DiaSorin Inc.
1951 Northwestern Ave – Stillwater, MN 55082 – USA
Tel 1.651.439.9710 – Fax 1.651.351.5669

Changes: § 5
Deletions: §

LIAISON® Progesterone II Gen (REF 310690)

1. INTENDED USE

The LIAISON® Progesterone II Gen assay is a chemiluminescent immunoassay (CLIA) for the quantitative determination of progesterone in human serum. The test has to be performed on the LIAISON® Analyzer Family*.

2. SUMMARY AND EXPLANATION OF THE TEST

Progesterone (pregn-4-ene-3,20-dione) is a steroid hormone with a molecular weight of 314. It is secreted by the corpus luteum in nonpregnant women and during pregnancy, by the placenta. It is also secreted by the adrenal cortex and by the testes.[1] Progesterone is synthesized from cholesterol and binds to corticosteroid binding globulin and, to a lesser extent, albumin.[2]

The primary function of progesterone is to prepare the uterus for implantation of a fertilized ovum and then to maintain pregnancy, should implantation occur. During a normal menstrual cycle, progesterone levels remain low during the follicular phase and then rise after ovulation, peaking in the mid-luteal phase. If implantation does not occur, progesterone levels fall during the late luteal phase. If a fertilized ovum is implanted, progesterone continues to be secreted by the corpus luteum for the first trimester of the pregnancy after which time the placenta takes over. Progesterone levels continue to rise throughout the pregnancy.[1]

Progesterone levels are measured in order to monitor ovulation for in vitro fertilization[4] (IVF) and to predict IVF success.[5,6] In cases of infertility, low progesterone levels can indicate a defective luteal phase.[1] In early pregnancy, low progesterone levels point to an increased risk of pregnancy loss.[3]

3. PRINCIPLE OF THE PROCEDURE

The method for quantitative determination of progesterone is a direct, competitive chemiluminescence immunoassay (CLIA). The LIAISON® Progesterone II Gen assay is a modified 2-step chemiluminescence immunoassay (CLIA) to determine the presence of progesterone in human serum. Specific antibody to progesterone is bound to magnetic particles (solid phase). Assay buffer, magnetic particles and controls, calibrators or patient samples are combined for the initial incubation. During the incubation, progesterone is dissociated from its binding protein, and binds to the solid phase specific antibody. Then labeled progesterone is added and competes 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 progesterone present in calibrators, controls, or patient samples.

4. MATERIALS PROVIDED

Reagent Integral

Magnetic Particles (2.4 mL)	SORB	Magnetic particles coated with donkey anti-sheep antibody, anti-progesterone sheep monoclonal antibody in phosphate buffer with surfactant and <0.1% Sodium Azide.
Conjugate (2.0 mL)	CONJ	Proprietary polymer conjugated with Progesterone and an isoluminol derivative, in phosphate buffer, surfactant and <0.1% Sodium Azide.
Assay Buffer (28 mL)	BUF AS	Citrate phosphate buffer with donkey and sheep serum, surfactant and <0.1% Sodium Azide.
Number of Tests		100

All reagents are supplied ready to use. The order of reagents reflects the layout of containers in the reagent integral.

Included with Integral

Calibrator 1 (1.0 mL)	CAL 1	Human serum containing progesterone, surfactant, 0.2% Proclin® 300 and <0.1% Sodium Azide. The calibrator concentrations (ng/mL) are referenced to an in-house standard preparation.
Calibrator 2 (1.0 mL)	CAL 2	Human serum containing progesterone, surfactant, 0.2% Proclin® 300 and <0.1% Sodium Azide. The calibrator concentrations (ng/mL) are referenced to an in-house standard preparation.
Specimen Diluent (2.0 mL)	DIL SPE	Progesterone free human serum, surfactant, 0.2% Proclin® 300 and <0.1% Sodium Azide.

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

*(LIAISON® and LIAISON® XL)

Materials required but not provided (system related)

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

Additional required materials

LIAISON® Progesterone II Gen Control Set (REF 310691)

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, 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:	CAL 1 CAL 2 DIL SPE	SORB CONJ CAL 1 CAL 2 BUF AS DIL SPE
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:

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.

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.

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

REAGENT INTEGRAL

Upon receipt, the reagent integral must be stored in the dark in an upright position to facilitate re-suspension of magnetic particles. Refer to the reagent integral preparation for resuspension instructions. 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 4 weeks when properly stored.

CALIBRATORS

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. After use, the calibrators should be re-capped, and returned to storage at 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.

8. SPECIMEN COLLECTION AND PREPARATION

Human serum must 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 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 large quantities of 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). If samples are stored frozen, mix thawed samples well before testing. 6 serum samples underwent 4 freeze thaw cycles. The results showed no significant differences. Self-defrosting freezers are not recommended for sample storage. The minimum volume required for a single determination is 190 µL specimen [40 µL specimen + 150 µL dead volume] (volume left at the bottom of the aliquot tube which the instrument cannot aspirate)].

9. CALIBRATORS LEVEL 1 and LEVEL 2

The LIAISON® Progesterone II Gen calibrators are liquid and ready to use. The barcode is present on the calibrator vial. Calibrator and reagent integral lot number are lot specific. Do not use calibrators matched with a different reagent lot in the same assay.
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 can be stored at 2-8°C for 4 weeks.

LIAISON® Analyzer:

Transfer the vial to the LIAISON® Analyzer "L" rack with the barcode showing outward and slide rack into LIAISON® Analyzer sample area.

LIAISON® XL Analyzer:

Transfer the vial to the LIAISON® XL "L" rack and place on the XL Analyzer.

10. CALIBRATION

Assay of calibrators allows the analyzer to recalibrate the stored master curve, as indicated via the bar codes on the reagent integral label. Test of assay specific calibrators allows the detected relative light units (RLU) values to adjust the assigned master curve. Each calibration solution allows 6 calibrations to be performed.
Recalibration in triplicate is mandatory whenever at least 1 of the following conditions occurs:

- A new lot of reagent integral or of Starter Kit is used.
- The previous calibration was performed more than 7 days before.
- The analyzer has been serviced.
- The values of the recommended LIAISON® Progesterone II Gen Controls lie outside the expected ranges.

Refer to the analyzer operator's manual or LIAISON® Quick Guide for calibration instructions.

Measuring range: The LIAISON® Progesterone II Gen assay measures between 0.12 and 60 ng/mL.
The lowest reportable value is 0.12 ng/mL. Values below 0.12 ng/mL should be reported as < 0.12 ng/mL. The highest reportable value without dilution is 60 ng/mL.

Samples that read above the assay range can be manually diluted using the specimen diluent provided and re-assayed. The suggested dilution for any sample above the assay range is 1:10 (i.e. 20 µL of sample + 180 µL of specimen diluent). The minimum total volume required for a diluted sample is 190 µL. The specimen diluent solution allows 10 dilutions to be performed.

11. ASSAY PROCEDURE

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

LIAISON® Analyzer: Each test parameter is identified via barcodes 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 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.

The analyzer operations are as follows:

LIAISON® Analyzer

1. Dispense sample, calibrator or control into reaction module.
2. Dispense assay buffer and magnetic particle 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.

LIAISON® XL Analyzer

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

12. QUALITY CONTROL

Quality control is performed once per day of use or in accordance with local, state and/or federal regulations or accreditation requirements and your laboratory's quality control procedures. 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® Progesterone II Gen controls should be equilibrated to room temperature, and mixed thoroughly before use either by rotation or gentle inversion.

LIAISON® Progesterone II Gen 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.
Quality control could be performed by running LIAISON® Progesterone II Gen Controls or dedicated commercial controls:

- at least once per day of use
- whenever the kit is calibrated
- whenever a new lot of Starter Reagents is 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.

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.

13. INTERPRETATION OF RESULTS

The LIAISON® Analyzer automatically calculates the concentration of Progesterone in the sample. This concentration is expressed in ng/mL. To convert results to nmol/L: ng/mL x 3.18 = nmol/L.

14. LIMITATIONS OF THE PROCEDURE

- 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.
- 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 1 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.
To assess the expected reference range, the LIAISON® Progesterone II Gen assay was performed on serum samples collected from 249 apparently healthy adult individuals (45 males, 43 females of child bearing age, 40 post menopausal females and 121 pregnant females broken into trimesters.

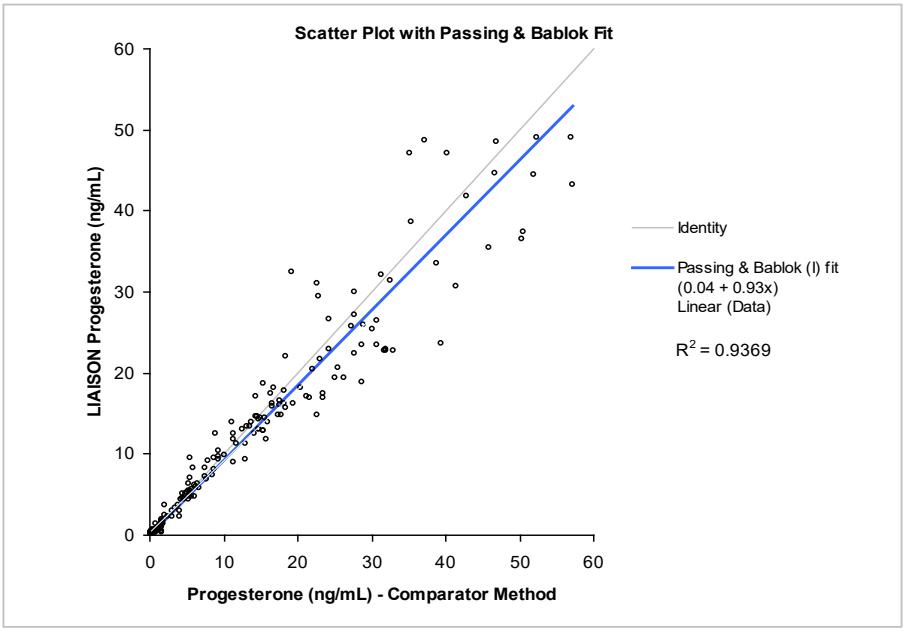
Based on the 95% confidence interval, the following values were established following CLSI guideline C28-A3. The following values were obtained:

Population	Median Progesterone	Central 95% Range
Males (45)	0.29 ng/mL	0.12 – 0.61 ng/mL
Population	**Median Progesterone**	**Central 95% Range**
Females:		
Follicular Phase (20)	0.26 ng/mL	< 0.12 – 2.7 ng/mL
Luteal Phase (34)	9.7 ng/mL	2.2 – 16.1 ng/mL
Mid-Luteal Phase (20)	10.1 ng/mL	4.0 – 17.1 ng/mL
Post Menopausal (40)	0.19 ng/mL	< 0.12 – 0.34 ng/mL
Pregnant Females:		
First Trimester (41)	13.1 ng/mL	4.0 – 26.1 ng/mL
Second Trimester (41)	35.9 ng/mL	13.8 – 118 ng/mL
Third Trimester (39)	90.2 ng/mL	34.2 – 254 ng/mL

16. SPECIFIC PERFORMANCE CHARACTERISTICS

16.1 Patient Correlation/Method Comparison:

A total of 230 serum samples or prepared samples spanning the assay range were tested by the LIAISON® Progesterone II Gen assay and by and by another automated method following CLSI EP9, and yielded the following Passing & Bablok regression analysis: LIAISON® Progesterone II Gen = 0.93x (Reference Method) + 0.04; R^2 = 0.94.



16.2 Precision

2 kit controls and 6 serum samples containing concentrations of Progesterone prepared to span the range of the assay were tested twice per day in duplicate, over 20 operating days using 1 reagent lot at DiaSorin. The testing was performed according to CLSI EP5-A2.

Sample ID	Mean (ng/mL)	Between Run		Total Within Lot	
		SD	%CV	SD	%CV
Kit Control Level 1	2.2	0.06	2.7%	0.15	6.8%
Kit Control Level 2	18.6	0.61	3.3%	1.31	7.1%
Progesterone S1	12.8	0.27	2.1%	0.83	6.5%
Progesterone S2	1.3	0.06	4.4%	0.10	8.2%
Progesterone S3	26.2	1.10	4.2%	2.09	8.0%
Progesterone S4	48.7	1.47	3.0%	3.30	6.8%
Progesterone S5	3.1	0.09	2.7%	0.25	8.1%
Progesterone S6	0.4	0.02	4.3%	0.07	17.1%

16.3 LoD (Limit of Detection)

Following the method from CLSI EP17-A, the limit of detection for the LIAISON® Progesterone II Gen assay for serum is 0.15 ng/mL.

16.4 LoB (Limit of Blank)

Following the method from CLSI EP17-A, the limit of blank for the LIAISON® Progesterone II Gen assay for serum is $\leq$ 0.12 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 LoQ (Limit of Quantitation)

Following the method from CLSI EP17-A, the limit of quantitation for LIAISON® Progesterone II Gen assay for serum is 0.17 ng/mL.

16.6 Trueness Dilution Test (Linearity)

1 serum sample was diluted and analyzed by the LIAISON® Progesterone II Gen assay following CLSI EP6-A. The results were analyzed by a linear regression of Observed Progesterone concentration versus Expected Progesterone Concentration.

The resulting equation for serum sample is: Observed LIAISON® Progesterone II Gen = 1.028x (Expected) + 0.142. R^2 = 0.998.

16.7 Recovery

6 high concentration serum samples and 6 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 of the 5 replicates are provided in the table below.

Serum Samples	Defined Concentration	Expected ng/mL	Observed ng/mL	% Recovery
High Sample 1 (HS1)	43.8			
2 HS1 : 1 LS1		29.5	27.5	93%
1 HS1 : 1 LS1		22.2	20.8	94%
1 HS1 : 2 LS1		14.8	14.3	96%
Low Sample 1 (LS1)	0.6			
High Sample 2 (HS2)	48.1			
2 HS2 : 1 LS2		32.5	33.2	102%
1 HS2 : 1 LS2		24.5	25.7	105%
1 HS2 : 2 LS2		16.5	17.5	106%
Low Sample 2 (LS2)	0.9			
High Sample 3 (HS3)	54.9			
2 HS3 : 1 LS3		37.6	37.0	98%
1 HS3 : 1 LS3		28.7	26.8	93%
1 HS3 : 2 LS3		19.8	18.2	92%
Low Sample 3 (LS3)	2.5			
High Sample 4 (HS4)	34.9			
2 HS4 : 1 LS4		23.5	24.3	103%
1 HS4 : 1 LS4		17.7	18.6	105%
1 HS4 : 2 LS4		11.9	12.6	106%
Low Sample 4 (LS4)	0.5			
High Sample 5 (HS5)	19.3			
2 HS5 : 1 LS5		13.1	12.4	95%
1 HS5 : 1 LS5		9.9	9.9	100%
1 HS5 : 2 LS5		6.7	6.6	99%
Low Sample 5 (LS5)	0.5			
High Sample 6 (HS6)	28.2			
2 HS6 : 1 LS6		19.0	17.7	93%
1 HS6 : 1 LS6		14.2	13.9	98%
1 HS6 : 2 LS6		9.5	9.6	102%
Low Sample 6 (LS6)	0.2			
		Mean Recovery		99%

16.8 Interfering substances

Controlled studies of potentially interfering substances at 2 progesterone levels in serum (1.25 and 30 ng/mL) were performed based on CLSI-EP7-A2.

Assay performance was not affected by cholesterol (up to 347 mg/dL), hemolysis (up to 600 mg/dL), bilirubin (up to 40 mg/dL) and triglyceride (up to 655 mg/dL).

16.9 Cross-reactants

Controlled studies of potentially Cross-reactive substances in serum samples were performed on the LIAISON® Progesterone II Gen assay at the concentrations listed below. The testing was based on CLSI-EP7-A2. The samples were analyzed and the percent cross-reactivity was calculated using the equation:

% Cross-reactivity = (Assay Value/Concentration Spiked)*100

The observed cross reactivites are listed below.

Cross Reactant	Concentration Tested (ng/mL)	% Cross Reactivity
Cortisol	1000	ND
11-Deoxycorticosterone	1000	≤ 1.72%
Corticosterone	1000	≤ 0.65%
DHEA-S	100000	ND
Testosterone	1000	≤ 0.03%
20α-Dihydroprogesterone	5000	≤ 0.18%
Aldosterone	1000	ND
Pregnenolone	1000	ND
Androstenediol	1000	ND
17 α -Hydroxyprogesterone	1000	≤ 0.19%
11-Deoxycortisol	1000	ND
Danazol	10000	ND
Prednisolone	1000	ND
17 β-Estradiol	100	ND
Estrone	100	≤ 0.03%
Estriol	100	≤ 0.05%
Clomiphene	100	≤ 0.02%
Bromocryptine	100	ND

*ND = non-detectable

17. References

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13. Clinical and Laboratory Standards Institute (CLSI) EP17-A2, Vol.32, No.8; Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline June 2012- Second Edition
14. Clinical and Laboratory Standards Institute (CLSI) EP6-A, Vol.23, No.16 Evaluation of Linearity of Quantitative Analytical Methods; Proposed Guideline- Approved Guideline
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DiaSorin Inc.
1951 Northwestern Avenue
Stillwater, MN 55082
USA

UK Responsible Person:
DiaSorin Italia S.p.A.
UK Branch
Central Road
Dartford Kent DA1 5LR
UK

EC REP
DiaSorin Italia S.p.A.
Via Crescentino snc
13040 Saluggia (VC)
Italy