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Changes: § 5
Deletions: §

LIAISON® Testosterone xt (REF 318410)

1. INTENDED USE

The LIAISON® Testosterone xt is a direct, competitive, chemiluminescence immunoassay (CLIA) intended for the quantitative determination of testosterone in human serum and EDTA plasma on the LIAISON® XL Analyzer. The assay is intended for *in vitro* diagnostic use.
Measurement of testosterone is used in the diagnosis and treatment of disorders involving the male sex hormones (androgens), including primary and secondary hypogonadism, delayed or precocious puberty, impotence in males and, in females hirsutism (excessive hair) and virilization (masculinization) due to tumors, polycystic ovaries, and adrenogenital syndromes.
The test has to be performed on the LIAISON® XL Analyzer.

2. SUMMARY AND EXPLANATION OF THE TEST

Testosterone (4-androsten-17β-ol-3-one) is an androgen steroid that is expressed in both men and women, although at different levels (2.0-11.0 ng/mL) (7-38 nmol/L) in adult men and (0.1-1.0 ng/mL) (0.35-3.47 nmol/L) in adult women.[1] Testosterone binds with high affinity to sex hormone-binding globulin (SHBG), and with a weaker affinity to albumin. Up to (97-99%) of testosterone is bound in the circulation.[2] Separation from the carrier proteins can be achieved by various methods including organic solvent extraction or the use of displacing, releasing, and denaturing agents.[3-7]
In men, Leydig cells in the testes synthesize the majority of testosterone, while a lesser amount is produced in the adrenal glands. A circadian pattern of testosterone expression is exhibited, with higher levels observed in the morning; this pattern diminishes in older men.[8] Measurement of testosterone levels is useful in the determination of testes and adrenal function. In target tissues, about (4-10%) of testosterone is metabolized to DHT, the main androgen hormone. Testosterone and DHT induce the expression of secondary male sex characteristics such as hair growth, external genitalia maturation and muscle mass increase. Low levels of testosterone may result in delayed puberty or infertility. Hypogonadism can be a clinical manifestation of certain chromosomal abnormalities, such as Kleinfelter's syndrome. Higher levels of testosterone may indicate an androgen-producing tumor.
Women produce about (5-10%) the amount of testosterone as men. The ovaries and adrenal glands contribute equally to the production of testosterone, with the majority resulting from the metabolism of prehormones, such as androstenedione. About 30% of testosterone is converted to DHT in women. Additionally, testosterone is metabolized to estradiol. The level of testosterone increases slightly during the follicular phase of the menstrual cycle, peaking just prior to ovulation.[9] Serum testosterone increases during pregnancy, but does not change with the use of oral contraceptives.[10] Decreased levels of testosterone in women can occur from adrenal, ovarian, or hypothalamic-pituitary deficiency or disease, as well as from HIV infection.[3] Increased amounts of testosterone are detected in women with hirsutism.

3. PRINCIPLE OF THE PROCEDURE

The LIAISON® Testosterone xt assay's method for quantitative determination of testosterone is a direct, competitive, chemiluminescence immunoassay (CLIA). Specific antibody to testosterone is bound to magnetic particles (solid phase) and testosterone is linked to an isoluminol derivative. During the incubation, testosterone is dissociated from its binding protein and competes with labeled testosterone for binding sites on the antibody. After the incubation, the unbound material is removed with a wash cycle. Subsequently, the starter reagents are added and a flash chemiluminescent reaction is initiated. The light signal is measured by a photomultiplier as relative light units (RLU) and is inversely proportional to the concentration of testosterone present in calibrators, controls, or samples.

4. MATERIALS PROVIDED

Reagent Integral

Magnetic Particles (2.4 mL)	SORB	Magnetic particles coated with mouse MAb against testosterone, phosphate buffer, BSA, goat immunoglobulin, and 0.2% Proclin® 300.
Conjugate (12 mL)	CONJ	Testosterone conjugated to an isoluminol derivative, in phosphate buffer with surfactant, BSA and <0.1% Sodium Azide.
Assay Buffer (12 mL)	BUF AS	Phosphate buffer with surfactant, BSA, and <0.1% Sodium Azide.
Number of Tests		100

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

All reagents are supplied ready to use. The order of the reagents refelects the layout of containers in the Reagent Integral.

Additional components not on the Reagent Integral

Calibrator 1 (2 x 2.0 mL)	CAL 1	Calibrator 1, low: containing hormone free human serum spiked with testosterone, 0.2% Proclin® 300.
Calibrator 2 (2 x 2.0 mL)	CAL 2	Calibrator 2: high: containing hormone free human serum spiked with testosterone, 0.2% Proclin® 300.

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

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

Materials required but not provided (system related)

LIAISON® XL 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)

Additional required materials

LIAISON® Testosterone xt Control Set (REF 318411)

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 pipet 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, Hapatitis 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:	SORB CAL 1 CAL 2	CONJ BUF AS
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. REAGENT INTEGRAL PREPARATION

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 color 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 resuspension 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® 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

Upon receipt, the Reagent Integral must be stored in the dark in an upright position to facilitate re-suspension of magnetic particles. When the Reagent Integral is stored unopened, light protected and kept upright, the reagents are stable at 2-8°C up to the expiry date. Do not freeze. The Reagent Integral should not be used past the expiry date indicated on the kit and Reagent Integral labels.

After opening and each use, the Reagent Integral should be sealed with the tape provided with the kit, placed in the kit box and returned to storage at 2-8°C. Undue exposure to light should be avoided. Open use is eight weeks when properly stored.

8. SPECIMEN COLLECTION AND PREPARATION

Either human serum or EDTA plasma may be used. The use of serum separator tubes is acceptable. 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 EDTA 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. If the assay is performed within 5 days of sample collection, the samples should be kept at 2-8°C; otherwise they should be stored frozen (-20°C or below). 6 samples of each specimen type underwent 4 freeze-thaw cycles. The results showed no significant differences. Specimens may be stored in glass or plastic vials.

The minimum specimen volume required for a single determination is 300 µL. [100 µL specimen for testing + 200 µL dead volume (volume left at the bottom of the aliquot tube which the instrument cannot aspirate)]. If samples are stored frozen, mix thawed samples well before testing.

51 matched patient sets of serum, SST serum, and EDTA plasma samples spanning the measuring range of the LIAISON® Testosterone assay were tested in singlicate to determine sample equivalence. Passing Bablok linear regression analysis reported the following results:

SST-Serum (Y) to Serum (X): $y = 1.02x + 1.6$, $R^2 = 1.0$.
EDTA Plasma (Y) to Serum (X): $y = 1.04x + 1.6$, $R^2 = 1.0$.

9. CALIBRATORS 1 and 2

LIAISON® Testosterone xt 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, avoid foaming. Calibrate the assay as described in the Operator's manual. Once opened, remaining liquid calibrators should be re-capped, and returned to storage at 2-8°C. Open use is 8 weeks when properly stored at 2-8°C. During handling, use appropriate precautions to avoid bacterial contamination of calibrators.

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® Testosterone xt 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 establish specific working curves based on the assigned master curve. Each calibration solution allows 6 calibrations to be performed.
Recalibration in triplicate is required whenever at least 1 of the following conditions occurs:

- With each new lot of reagent (Reagent Integral or Starter Reagents).
- The previous calibration was performed more than 28 days before.
- 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® Testosterone xt assay measures between 0.024 and 15.0 ng/mL (2.4 and 1500 ng/dL). The lowest reportable value is 0.024 ng/mL (2.4 ng/dL). Values below 0.024 ng/mL (2.4 ng/dL) should be reported as < 0.024 ng/mL (< 2.4 ng/dL). The highest reportable value without dilution is 15.0 ng/mL (1500 ng/dL).

11. ASSAY PROCEDURE

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

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® XL Analyzer:

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 the user refer to 4th ed. CLSI guideline C24 and 42 CFR 493.1256(c) for guidance on appropriate quality control practices.

LIAISON® Testosterone xt 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.

Control values must lie within the expected ranges: whenever one of the controls lies outside the expected ranges, calibration should be repeated and controls retested. If control values obtained after successful calibration lie repeatedly outside the predefined ranges, the test should be repeated using an unopened control vial. If control values lie outside the expected ranges, patient results must not be reported.

13. INTERPRETATION OF RESULTS

The Analyzer automatically calculates the concentration of Testosterone in the sample. This concentration is expressed in ng/mL. To convert results to nmol/L, ng/mL x 3.47 = nmol/L. To convert ng/mL to ng/dL, ng/mL x 100 = ng/dL.

14. LIMITATIONS OF THE PROCEDURE

- **Caution: US Federal Law restricts this device to sale by or on the order of a licensed practitioner.**
- A skillful technique and strict adherence to the instructions are necessary to obtain reliable results.
- Bacterial contamination of samples may affect the test results.
- Heterophilic antibodies in human serum can react with reagent immunoglobulins or other reagent material, interfering with in vitro immunoassays.
- 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.
- Assay results should be utilized in conjunction with other clinical and laboratory data to assist the clinician in making individual patient management decisions in an adult population.

15. EXPECTED VALUES

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

Adult Reference Range

The LIAISON® Testosterone xt was used to test serum samples from apparently healthy adults to determine the reference range for the LIAISON® Testosterone xt assay. Contraceptive use is unknown for the study participants. The 95% reference intervals for males and females are listed below.

Population	N	Median ng/mL (ng/dL)	Central 95% Interval ng/mL (ng/dL)
Males 22-49 years	134	5.53 (553)	1.615 – 11.337 (161.5 - 1134)
Males ≥ 50 years	140	4.35 (435)	0.985 – 9.009 (98.5 - 900.9)
Females 22-49 years	128	0.344 (34.4)	0.144 - 0.873 (14.4 - 87.3)
Females ≥ 50 years	176	0.2285 (22.85)	0.0666 - 0.6367 (6.66 - 63.67)

Consider these limits as guidelines only. It is important for each laboratory to establish its own reference range, representative of its typical population.

16. SPECIFIC PERFORMANCE CHARACTERISTICS

16.1 Limit of Blank (LoB)*

Following the method from CLSI EP17-A2, the limit of blank for the LIAISON® Testosterone xt assay is ≤ 0.005 ng/mL (≤ 0.5 ng/dL).

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

16.2 Limit of Detection (LoD)

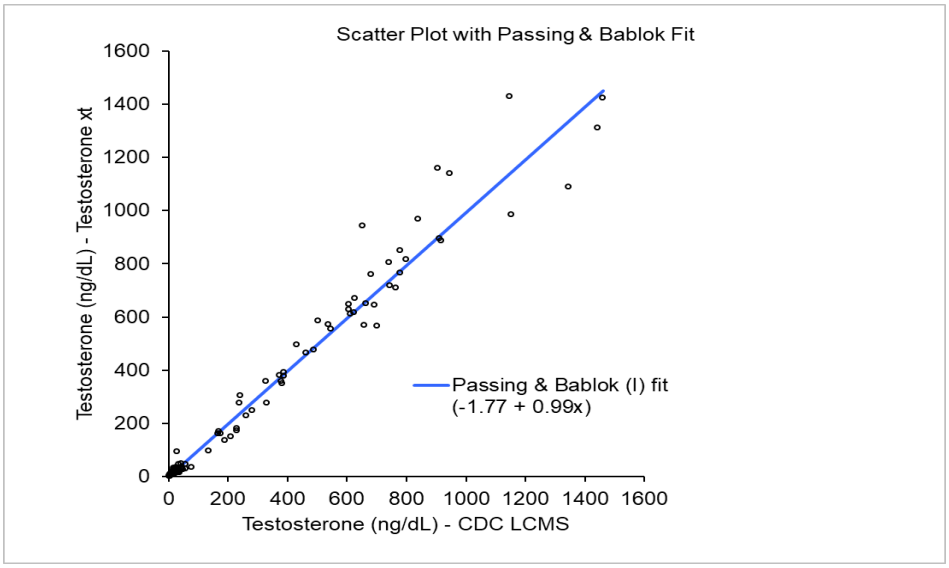
Following the method from CLSI EP17-A2, the limit of detection for the LIAISON® Testosterone xt assay is 0.01 ng/mL (1.0 ng/dL).

16.3 Limit of Quantitation(LoQ) (also called Functional Sensitivity)

Following the method from CLSI EP17-A2, the limit of quantitation for the LIAISON® Testosterone xt assay is defined as the concentration at which the inter-assay precision (%CV) exceeds 20%. The derived limit of quantitation from the regression analysis of the precision profile is 0.024 ng/mL (2.4 ng/dL).

16.4 Method Comparison:

A total of 120 serum samples spanning the assay measuring range were tested by LIAISON® Testosterone xt and compared to the CDC HoSt Testosterone RMP ID-LC-MS/MS* values. The method comparison study was performed according to 3rd ed. CLSI guideline EP09c. A Passing-Bablok regression analysis was performed on the results across the range of the LIAISON® Testosterone xt assay yielding agreement of y = 0.99x – 1.77 ng/dL; R = 0.984. The 95% confidence intervals for the slope are 0.97 to 1.02 and -3.22 to -0.35 ng/dL for the intercept.



*Centers for Disease Control and Prevention (CDC) Hormone Standardization Program (HoSt) Testosterone Reference Measurement Procedure (RMP) ID-LC-MS/MS.

16.5 Precision LIAISON® XL

2 kit controls and 6 serum samples containing different concentrations of analyte prepared to span the measuring range of the assay were assayed in duplicate, 2 runs per day, over 20 operating days, using 2 LIAISON® XL Analyzers at 1 site using 2 reagent lots to determine the repeatability and reproducibility of the assay. The testing was performed according to CLSI EP5-A3.

Reproducibility/Precision Results – 20 Day Combined 1 Site

Sample ID#	N	Mean ng/dL	Between-Lot/Within Site		Total/Across Lots/Within Site	
			SD ng/dL	%CV	SD ng/dL	%CV
Level 1	160	172	11.6	6.7%	8.63	5.0%
Level 2	160	613	34.9	5.7%	21.4	3.5%
Sample 1	160	46	2.54	5.5%	3.62	7.9%
Sample 2	160	155	11.6	7.5%	8.68	5.6%
Sample 3	160	206	14.0	6.8%	9.02	4.4%
Sample 4	160	522	34.7	6.7%	24.1	4.6%
Sample 5	160	899	48.3	5.4%	38.2	4.2%
Sample 6	160	1314	83.7	6.4%	62.1	4.7%

16.6 Linearity Study:

Three (3) high samples, one of each specimen type (serum, SST serum, EDTA plasma), containing spiked testosterone levels above the measuring range of the assay (15 ng/mL) were diluted to yield sample concentrations that span the measuring range of the assay (0.024 – 15 ng/mL). An additional low serum sample was diluted to yield sample concentrations that span the lower end of the assay measuring range (0.024 – 0.16 ng/mL). The samples were tested by the LIAISON® Testosterone xt assay following CLSI EP6-A. The results for each sample were analyzed by linear regression (slope, intercept and R^2 value) of Observed Testosterone Concentration versus Expected Testosterone Concentration in ng/mL.

The resulting equations for each sample type are:
Serum: Observed Analyte = 0.995 x + 0.0346; R^2 = 0.9928
SST Serum: Observed Analyte = 1.0225x – 0.5785; R^2 = 0.9914
EDTA plasma: Observed Analyte = 1.0337x – 0.3189; R^2 = 0.9955

16.7 Recovery

5 high concentration (endogenous or spiked) serum samples and 5 low concentration samples were blended together at 3 ratios. Each neat serum along with each blend was analyzed with the LIAISON® Testosterone assay. The observed values were then compared to the expected values, based on the neat serum concentrations to determine the % recovery. The mean recovery is 99%.

Serum Samples	Defined Concentration	Expected ng/dL	Observed ng/dL	% Recovery
Serum High Sample 1 (HS1)	981			
2 HS1 : 1LS1		678	676	100%
1 HS1 : 1LS1		521	515	99%
1 HS1 : 2LS1		365	361	99%
Serum Low Sample 1 (LS1)	61			
Serum High Sample 2 (HS2)	1472			
2 HS2 : 1LS2		995	968	97%
1 HS2 : 1LS2		749	709	95%
1 HS2 : 2LS2		503	465	93%
Serum Low Sample 2 (LS2)	26			
Serum High Sample 3 (HS3)	1254			
2 HS3 : 1LS3		963	1004	104%
1 HS3 : 1LS3		813	808	99%
1 HS3 : 2LS3		663	694	105%
Serum Low Sample 3 (LS3)	373			
Serum High Sample 4 (HS4)	1408			
2 HS4 : 1LS4		1149	1148	100%
1 HS4 : 1LS4		1016	1012	100%
1 HS4 : 2LS4		883	875	99%
Serum Low Sample 4 (LS4)	625			
Serum High Sample 5 (HS5)	1250			
2 HS5 : 1LS5		847	835	99%
1 HS5 : 1LS5		639	625	98%
1 HS5 : 2LS5		432	423	99%
Serum Low Sample 5 (LS5)	29			
			Mean Recovery	**99%**

16.8 Specificity

The cross-reactivity of the LIAISON® Testosterone xt assay was evaluated by adding the following substances to vehicle control sera. The samples were analyzed and the % cross-reactivity calculated using the following formula: % Cross-reactivity = (Corrected Assay Value/Concentration Spiked)*100

The observed cross-reactivities are listed below.

Cross reactant	Concentration ng/mL	% Cross reactivity
Androstenedione	100	≤ 4.27
Cortisol	1000	≤ 0.03
Cortisone	2000	≤ 0.01
Danazol	1000	≤ 0.02
Dexamethasone	2000	≤ 0.01
DHEA	1000	≤ 0.02
DHEA-S	50000	≤ 0.01
D-5-Androstene-3B-17B-diol	1000	≤ 0.06
Estrone	1000	≤ 0.03
Ethisterone	1000	≤ 0.43
Nandrolone	100	≤ 3.33
Norgesterel	1000	≤ 0.02
Testosterone propionate	50	≤ 7.48
5-a-Androstane-3B,17B-diol	500	≤ 0.81
5-a-Dihydrotestosterone	500	≤ 2.37
11-B-Hydroxytestosterone	50	≤ 15.28
11-Keto-testosterone	10	≤ 37.70
Prednisone	1000	≤ 0.03
Prednisolone	1000	≤ 0.04
Progesterone	1000	≤ 0.12
17-a-Estradiol	1000	≤ 0.02

16.9 Interfering substances

Controlled studies of potentially interfering substances at 2 testosterone levels showed no interference at the concentration for each substance listed below in the LIAISON® Testosterone. *In vitro* tests were performed on 19 commonly used pharmaceuticals, no interference with the assay was found.
The testing was based on CLSI-EP7-A2.

Substance	Concentration Tested
Hemoglobin	600 mg/dL
Bilirubin (unconjugated)	20 mg/dL
Triglycerides	1000 mg/dL
Cholesterol	500 mg/dL
HAMA	1753 ng/mL

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