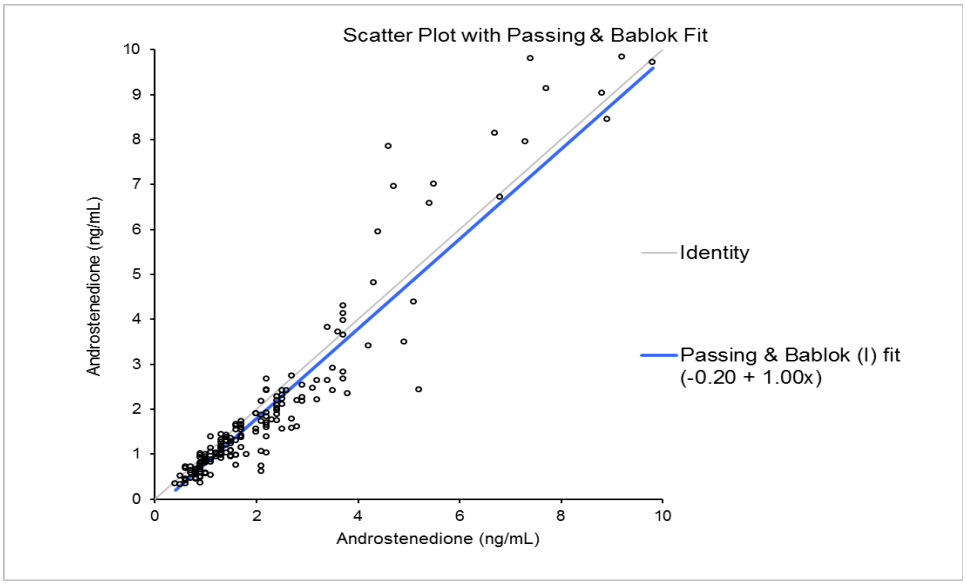
Adult Population	Median	Observed Range 2.5^{th} to 97.5^{th} Percentile
Males (n=177)	1.80 ng/mL	0.5 ng/mL – 3.5 ng/mL
Postmenopausal Females (n=123)	0.70 ng/mL	0.1 ng/mL – 2.1 ng/mL
Premenopausal Females (n=171)	1.60 ng/mL	0.4 ng/mL – 3.4 ng/mL

Pediatric population(s)	Age (years)	Median (ng/mL)	Observed Range (ng/mL) 2.5^{th} to 97.5^{th} Percentile
Females	2-6 (n=251)	0.10	0.00-0.34
	7-11 (n=252)	0.35	0.12-2.41
	12-16 (n=252)	1.62	0.42-3.41
	17-21 (n=248)	2.01	0.70-4.31
Males	2-6 (n=252)	0.11	0.02-0.29
	7-11 (n=251)	0.23	0.07-0.74
	12-16 (n=252)	0.84	0.25-2.21
	17-21 (n=251)	1.28	0.44-2.65

16. SPECIFIC PERFORMANCE CHARACTERISTICS

16.1 Method Correlation:

A total of 171 (type serum, EDTA plasma) samples spanning the assay range, were tested by the LIAISON® Androstenedione and by another commercially available method following CLSI EP9, and yielded the following Passing & Bablok regression analysis: LIAISON® Androstenedione = 1.00 (Reference Method) – 0.20; R = 0.953.



16.2 Precision with LIAISON® Analyzer

1 lot of kit controls and 6 serum samples spanning the range of the assay, were tested twice per day in duplicate, over 20 operating days using 1 reagent lot at DiaSorin Inc. The testing was performed according to CLSI EP5-A3.

Repeatability	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**
Number of determinations	80	80	80	80	80	80	80	80
Mean (ng/mL)	0.76	0.87	1.42	2.30	3.55	6.48	6.77	8.75
Standard Deviation (ng/mL)	0.023	0.030	0.034	0.034	0.049	0.158	0.139	0.178
Coefficient of variation (%)	3.0%	3.4%	2.4%	1.5%	1.4%	2.4%	2.1%	2.0%

Reproducibility	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**
Number of determinations	80	80	80	80	80	80	80	80
Mean (ng/mL)	0.76	0.87	1.42	2.30	3.55	6.48	6.77	8.75
Standard Deviation (ng/mL)	0.042	0.108	0.072	0.077	0.140	0.500	0.246	0.695
Coefficient of variation (%)	5.6%	12.3%	5.1%	3.4%	3.9%	7.7%	3.6%	7.9%

16.3 Precision with LIAISON® XL Analyzer

1 lot of kit controls and 6 serum samples spanning the range of the assay, were tested twice per day in duplicate, over 20 operating days using 1 reagent lot at DiaSorin Inc. The testing was performed according to CLSI EP5-A3.

Repeatability	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**
Number of determinations	80	80	80	80	80	80	80	80
Mean (ng/mL)	0.77	1.05	1.50	2.49	3.87	6.30	6.98	9.45
Standard Deviation (ng/mL)	0.017	0.024	0.039	0.025	0.038	0.084	0.144	0.115
Coefficient of variation (%)	2.3%	2.3%	2.6%	1.0%	1.0%	1.3%	2.1%	1.2%

Reproducibility	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**
Number of determinations	80	80	80	80	80	80	80	80
Mean (ng/mL)	0.77	1.05	1.50	2.49	3.87	6.30	6.98	9.45
Standard Deviation (ng/mL)	0.048	0.102	0.068	0.079	0.146	0.150	0.309	0.687
Coefficient of variation (%)	6.2%	9.7%	4.5%	3.2%	3.8%	2.4%	4.4%	7.3%

16.4 Limit of Blank (LoB)*
Following the method from CLSI EP17-A2, the limit of blank for the LIAISON® Androstenedione assay for serum is ≤ 0.17 ng/mL.

*Limit of Blank, or the highest value likely to be observed with a sample containing no analyte, replaces the term "analytical sensitivity".

16.5 Limit of Detection (LoD)
Following the method from CLSI EP17-A, the limit of detection for the LIAISON® Androstenedione assay for serum is 0.24 ng/mL.

16.6 Limit of Quantitation (LoQ)
Following the method from CLSI EP17-A, the limit of quantitation for LIAISON® Androstenedione assay for serum is 0.30 ng/mL.

16.7 Linearity Study
1 high sample pool of each specimen type (serum, SST serum, EDTA plasma) containing endogenous and/or spiked Androstenedione above the measuring range of the assay at 10 ng/mL were diluted and tested by the LIAISON® Androstenedione assay following CLSI EP6-A. The results for each sample were analyzed by regression of observed concentration versus expected concentration.

The resulting equations for each sample type are:
Serum: Observed Androstenedione = 1.015x – 0.0186; R^2 = 0.9993
SST Serum: Observed Androstenedione = 0.9854x – 0.0227; R^2 = 0.9992
EDTA plasma: Observed Androstenedione = 1.001x + 0.1845; R^2 = 0.9965

16.8 Recovery
5 high concentration (endogenous or spiked) serum samples and 5 low concentration serum samples were analyzed neat. Recovery samples were then prepared by mixing defined ratios of the high and low samples and tested in replicates of 5. The mean results of the 5 replicates are provided in the table below.

	Defined concentration	Expected (ng/mL)	Observed (ng/mL)	% Recovery
Sample 1				
High neat	9.1	-		-
2 H:1 L		6.3	6.4	101%
1 H:1 L		4.9	4.9	100%
1 H:2 L		3.5	3.5	101%
Low neat	0.72	-		-
Sample 2				
High neat	6.9	-		-
2 H:1 L		5.0	4.5	90%
1 H:1 L		4.0	3.7	93%
1 H:2 L		3.0	2.7	90%
Low neat	1.1	-		-
Sample 3				
High neat	6.3	-		-
2 H:1 L		4.6	4.4	95%
1 H:1 L		3.8	3.8	99%
1 H:2 L		2.9	2.8	96%
Low neat	1.3	-		-
Sample 4				
High neat	8.1	-		-
2 H:1 L		6.0	5.9	97%
1 H:1 L		4.9	4.6	94%
1 H:2 L		3.9	3.7	95%
Low neat	1.8	-		-
Sample 5				
High neat	9.0	-		-
2 H:1 L		6.5	6.5	101%
1 H:1 L		5.2	5.3	102%
1 H:2 L		3.9	4.1	103%
Low neat	1.5	-		-
			Mean Recovery	**97%**

16.9 Interfering Substances

Controlled studies of potentially interfering substances performed in serum at 2 (1 and 3 ng/mL) showed no interference in the LIAISON® Androstenedione at the highest concentration for each substance listed below. The testing was based on CLSI-EP7-A2.

Drug/Substance	Concentration Tested
Hemoglobin	300 mg/dL
Bilirubin (conjugated)	40 mg/dL
Bilirubin (unconjugated)	40 mg/dL
Triglycerides	2,000 mg/dL
Cholesterol	500 mg/dL
Albumin	10.7 g/dL
HAMA	802 ng/mL
Rheumatoid Factor	4570 IU/mL

16.10 Specificity/Cross-Reactivity

Controlled Studies of potentially cross-reacting substances were performed on the LIAISON® Androstenedione assay at the concentrations listed below. The testing was based on CLSI-EP7-A2.

Cross-Reactant	Spiked Concentration	% Cross Reactivity
Andrenosterone	100 ng/mL	0.003%
DHEA	100 ng/mL	0.433%
Testosterone	100 ng/mL	0.433%
4-Androsten-11β-ol-3, 17-dione	100 ng/mL	0.063%
Androsterone	500 ng/mL	0.079%
Dexamethasone	1000 ng/mL	0.003%
Cholesterol	1000 ng/mL	0.005%
Corticosterone	1000 ng/mL	0.006%
Estriol	1000 ng/mL	0.005%
Estrone	1000 ng/mL	0.029%
Norethindrone	1000 ng/mL	0.005%
Progesterone	1000 ng/mL	0.014%
Spironolactone	1000 ng/mL	0.012%
5α-Dihydrotestosterone	1000 ng/mL	0.003%
11-Ketosterone	1500 ng/mL	0.000%
Cortisone	6000 ng/mL	0.002%
Pregnenolone	10,000 ng/mL	-0.016%
Deoxycorticosterone	10,000 ng/mL	0.001%
Estradiol-17β	10,000 ng/mL	0.000%
Aldosterone	10,000 ng/mL	0.001%
17α-Hydroxyprogesterone	10,000 ng/mL	0.006%
Prednisone	10,000 ng/mL	0.001%
Cortisol	10,000 ng/mL	0.001%
DHEA-SO4	15,000 ng/mL	0.002%
Isoandrosterone	10,000 ng/mL	0.120%
21-Deoxycortisol	10,000 ng/mL	0.000%

17. References

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