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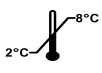
Instructions for use

17-OH-Progesterone ELISA

REF **FR E-2800**



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17-OH-Progesterone ELISA

1 INTRODUCTION

1.1 Intended use

The 17-OH-Progesterone ELISA is an enzyme immunoassay for the quantitative determination of 17-OH-Progesterone in human serum and plasma (Li-Heparin).
The assay is intended for *in-vitro* diagnostic use by professional users only. All therapeutic consequences must take not only the test result but always also all clinical and laboratory diagnostic results into account. The laboratory values themselves must never be the sole reason for therapeutic consequences derived from them. Manual processing is recommended. The usage of laboratory automats is the user's sole responsibility. The kit is intended for single use only.

1.2 Description of the analyte

The steroid hormone 17-OH-Progesterone (17-OHP) is produced in the adrenal cortex and in the gonads. Gestagenic effects exerted by 17-OHP are small. Nevertheless, this hormone is of clinical significance because it represents the ultimate precursor of 11β-desoxycortisol (compound S, CpS). CpS is formed by hydroxylation of the carbon atom C 21 of 17-OHP. Enzyme activity of 21-hydroxylase in the adrenal cortex may thus be monitored by analyzing the level of 17-OHP in the blood.
Deficiencies in 21-hydroxylase, most commonly found in congenital adrenal hyperplasia (CAH), result in excessive secretion of 17-OHP and consequently in enhanced blood levels. Deficiencies in 11-hydroxylase, however, merely lead to moderately increased values of 17-OHP. The analysis of this steroid hormone therefore plays a significant role in the differential diagnosis of congenital adrenal hyperplasia.
In adult non-pregnant women, 17-OHP levels in the blood depend on the phase of the menstrual cycle. Like progesterone, 17-OHP is secreted by the mature follicle and the corpus luteum. Concentrations are generally higher after ovulation.
In addition, levels of 17-OHP are influenced by daytime rhythms which correlate with the adrenal secretion of cortisol. Maximal levels are found in samples collected in the early morning.
In adult men, there are few indications of similar fluctuations of 17-OHP levels.
During pregnancy, large amounts of 17-OHP are produced by the fetus, the placenta, and the adrenal cortex. The hormone is secreted into the fetal and maternal blood circulation. Maternal values of 17-OHP strongly increase after the 32. week of pregnancy reaching fourfold higher levels than during the luteal phase of the menstrual cycle.

2 PRINCIPLE

The 17-OH-Progesterone ELISA is a solid phase enzyme-linked immunosorbent assay (ELISA) based on the competition principle. An unknown amount of antigen present in the sample and enzyme-labeled antigen compete for the binding sites of antibodies coated onto the wells. After incubation the unbound conjugate is washed off. The amount of bound peroxidase conjugate is inversely proportional to the concentration of 17-OHP in the sample. After addition of the substrate solution, the intensity of color developed is inversely proportional to the concentration of 17-OHP in the sample. The enzymatic reaction is stopped by addition of stop solution and the optical density (OD) is measured. A standard curve is constructed by plotting OD values against concentrations of standards, and concentrations of unknown samples are determined using this standard curve.

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. All human source material used in the preparation of the reagents has been tested and found negative for antibodies to HIV 1&2, HbsAg, and HCV. No test method however can offer complete assurance that HIV, HBV, HCV or other infectious agents are absent. Therefore, the reagents should be handled in the same manner as potentially infectious material.
4. The microtiter plate contains break-apart strips. Unused wells must be stored at 2 – 8 °C in the sealed foil pouch and used in the frame provided.
5. Pipetting of samples and reagents must be done as quickly as possible and in the same sequence for each step.
6. Use reservoirs only for single reagents. This especially applies to the substrate reservoirs. Using a reservoir for dispensing substrate solution that had previously been used for conjugate solution may turn solution colored. Do not pour reagents back into vials as reagent contamination may occur.
7. Mix the contents of the microtiter plate wells thoroughly to ensure good test results. Do not reuse wells.
8. Do not let wells dry during assay, add reagents immediately after completing the washing steps.
9. Allow the reagents to reach room temperature (18 – 25 °C) before starting the test. Temperature will affect the optical density of the assay.
10. Never pipet by mouth and avoid contact of reagents and specimens with skin and mucous membranes.
11. Do not smoke, eat, drink or apply cosmetics in areas where specimens or kit reagents are handled.

12. Wear disposable protective gloves when handling specimens and reagents. Microbial contamination of reagents or specimens may give false results.
13. Handling should be done in accordance with the procedures defined by an appropriate national biohazard safety guideline or regulation.
14. Do not use reagents beyond expiry date as shown on the kit labels.
15. All indicated volumes have to be performed according to the protocol. Optimal test results are only obtained when using calibrated pipettes and microtiter plate readers.
16. 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 be slightly different.
17. Avoid contact with Stop Solution. It may cause skin irritation and burns.
18. Some reagents contain Proclin 300, CMIT and/or MIT as preservatives. In case of contact with eyes or skin, flush immediately with water.
19. Chemicals and prepared or used reagents have to be treated as hazardous waste according to the national biohazard safety guideline or regulation.
20. For information on hazardous substances included in the kit please refer to Safety Data Sheets. Safety Data Sheets for this product are available upon request directly from the manufacturer.
21. All serious incidents occurring in relation to products made available on the EU market in accordance with Article 2(61) of Regulation (EU) 2017/746 shall be notified to the manufacturer and to the competent authority of the Member State where the user or patient is established in accordance with Article 82 of Regulation (EU) 2017/746.
22. If product information, including labeling, is incorrect or inaccurate, please contact the kit manufacturer or supplier.

4 REAGENTS

4.1 Reagents provided

FR E-2831 MTP 96 **Microtiterplate**
Content: 12x8 (break-apart) strips, 96 wells; wells coated with a polyclonal anti-17-OH-Progesterone antibody.

Standards and **Controls** – Ready to use

Cat. no.	Component	Concentration	Volume/Vial
FR E-2801*1	**STANDARD A**	0 ng/ml	1 ml
FR E-2802*2	**STANDARD B**	0.1 ng/ml	0.5 ml
FR E-2803*2	**STANDARD C**	0.4 ng/ml	0.5 ml
FR E-2804*2	**STANDARD D**	1.6 ng/ml	0.5 ml
FR E-2805*2	**STANDARD E**	6.5 ng/ml	0.5 ml
FR E-2806*2	**STANDARD F**	25 ng/ml	0.5 ml
FR E-2851*2	**CONTROL 1**	For control values and ranges please refer to QC-Report.	0.5 ml
FR E-2852*2	**CONTROL 2**		0.5 ml

*1 containing steroid free-serum

*2 containing 17-OH-Progesterone in serum

FR E-2840 **CONJUGATE** **Enzyme Conjugate** – Ready to use
Content: 17-OH-Progesterone conjugated to horseradish peroxidase; containing <0.01% CMIT/MIT and <0.02% MIT.
Volume: 1 x 11 ml
Hazards identification:

H317 May cause an allergic skin reaction.

AR E-0055 **SUBSTRATE** **Substrate Solution** – Ready to use
Content: Tetramethylbenzidine (TMB)
Volume: 1 x 22 ml

AR E-0080 **STOP-SOLN** **Stop Solution** – Ready to use

Content: Contains 2 N acidic solution.
Avoid contact with the stop solution. It may cause skin irritations and burns.

Volume: 1 x 7 ml

AR E-0030 **WASH-CONC** **10x** **Wash Solution** – 10x concentrated

Volume: 1 x 50 ml

see "Reagent preparation" (4.4)

4.2 Material required but not provided

- A microtiter plate reader capable for endpoint measurement at 450 nm
- Calibrated variable precision micropipettes and multichannel pipettes with disposable pipette tips
- Microtiter plate mixer operating at 900 rpm
- Manual or automatic equipment for microtiter plate washing
- Absorbent paper
- Deionized water
- Timer
- Semilogarithmic graph paper or software for data reduction
- Vortex mixer

4.3 Storage conditions

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

4.4 Reagent preparation

Allow the reagents and the required number of wells to reach room temperature (18 – 25 °C) before starting the test.

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 12 weeks at room temperature (18 – 25 °C). Precipitates may form when stored at 2 – 8 °C, which should dissolve again by swirling at room temperature (18 – 25 °C). The Wash Solution should only be used when the precipitates have completely dissolved.

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 Safety Data Sheet.

4.6 Damaged test kits

In case of any severe damage of the test kit or components, the manufacturer has to be informed in writing within 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. Afterwards they should be disposed according to the official regulations.

5 SPECIMEN COLLECTION AND STORAGE

For determination of 17-OH-Progesterone **serum or plasma** (Li-Heparin) can be used.
On average EDTA plasma and Citrate plasma values seem to be approx. 10 – 15 % lower than serum values.
The usual precautions for venipuncture should be observed (1). It is important to preserve the chemical integrity of a blood specimen from the moment it is collected until it is assayed. Do not use hemolytic, icteric, or lipemic specimens. Furthermore, special caution is recommended when using gel collection systems, as an influence on the measurement results cannot be excluded in case of improper handling. Samples containing sodium azide should not be used in the assay.
The procedure calls for 25 µl sample per well. The samples should be assayed immediately or aliquoted and stored at ≤ -20 °C up to 12 months. Thawed samples should be inverted several times prior to testing. Avoid repeated freeze-thaw cycles. Samples expected to contain 17-OH-Progesterone concentrations higher than the highest standard (25 ng/ml) must be diluted with Standard A before assayed. The additional dilution step has to be taken into account for the calculation of the results.

6 ASSAY PROCEDURE

6.1 General remarks

- All reagents and specimens must be allowed to come to room temperature (18 – 25 °C) before use. All reagents must be mixed without foaming.
- Once the test has been started, all steps must be completed without interruption.
- Use new disposal plastic pipette tips for each Standard, Control, and sample in order to avoid cross-contamination.
- Optical density 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.
- Standards, Controls, and samples should at least be assayed in double determinations.
- Microtiter plate washing is important. Improperly washed wells will give erroneous results. It is recommended to use a multichannel pipette or a multistepper, respectively, or an automatic microtiter plate washing system. Do not allow wells to dry between incubations. Do not scratch coated wells during rinsing and aspiration. Rinse and fill all reagents with care. While rinsing, check that all wells are filled precisely with Wash Solution, and that there are no residues in the wells.
- A Standard curve must be established for every run.

6.2 Assay procedure

1.	Prepare a sufficient number of microtiter plate wells to accommodate Standards, Controls and Samples in duplicates.
2.	Dispense **25 µl** of each **Standard**, **Control**, and **Sample** with new disposable tips into appropriate wells.
3.	Dispense **100 µl Enzyme Conjugate** into each well.
4.	Incubate for **60 minutes** at room temperature (18 – 25 °C) on a microtiter plate shaker (900 rpm).
5.	Briskly empty the contents of the wells by aspiration or by decanting. Rinse the wells **4 times** with diluted **Wash Solution** (300 µl per well). Strike the wells sharply on absorbent paper to remove residual droplets. **Important note:** The sensitivity and precision of this assay is markedly influenced by the correct performance of the washing procedure!
6.	Add **200 µl** of **Substrate Solution** to each well.
7.	Incubate for **30 minutes** without shaking in the dark at room temperature (18 – 25 °C).
8.	Stop the enzymatic reaction by adding **50 µl** of **Stop Solution** to each well.
9.	Determine the optical density of each well at 450 nm and read the wells within 15 minutes.

6.3 Calculation of results

1. Calculate the average optical density (OD) values for each set of Standards, Controls, and samples.
2. The obtained optical densities of the Standards (y-axis, linear) are plotted against their corresponding concentrations (x-axis, logarithmic) either on semi-logarithmic paper or using an automated method.
3. Using the mean OD value for each sample, determine the corresponding concentration from the Standard curve.
4. Automated method: The results in the package insert have been calculated automatically using a 4 PL (4 Parameter Logistics) curve fit. 4 Parameter Logistics is the preferred calculation method. Other data reduction functions may give slightly different results.
5. The concentration of the samples can be read directly from this Standard curve. Samples with concentrations higher than that of the highest Standard have to be further diluted with Standard A. For the calculation of the concentrations this dilution factor has to be taken into account.

Conversion to SI units:
17-OH-Progesterone (ng/ml) x 3.03 = nmol/l

6.3.1 Example of typical Standard curve

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

Standard		Optical Density (450 nm)
Standard A	0 ng/ml	2.820
Standard B	0.1 ng/ml	2.239
Standard C	0.4 ng/ml	1.416
Standard D	1.6 ng/ml	0.663
Standard E	6.5 ng/ml	0.259
Standard F	25 ng/ml	0.127

7 EXPECTED NORMAL VALUES

It is strongly recommended that each laboratory should determine its own normal and pathological values. Samples from apparently normal healthy adults, collected in the morning between 8 and 10 a.m. (with the exception of pregnant women), were analyzed using the 17-OH-Progesterone ELISA. Following values are observed:

			ng/ml			
Population		**n**	**Range**	**Median**	**2.5 percentile**	**97.5 percentile**
Female <50 years	Follicular phase	20	0.63 – 2.43	1.24	0.70	2.26
	Luteal phase	20	0.94 – 3.66	1.88	0.95	3.63
	Pregnancy 3rd trimester	38	3.03 – 22.42	6.24	3.27	14.52
Female ≥50 years		20	0.22 – 1.44	0.77	0.28	1.42
Male <50 years		20	0.95 – 2.98	1.89	1.00	2.71
Male ≥50 years		20	0.82 – 3.50	1.12	0.84	2.90

These results alone should not be the only reason for any therapeutic consequences. They have to be correlated to other clinical observations and diagnostic tests.

8 QUALITY CONTROL

Good laboratory practice requires to run controls with each standard 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 state and federal 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 kit-control values and the corresponding results are stated in the QC certificate present in the kit. The values and ranges stated on the QC certificate 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 analyzing control values and trends. If the results of the assay do not fit to the established acceptable ranges of control materials patient 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 the manufacturer directly.

9 PERFORMANCE CHARACTERISTICS

9.1 Analytical Sensitivity

The analytical sensitivity of the 17-OH-Progesterone ELISA was calculated by subtracting two standard deviations from the mean of 20 replicate analyses of Standard A. The analytical sensitivity of the assay is 0.022 ng/ml.

9.2 Specificity (Cross Reactivity)

The following materials have been evaluated for cross reactivity. The percentage indicates cross-reactivity at 50 % displacement compared to 17-OH-Progesterone.

Substance	% Cross-reactivity
Androstenedione	0.01
Testosterone	0.02
Cortisol	0.02
11-Desoxycortisol	0.42
Cortisone	< 0.01
Corticosterone	< 0.01
11-Deoxycorticosterone	0.03
Progesterone	1.26
Estradiol	< 0.01
Estriol	< 0.01
Estrone	< 0.01
Pregnenolone	0.21
Prednisolone	0.01
Prednisone	< 0.01
DHEA	0.01
DHEA-S	< 0.01
Danazole	< 0.01
Dexamethasone	< 0.01

9.3 Assay Dynamic Range

The range of the assay is between 0.1 – 25 ng/ml.

9.4 Reproducibility

9.4.1 Intra-Assay

The intra-assay variation was determined by 20 replicate measurements of three serum samples within one run using the 17-OH-Progesterone ELISA.

	Sample 1	Sample 2	Sample 3
Mean (ng/ml)	1.11	8.29	12.18
SD (ng/ml)	0.06	0.58	0.82
CV (%)	5.1	6.9	6.7
n =	20	20	20

9.4.2 Inter-Assay

The inter-assay variation was determined by duplicate measurements of three serum samples in ten different runs using the 17-OH-Progesterone ELISA.

	Sample 1	Sample 2	Sample 3
Mean (ng/ml)	1.09	7.47	12.80
SD (ng/ml)	0.07	0.39	1.18
CV (%)	6.6	5.2	9.2
n =	10	10	10

9.5 Recovery

Recovery was determined by adding increasing amounts of the analyte to three different serum samples containing different amounts of endogenous analyte. Each sample (non-spiked and spiked) was assayed and analyte concentrations of the samples were calculated from the standard curve. The percentage recoveries were determined by comparing expected and measured values of the samples.

Sample	Spiking (ng/ml)	Observed (ng/ml)	Expected (ng/ml)	Recovery (%)
1	native	0.51	–	–
	4	4.92	4.51	109
	8	8.25	8.51	97
	16	16.71	16.51	101
2	native	0.40	-	–
	4	4.76	4.40	108
	8	7.83	8.40	93
	16	14.27	16.40	87
3	native	0.36	–	–
	4	4.01	4.36	92
	8	8.57	8.36	103
	16	15.12	16.36	92

9.6 Linearity

Three serum samples containing different amounts of analyte were assayed undiluted and diluted with Standard A. The percentage linearity was calculated by comparing the expected and measured values for 17-OH-Progesterone.

Sample	Dilution	Observed (ng/ml)	Expected (ng/ml)	Linearity (%)
1	native	17.04	–	–
	1 : 2	8.60	8.52	101
	1 : 4	4.48	4.26	105
	1 : 8	2.26	2.13	106
2	native	8.01	–	–
	1 : 2	3.71	4.01	93
	1 : 4	1.74	2.00	87
	1 : 8	0.84	1.00	84
3	native	9.38	–	–
	1 : 2	4.62	4.69	99
	1 : 4	2.45	2.35	104
	1 : 8	1.14	1.17	97

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 Interfering Substances

- Hemoglobin (up to 250 mg/dl), bilirubin (up to 40 mg/dl), and lipids (up to 30 mg/ml) show no significant influence on the assay results. However, we recommend not to use any hemolytic, icteric, or lipemic specimens to avoid any interferences.
- Samples containing sodium azide should not be used in the assay.
- The result of any immunological test system may be affected by heterophilic antibodies, anti-species antibodies or rheumatoid factors present in human samples (12 – 14). For example, the presence of heterophilic antibodies in patients who are regularly exposed to animals or animal products may interfere with immunological tests. Therefore, interference with this *in-vitro* immunoassay cannot be excluded. If false results are suspected, they should be considered invalid and verified by further testing. For diagnostic purposes, results should always be considered only in conjunction with the patient's clinical picture and further diagnostic tests.

10.2 Drug Interferences

Until today no substances (drugs) are known to us, which have an influence to the measurement of 17-OH-Progesterone in a sample.
The clinical significance of the determination of 17-OH-Progesterone can be invalidated if the patient was treated with natural or synthetic steroids. Any medication should be taken into account when assessing the results.

10.3 High Dose Hook Effect

A High Dose Hook Effect is not detected up to a concentration of 500 ng/ml.

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 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, the manufacturer should be contacted.

11.2 Therapeutic Consequences

Therapeutic consequences should never be based on laboratory results alone even if all test results are in agreement with the items as stated under point 11.1. Any laboratory result is only a part of the total clinical picture of a patient.
Only in cases where the laboratory results are in acceptable agreement with the overall clinical picture of the patient should therapeutic consequences be derived.
The test result itself should never be the sole determinant for deriving any therapeutic consequences.

11.3 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.
Claims submitted due to customer misinterpretation of laboratory results subject to point 11.2. are also invalid. 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.

12 REVISION HISTORY OF INSTRUCTION FOR USE

Changes from the previous version 9.0 to actual version 10.0a

General	Complete revision; editorial changes
Chapter 1	Adaptation of sample types in intended use: Li-Heparin plasma added, EDTA plasma removed
Chapter 2	updated; editorial changes
Chapter 3	additional information
Chapter 4.1	Hazard labelling for component AR E-0080 removed
Chapter 4.2	updated
Chapter 5	updated; adaption of sample types: Li-Heparin added, EDTA- and Citrate plasma limited
Chapter 6.1	additional information
Chapter 6.3	updated
Chapter 7	updated normal values
Chapter 9	updated assay characteristics
Chapter 10	additional information, updates, High-Dose-Hook-Effect added (10.3)
Chapter 12	added
Chapter 13	References added

13 REFERENCES

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Symbols:

	Storage temperature		Manufacturer		Contains sufficient for <n> tests
	Use-by date	LOT	Batch code	I V D	For in-vitro diagnostic use only!
	Consult instructions for use	CONT	Content	CE	CE marking of conformity
	Caution	REF	Catalogue number		Distributor
	Date of manufacture				