Product information

Useŕs Manual

Progesterone free in Saliva ELISA

Enzyme immunoassay for the in vitro diagnostic quantitative measurement of active free progesterone in saliva

REF **IB79314**

Σ **96 Wells**

IVD **For *in-vitro* diagnostic use.**

Immuno-Biological Laboratories, Inc. (IBL-America)
8201 Central Ave. NE, Suite P, Minneapolis, Minnesota 55432, USA
Phone: +1 (763) - 780-2955 Fax.: +1 (763) - 780-2988
Email: ibl@ibl-america.com Web: www.ibl-america.com

Version 7-03/17
DMC
Updated 170315

CONTENTS

1 INTRODUCTION 3

2 PRINCIPLE 3

3 WARNINGS AND PRECAUTIONS 3

4 REAGENTS 4

5 SAMPLE COLLECTION AND PREPARATION 5

6 ASSAY PROCEDURE 6

7 EXPECTED NORMAL VALUES 7

8 QUALITY CONTROL 7

9 PERFORMANCE CHARACTERISTICS 8

10 LIMITATIONS OF PROCEDURE 10

11 LEGAL ASPECTS 10

12 REFERENCES 11

SYMBOLS USED WITH IBL-AMERICA ELISA 12

Immuno-Biological Laboratories, Inc. (IBL-America)
8201 Central Ave. NE, Suite P, Minneapolis, Minnesota 55432, USA
Phone: +1 (763) - 780-2955 Fax.: +1 (763) - 780-2988
Email: ibl@ibl-america.com Web: www.ibl-america.com

1 INTRODUCTION

1.1 Intended Use

Enzyme immunoassay for the determination of active free progesterone in saliva. Measurements obtained by this device may be used in the diagnosis and treatment of disorders of the ovaries or placenta and as an aid to confirm that ovulation takes place.
For *in-vitro* diagnostic use.

1.2 Summary and explanation

Progesterone (4-pregnene-3, 20-dione) is a C21 steroid hormone containing a keto-group (at C-3) and a double bond between C-4 and C-5. Like other steroids, it is synthesized from cholesterol via a series of enzyme-mediated steps *(1*). Progesterone is a female sex hormone of primary importance in ovulation, fertility and menopause. It is particularly important in preparing the endometrium for the implantation of the blastocyte and in maintaining pregnancy (*2*). In the follicular phase of menstrual cycle progesterone is produced in low levels. It increases to the LH peak and then sharply rises to high levels during luteal phase. Next there is a sharp decline to low levels of follicular phase. In non-pregnant women progesterone is mainly secreted by the corpus luteum whereas in pregnancy the placenta becomes the major source (*3,4*). Minor sources for progesterone are the adrenal cortex for both sexes and the testes for males.
The determination of progesterone in saliva combines a highly sensitive technique and non-invasive collection and represents the concentration of the metabolic active free progesterone.

2 PRINCIPLE

The **IBL-AMERICA Progesterone free in Saliva ELISA** kit is a solid phase enzyme-linked immunosorbent assay (ELISA), based on the principle of competitive binding. An unknown amount of free progesterone present in the sample and a defined amount of progesterone conjugated to horseradish peroxidase compete for the binding sites of rabbit polyclonal progesterone antiserum coated to the wells of a microplate. After one-hour incubation on a shaker the microplate is washed four times. After addition of the substrate solution the concentration of progesterone is inversely proportional to the optical density measured.

3 WARNINGS AND PRECAUTIONS

1. This kit is for in vitro diagnostic use only. For professional use only.
2. Before starting the assay, read the instructions completely and carefully. Use the valid version of the package insert provided with the kit. Be sure that everything is understood.
3. The microplate contains snap-off strips. Unused wells must be stored at 2 °C to 8 °C in the sealed foil pouch and used in the frame provided.
4. Pipetting of samples and reagents must be done as quickly as possible and in the same sequence for each step.
5. Use reservoirs only for single reagents. This especially applies to the substrate reservoirs. Using a reservoir for dispensing a substrate solution that had previously been used for the conjugate solution may turn solution colored. Do not pour reagents back into vials as reagent contamination may occur.
6. Mix the contents of the microplate wells thoroughly to ensure good test results. Do not reuse microwells.
7. Do not let wells dry during assay; add reagents immediately after completing the rinsing steps.
8. Allow the reagents to reach room temperature (21-26°C) before starting the test. Temperature will affect the absorbance readings of the assay. However, values for the samples will not be affected.
9. Never pipet by mouth and avoid contact of reagents and samples with skin and mucous membranes.
10. Do not smoke, eat, drink or apply cosmetics in areas where samples or kit reagents are handled.
11. Wear disposable latex gloves when handling samples and reagents. Microbial contamination of reagents or samples may give false results.
12. Handling should be done in accordance with the procedures defined by an appropriate national biohazard safety guideline or regulation.
13. Do not use reagents beyond expiry date as shown on the kit labels.
14. All indicated volumes have to be performed according to the protocol. Optimal test results are only obtained when using calibrated pipettes and microtiterplate readers.
15. Do not mix or use components from kits with different lot numbers. It is advised not to exchange wells of different plates even of the same lot. The kits may have been shipped or stored under different conditions and the binding characteristics of the plates may result slightly different.

16. Avoid contact with Stop Solution. It may cause skin irritation and burns.
17. Chemicals and prepared or used reagents have to be treated as hazardous waste according to the national biohazard safety guideline or regulation.
18. For information please refer to Material Safety Data Sheets. Safety Data Sheets for this product are available upon request directly from IBL-America.

4 REAGENTS

4.1 Reagents provided

1. **SORB | MT Microtiterplate**, 12 x 8 (break apart) strips with 96 wells;
   Wells coated with an anti-Progesterone antibody (rabbit polyclonal antibody).
2. **CAL | 0 Calibrator 0,** 1 vial, 3.0 ml, ready to use
3. **CAL | 1-6 Calibrator (Calibrator 1-6),** 6 vials, 1 ml each, ready to use;
   Concentrations: 10 – 30 – 100 – 300 – 1000 – 5000 pg/ml
   Conversion: Progesterone (pg/ml) x 3.18 = pmol/l
4. **CONTROL | 1-2 Control low / Control high**, 2 vials, 1.0 ml each, ready to use;
   For control values and ranges please refer to QC-Datasheet.
5. **ENZ | CONJ Enzyme Conjugate**, 1 vial, 7 ml, ready to use;
   Progesterone conjugated to horseradish peroxidase
6. **SUB | TMB Substrate Solution**, 1 vial, 22 ml, ready to use;
   contains tetramethylbenzidine (TMB).
7. **STOP | SOLN Stop Solution**, 1 vial, 7 ml, ready to use;
   contains 2 N Hydrochloric Acid solution.
8. **WASH | SOLN | 10x Wash Solution**, 1 vial, 50 ml (10X concentrated);
   see „Preparation of Reagents“.

Note: Additional Calibrator 0 for sample dilution is available upon request.

4.2 Materials required but not provided

- A microtiterplate reader capable for endpoint measurement at 450nm
- Calibrated variable precision micropipettes (50 µl, 100 µl, 200 µl).
- Microplate mixer operating more than 600 rpm
- Microcentrifuge
- Vortex mixer
- Absorbent paper.
- Distilled or deionized water
- Timer
- Semi logarithmic graph paper or software for data reduction

4.3 Storage conditions

When stored at 2°C to 8°C unopened reagents will be stable until expiration date. Do not use reagents beyond this date.
Opened reagents must be stored at 2°C to 8°C. After first opening the reagents are stable for 30 days if used and stored properly. Microtiter wells must be stored at 2°C to 8°C. Take care that the foil bag is sealed tightly.

4.4 Reagent preparation

All reagents should be at room temperature before use.

Wash Solution:
Dilute 50 ml of 10X concentrated *Wash Solution* with 450 ml deionized water to a final volume of 500 ml.
The diluted Wash Solution is stable for at least 3 months at room temperature.

4.5 Disposal of the kits

The disposal of the kit must be made according to the national regulations. Special information for this product is given in the Material Safety Data Sheet.

4.6 Damaged test kits

In case of any severe damage of the test kit or components, IBL-AMERICA has to be informed in writing, latest one week after receiving the kit. Severely damaged single components should not be used for a test run. They have to be stored until a final solution has been found. After this, they should be disposed according to the official regulations.

5 SAMPLE COLLECTION AND PREPARATION

Samples containing sodium azide should not be used in the assay. The saliva samples should be completely colorless. Even the slightest red color shows blood contamination resulting in falsely elevated concentration values. In case of visible blood contamination the individual should discard the sample, rinse the sampling device with water, wait for 10 minutes and take a new sample. Do not chew anything during the sampling period. Any pressure on the teeth may result in falsely elevated measurements due to an elevated content of gingival liquid in the saliva sample.

5.1 Sample Collection

For the correct collection of saliva we are recommending to only use appropriate devices made from ultra-pure polypropylene. Do not use any PE devices or cotton based Salivettes for sampling. False readings will result. Glass tubes can be used as well, but in this case special attention is necessary for excluding any interference caused by the stopper. Please contact IBL-America Diagnostics for more details.
As food might contain significant amounts of steroid hormones samples preferably should be taken while fasting. If fasting should be a problem at least any food of animal origin (meat or dairy products) should be avoided prior to finalizing the collection. In the morning breakfast should be done only after finalizing the collection procedure. During the day the collection period should be timed just before an anticipated meal. As the steroid hormone secretion in saliva as well in serum shows an obvious dynamic secretion pattern throughout the day it is important to always collect 5 samples during a 2 hour period; this means every 30 minutes one sample. If possible the volume of each single sample should be a minimum of 0.5 ml (better 1 ml). Saliva flow may be stimulated by drinking water. This is allowed and even recommended before and during the collection period. Drinking of water is not allowed during the last 5 minutes before taking the single samples.

5.2 Sample Storage and Preparation

Saliva samples in general are stable at ambient temperature for up to seven days. Therefore mailing of such samples by ordinary mail without cooling will not create any problem. Storage at 4°C can be done for a period of up to one month. Whenever possible samples should preferably be kept at a temperature of -20°C. Even repeated thawing and freezing is not a problem. Each sample has to be frozen, thawed, and centrifuged at least once anyhow in order to precipitate the mucins by centrifugation. Upon arrival of the samples at the lab the samples have to be kept frozen at least overnight. Next morning the samples are thawed and mixed carefully. The samples have to be centrifuged for 5 to 10 minutes. The clear colorless supernatant is easy to pipette. If the sample should show even a slightly red color it should be discarded. Otherwise the value most probably will be falsely elevated. Due to the episodic variations of the steroid secretion we highly recommend the strategy of multiple sampling. If such a set of multiple samples has to be tested the lab (after at least one freezing, thawing, and centrifugation cycle) should mix aliquots of the 5 single samples and perform the determination using the mixture.

5.3 Sample Dilution

Samples expected to contain progesterone concentrations higher than the highest calibrator (5000 pg/ml) should be diluted with the zero calibrator before performing the assay. The additional dilution step has to be taken into account for the calculation of the result.
Example:
a) Dilution 1:10: 10 µl saliva + 90 µl Calibrator 0 (mix thoroughly)
b) Dilution 1:100: 10 µl of dilution a) + 90 µl Calibrator 0 (mix thoroughly).

6 ASSAY PROCEDURE

6.1 General Remarks

- All reagents and samples must be allowed to come to room temperature before use. All reagents must be mixed without foaming.
- Once the test has been started, all steps should be completed without interruption.
- Use new disposal plastic pipette tips for each standard, control or sample in order to avoid cross contamination.
- Absorbance is a function of the incubation time and temperature. Before starting the assay, it is recommended that all reagents are ready, caps removed, all needed wells secured in holder, etc. This will ensure equal elapsed time for each pipetting step without interruption.
- As a general rule the enzymatic reaction is linearly proportional to time and temperature.
- Respect the incubation times as stated in this instructions for use.

6.2 Assay procedure

Each run must include a standard curve.

1. Prepare a sufficient number of microplate wells to accommodate calibrators, controls and samples.
2. Dispense **100 µl** of each **calibrator, control and sample** with new disposable tips into appropriate wells.
3. Dispense **50 µl** of **Enzyme Conjugate** into each well.
4. Incubate for **60 minutes** at room temperature on a microplate mixer.

   Important Note:
   Optimal reaction in this assay is markedly dependent on shaking of the microplate!
5. Discard the content of the wells and rinse the wells **4 times** with diluted **Wash Solution** (300 µl per well). Remove as much Wash Solution as possible by striking the microplate on absorbent paper.
6. Add **200 µl** of **Substrate Solution** to each well.
7. Incubate without shaking for **30 minutes** in the dark.
8. Stop the reaction by adding **50 µl** of **Stop Solution** to each well.
9. Determine the absorbance of each well at 450 nm. It is recommended to read the wells within 15 minutes.

6.3 Results

1. Calculate the average absorbance values for each set of calibrators, controls and samples.
2. Using semi logarithmic graph paper, construct a standard curve by plotting the mean absorbance obtained from each standard against its concentration with absorbance value on the vertical (Y) axis and concentration on the horizontal (X) axis.
3. Using the mean absorbance value for each sample, determine the corresponding concentration from the calibration curve.
4. Automated method: Computer programs using cubic spline, 4 PL (4 Parameter Logistics) or Logit-Log are recommended.
5. The concentration of the samples can be determined directly from this calibrator curve. Samples with concentrations higher than that of the highest calibrator have to be further diluted. For the calculation of the concentrations, this dilution factor has to be taken into account.

Conversion to SI units:

Progesterone (pg/ml) x 3.18 = pmol/l

Immuno-Biological Laboratories, Inc. (IBL-America)
8201 Central Ave. NE, Suite P, Minneapolis, Minnesota 55432, USA
Phone: +1 (763) - 780-2955 Fax.: +1 (763) - 780-2988
Email: ibl@ibl-america.com Web: www.ibl-america.com

6.3.1 Example of typical calibrator curve

Following data are intended for illustration only and should not be used to calculate results from another run.

Standard	Absorbance Units
Calibrator 0 (0 pg/mL)	2.326
Calibrator 1 (10 pg/mL)	2.103
Calibrator 2 (30 pg/mL)	1.912
Calibrator 3 (100 pg/mL)	1.548
Calibrator 4 (300 pg/mL)	1.257
Calibrator 5 (1000 pg/mL)	0.831
Calibrator 6 (5000 pg/mL)	0.455

7 EXPECTED NORMAL VALUES

In order to determine the normal range of salivary Progesterone, saliva samples from 101 adult male and 268 adult female apparently healthy subjects, ages 15 to 75 years, were collected in the morning and analyzed using the IBL-AMERICA Progesterone free in Saliva ELISA kit. The following ranges are calculated with the results of this study.

	Age group		Salivary progesterone pg/ml (5 – 95% Percentile)
Women	15 - 55 yrs.	Follicular phase n = 38	3.7 – 81.4 pg/ml
	15 - 55 yrs.	Luteal phase n = 116	73.1 – 271.5 pg/ml
	> 55 yrs.	Postmenopausal n = 114	5.5 – 98.9 pg/ml
Men	15 - 75 yrs.	n = 101	8.6 – 107.0 pg/ml
Children (boys)	< 12 yrs.	n = 7	14.5 – 43.4 pg/ml

We recommend that each laboratory establish its own range for the population tested, because the values differ between age, new born, children, adolescents and adults.

8 QUALITY CONTROL

Good laboratory practice requires that controls should be run with each calibration curve. A statistically significant number of controls should be assayed to establish mean values and acceptable ranges to assure proper performance.
It is recommended to use control samples according to national regulations. The use of control samples is advised to assure the day to day validity of results. Use controls at both normal and pathological levels.
The controls and the corresponding results of the QC-Laboratory are stated in the QC certificate added to the kit. The values and ranges stated at the QC sheet always refer to the current kit lot and should be used for direct comparison of the results.
It is also recommended to make use of national or international Quality Assessment programs in order to ensure the accuracy of the results.
Employ appropriate statistical methods for analysing control values and trends. If the results of the assay do not fit to the established acceptable ranges of control materials results should be considered invalid.
In this case, please check the following technical areas: Pipetting and timing devices; photometer, expiration dates of reagents, storage and incubation conditions, aspiration and washing methods.
After checking the above mentioned items without finding any error contact your distributor or IBL-AMERICA directly.

Immuno-Biological Laboratories, Inc. (IBL-America)
8201 Central Ave. NE, Suite P, Minneapolis, Minnesota 55432, USA
Phone: +1 (763) - 780-2955 Fax.: +1 (763) - 780-2988
Email: ibl@ibl-america.com Web: www.ibl-america.com

9 PERFORMANCE CHARACTERISTICS

9.1 Analytical Sensitivity

The lowest analytical detectable level of progesterone that can be distinguished from the Zero Calibrator is 5.0 pg/ml at the 2SD confidence limit.

9.2 Specificity (Cross Reactivity)

The following materials have been evaluated for cross reactivity. The percentage indicates the cross reactivity at 50% displacement compared to Progesterone.

Steroid	% Cross reaction
Androstenedione	4.0
Androsterone	< 0.1
Cortisol	< 0.1
Cortison	< 0.1
Corticosterone	2.1
Danazol	< 0.1
11-Desoxycorticosterone	4.4
11-Desoxycortisol	< 0.1
Dexamethasone	< 0.1
5α-Dihydrotestosteron	< 0.1
Estradiol	< 0.1
Estriol	< 0.1
Estrone	< 0.1
17α-Hydroxyprogesterone	1.6
Prednisolon	< 0.1
Prednison	< 0.1
Pregnenolone	< 0.1
Testosterone	< 0.1

9.3 Assay dynamic range

The range of the assay is between 10 – 5000 pg/ml.

9.4 Reproducibility

9.4.1 Intra-Assay

The intra-assay variation was determined by 20 replicate measurements of 3 saliva samples within one run. The within-assay variability is shown below:

Mean (pg/ml)	130	865	2,203
SD	7.7	56	212
CV (%)	6.0	6.4	9.6
n =	20	20	20

9.4.2 Inter-Assay

The inter-assay (between-run) variation was determined by duplicate measurements of 3 saliva samples over 10 days.

Mean (pg/ml)	111	1,192	2,286
SD	9.5	111.5	231
CV (%)	8.6	9.4	10.1
n =	10	10	10

Immuno-Biological Laboratories, Inc. (IBL-America)
8201 Central Ave. NE, Suite P, Minneapolis, Minnesota 55432, USA
Phone: +1 (763) - 780-2955 Fax.: +1 (763) - 780-2988
Email: ibl@ibl-america.com Web: www.ibl-america.com

9.5 Recovery

Using the Calibrator Matrix four spiking solutions were prepared (A = 2,000 pg/ml, B = 5,000 pg/ml, C = 10,000 pg/ml, D = 20,000 pg/ml). A 25 µl aliquot of each solution was spiked into 475 µl of different salivas, for a spiking ratio of 1 to 20, leaving the saliva matrix of the spiked samples relatively intact. All samples were then measured by Salivary Progesterone procedure. To calculate expected values 95% of the unspiked values were added to 5% of the spiking solution concentrations.

Sample	Measured (pg/ml)	Expected (pg/ml)	Recovery (%)
1	204	-	-
	302	294	102,7%
	414	444	93,2%
	558	694	80,4%
2	50	-	-
	151	148	102,0%
	249	298	83,6%
	470	548	85,8%
3	1,852	-	-
	2,061	2,009	102,6%
	2,255	2,259	99,8%
	2,734	2,759	99,1%

Sample	Measured (pg/ml)	Expected (pg/ml)	Recovery (%)
4	271	-	-
	439	507	86,6%
	593	757	78,3%
	1,089	1,257	86,6%
5	954	-	-
	1,218	1,156	105,4%
	1,299	1,406	92,4%
	2,365	1,906	124,1%
6	122	-	-
	386	366	105,5%
	582	616	94,5%
	1,098	1,116	98,4%

9.6 Linearity

Six saliva samples were assayed undiluted and diluted with the calibrator matrix.

Saliva	Dilution	Observed (0)	Expected (E)	O/E %
1	native	1,242	-	-
	1 in 2	642	621	103,4%
	1 in 4	354	310	114,2%
	1 in 8	182	155	117,4%
2	native	862	-	-
	1 in 2	440	431	102,1%
	1 in 4	223	216	103,2%
	1 in 8	101	108	93,5%
3	native	1,704	-	-
	1 in 2	958	852	112,4%
	1 in 4	470	426	110,3%
	1 in 8	247	213	115,9%
4	native	2,527	-	-
	1 in 2	1,290	1,264	102,1%
	1 in 4	580	632	91,8%
	1 in 8	269	316	85,1%
5	native	324	-	-
	1 in 2	151	162	93,2%
	1 in 4	86	81	106,2%
	1 in 8	40	41	97,5%
6	native	1,724	-	-
	1 in 2	856	862	99,3%
	1 in 4	354	431	82,1%
	1 in 8	190	216	88,0%

Immuno-Biological Laboratories, Inc. (IBL-America)
8201 Central Ave. NE, Suite P, Minneapolis, Minnesota 55432, USA
Phone: +1 (763) - 780-2955 Fax.: +1 (763) - 780-2988
Email: ibl@ibl-america.com Web: www.ibl-america.com

10 LIMITATIONS OF PROCEDURE

Reliable and reproducible results will be obtained when the assay procedure is performed with a complete understanding of the package insert instruction and with adherence to good laboratory practice.
Any improper handling of samples or modification of this test might influence the results.

10.1 Drug Interferences

Any medication (cream, oil, pill etc) containing Progesterone of course will significantly influence the measurement of this analyte in a saliva sample. The same can be true for Progesterone derivatives.

11 LEGAL ASPECTS

11.1 Reliability of Results

The test must be performed exactly as per the manufacturer's instructions for use. Moreover the user must strictly adhere to the rules of GLP (Good Laboratory Practice) or other applicable national standards and/or laws. This is especially relevant for the use of control reagents. It is important to always include, within the test procedure, a sufficient number of controls for validating the accuracy and precision of the test.
The test results are valid only if all controls are within the specified ranges and if all other test parameters are also within the given assay specifications. In case of any doubt or concern please contact IBL-America.

11.2 Liability

Any modification of the test kit and/or exchange or mixture of any components of different lots from one test kit to another could negatively affect the intended results and validity of the overall test. Such modification and/or exchanges invalidate any claim for replacement.
Regardless, in the event of any claim, the manufacturer's liability is not to exceed the value of the test kit. Any damage caused to the test kit during transportation is not subject to the liability of the manufacturer.

Immuno-Biological Laboratories, Inc. (IBL-America)
8201 Central Ave. NE, Suite P, Minneapolis, Minnesota 55432, USA
Phone: +1 (763) - 780-2955 Fax.: +1 (763) - 780-2988
Email: ibl@ibl-america.com Web: www.ibl-america.com

12 REFERENCES

1. Wegerer M., Kerschbaum H., Blechert J. Wilhelm FH Low levels of estradiol are associated with elevated conditioned responding during fear extinction and with intrusive memories in daily life Neurobiology of Learning and Memory 116 (2014) 145-154
2. Bhanu P, Mustafa M, Guleria K, Vaid N, Banerjee B, Ahmed R Salivary progesterone as a biochemical marker to predict early preterm birth in asymptomatic high-risk women BJOG 2013;120:1003-1011
3. Jung K. Choe, Firyal S. Khan-Dawood, M. Yusoff Dawood Progesterone and Estradiol in the saliva and plasma during the menstrual cycle. Amer. J. of Obstetrics & Gynecology 1983, Vol 147 (5), pages 557 - 562
4. Michael R. Soules, Donald K. Clifton, Robert A. Steiner et.al. The Corpus Luteum: Determinants of Progesterone Secretion in the Normal Menstrual Cycle. Obstetrics and Gynaecology 1988 (71 no.5) pages 659 – 666
5. Taru Vuorento, Ilpo Huhtaniemi Daily levels of salivary Progesterone during menstrual cycle in adolescent girls. Fertility and Sterility 1992 (58:4) pages 685 - 690.
6. M.M. Finn, J.P. Gosling, D.F. Tallon, S. Baynes, F.P. Meehan et.al. The frequency of salivary Progesterone sampling and the diagnosis of luteal phase insufficiency. Gynecol. Endocrinol. 1992 6 pages 127 - 134
7. T. Blom, A. Ojanotko-Harri, M. Laine, I. Huhtaniemi Metabolism of Progesterone and Testosterone in human parotid and submandibular salivary glands in vitro. J Steroid Biochem Molec Biol 1993, Vol. 44 No.1, pages 69-76
8. T.M.Delfs, Olaf G.Naether, Susann Klein, Freimut A..Leidenberger, Patrick Fottrell, Ralf C.Zimmermann 24-Hour profiles of salivary Progesterone Fertility and Sterility 1994 (62 no.5) pages 960 – 966
9. Peter O'Leary, Peter Feddema, Katharine Chan, Mario Taranto, Sharon Evans Salivary, but not serum or urinary levels of Progesterone are elevated after topical application of Progesterone cream to pre- and postmenopausal women. Clinical Endocrinology 2000, Vol 53, pages 615 - 620.
10. M. Gröschl, M. Rauh, P. Schmid, HG Dörr Relationship between salivary Progesterone, 17OH-Progesterone, and Cortisol levels throughout the normal menstrual cycle of healthy postmenarcheal girls. Fertility and Sterility 2001, Vol 76 (3), pages 615 - 617
11. T. Vimpeli, H. Tinkanen,H. Huhtala, L. Rönnberg, E. Kujansuu Salivary and serum Progesterone concentrations during two luteal support regiments used in in-vitro fertilization treatments Fertility & Sterility 2001, Vol.4, pages 847-848
12. M Gröschl, M Rauh, HG Dörr Circadian rhythm of salivary Cortisol. 17OHP, and Progesterone in healthy children. Clin Chem. 2003, Vol. 49 (10), pages 1688-1691
13. RT Chatterton, ET Mateo, N Hou, AW Rademaker, S Acharya, VC Jordan Characteristics of salivary profiles of Estradiol and Progesterone in postmenopausal women. Journal of Endocrinology 2005, Vol. 186, pages 77-84
14. A. Nunez-de-la-Mora, R.T. Chatterton, O.A. Choudhury, G.R. Bently Childhood Conditions Influence Adult Progesterone Levels www.PLOSMedicine.org 2007, Vol.4 (5) pages 1-8
15. K. Gandara, L. Leresche, L. Mancl Patterns of salivary Estradiol and Progesterone across the menstrual cycle. Ann. NY Acad. Sci. 2007, Vol. 1098, pages 446-450

Manufactured for :
Immuno-Biological Laboratories, Inc. (IBL-America)
8201 Central Ave. NE, Suite P, Minneapolis, Minnesota 55432, USA
Phone: +1 (763) - 780-2955 Fax.: +1 (763) - 780-2988
Email: ibl@ibl-america.com Web: www.ibl-america.com

SYMBOLS USED WITH IBL-AMERICA ELISA

Symbol	English	Deutsch	Francais	Espanol	Italiano
CE	European Conformity	CE-Konfirmitäts-kennzeichnung	Conforme aux normes européennes	Conformidad europea	Conformità europea
	Consult instructions for use	Gebrauchsanweisung beachten	Consulter les instructions d'utilisation	Consulte las Instrucciones	Consultare le istruzioni per l'uso
IVD	In vitro diagnostic device	In-vitro-Diagnostikum	Ussage Diagnostic in vitro	Diagnóstico in vitro	Per uso Diagnostica in vitro
RUO	For research use only	Nur für Forschungszwecke	Seulement dans le cadre de recherches	Sólo para uso en investigación	Solo a scopo di ricerca
REF	Catalogue number	Katalog-Nr.	Référence	Número de catálogo	No. di Cat.
LOT	Lot. No. / Batch code	Chargen-Nr.	No. de lot	Número de lote	Lotto no
Σ	Contains sufficient for <n> tests/	Ausreichend für "n" Ansätze	Contenu suffisant pour "n" tests	Contenido suficiente para <n> ensayos	Contenuto sufficiente per "n" saggi
	Note warnings and precautions	Warnhinweise und Vorsichtsmaßnahmen beachten	Avertissements et mesures de précaution font attention	Tiene en cuenta advertencias y precauciones	Annoti avvisi e le precauzioni
	Storage Temperature	Lagerungstemperatur	Temperature de conservation	Temperatura de conservacion	Temperatura di conservazione
	Expiration Date	Mindesthaltbarkeits-datum	Date limite d'utilisation	Fecha de caducidad	Data di scadenza
	Legal Manufacturer	Hersteller	Fabricant	Fabricante	Fabbricante
Distributed by	Distributor	Vertreiber	Distributeur	Distribuidor	Distributtore

Immuno-Biological Laboratories, Inc. (IBL-America)
8201 Central Ave. NE, Suite P, Minneapolis, Minnesota 55432, USA
Phone: +1 (763) - 780-2955 Fax.: +1 (763) - 780-2988
Email: ibl@ibl-america.com Web: www.ibl-america.com

Symbol	Portugues	Dansk	Svenska	Ελληνικά
CE	Conformidade com as normas europeias	Europaeisk overensstemmelse	Europeisk överensstämmelse	Ευρωπαϊκή Συμμόρφωση
	Instruções de uso	Brugermanual	Användar manual	Εγχειρίδιο χρήστη
IVD	Diagnóstico in vitro	In vitro diagnostik	Diagnostik in vitro	in vitro διαγνωστικό
REF	Catálogo n.º	Katalognummer	Katalog nummer	Αριθμός καταλόγου
LOT	No do lote	Lot nummer	Batch-nummer	Αριθμός Παρτίδος
		Indeholder tilsttrækkeligt til ”n” test	Innehåller tillräckligt till “n” tester	Περιεχόμενο επαρκές για «n» εξετάσεις
	Temperatura de conservação	Opbevaringstemperatur	Förvaringstempratur	Θερμοκρασία αποθήκευσης
	Prazo de validade	Udløbsdato	Bäst före datum	Ημερομηνία λήξης
	Fabricante	Producent	Tillverkare	Κατασκευαστής
Distributed by				
Content	Conteúdo	Indhold	Innehåll	Περιεχόμενο
Volume/No.	Volume/Número	Volumen/antal	Volym/antal	Όγκος/αριθ..
Microtiterwells	Alvéolos de microtitulação	Mikrotiterbrønde	Brunnar i Mikrotiterplatta	Πηγαδάκια Μικροτιτλοδοτήσεως
Enzyme Conjugate	Conjugado enzimático	Enzymkonjugat	Enzymkonjugat	Συζευγμένο ενζυμο
Substrate Solution	Solução de substrato	Substratopløsning	Substratlösning	Διάλυμα υποστρώματος
Stop Solution	Solução de paragem	Stopopløsning	Stopp lösning	Διάλυμα τερματισμού
Zero Standard	Padrão zero	Standard 0	Standard 0	Πρότυπο Μηδέν
Standard	Calibrador	Standard	Standard	Πρότυπα
Control	Controlo	Kontrol	Kontroll	Έλεγχος
Wash Solution	Solução de lavagem	Vaskebuffer	Tvätt lösning	Διάλυμα πλύσεως
Conjugate Diluent				

Immuno-Biological Laboratories, Inc. (IBL-America)
8201 Central Ave. NE, Suite P, Minneapolis, Minnesota 55432, USA
Phone: +1 (763) - 780-2955 Fax.: +1 (763) - 780-2988
Email: ibl@ibl-america.com Web: www.ibl-america.com