Product information

Useŕs Manual

Testosterone free in Saliva ELISA

Enzyme immunoassay for the determination of free active testosterone in saliva

REF **IB79316**

Σ **96 Wells**

RUO **For Research Use Only – Not for Use in Diagnostic Procedures**

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1 INTRODUCTION

1.1 Intended Use

The Testosterone free in Saliva ELISA is an enzyme immunoassay for the determination of testosterone in human saliva. **For Research Use Only – Not for Use in Diagnostic Procedures.**

2 PRINCIPLE

The IBL-America Testosterone free in Saliva 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 testosterone in the sample. After addition of the substrate solution, the intensity of color developed is inversely proportional to the concentration of testosterone 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 research use only. For professional use only. Not for use in diagnostic procedures
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.
9. Never pipet by mouth and avoid contact of reagents and specimens with skin and mucous membranes.
10. Do not smoke, eat, drink or apply cosmetics in areas where specimens or kit reagents are handled.
11. Wear disposable latex gloves when handling specimens and reagents. Microbial contamination of reagents or specimens 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. Some reagents contain Proclin 300, CMIT and MIT as preservatives. In case of contact with eyes or skin, flush immediately with water.
18. Chemicals and prepared or used reagents have to be treated as hazardous waste according to the national biohazard safety guideline or regulation.
19. For information on hazardous substances included in the kit please refer to Material Safety Data Sheets. Safety Data Sheets for this product are available upon request directly from IBL-America.
20. If product information, including labeling, is incorrect or inaccurate, please contact the kit manufacturer or supplier.

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4 REAGENTS PROVIDED

4.1 Reagents provided

1. **SORB | MT Microtiterwells**, 12x8 (break apart) strips, 96 wells;
   Wells coated with an anti-Testosterone antibody (rabbit polyclonal antibody).
2. **CAL | 0 Calibrator 0,** 1 vial, 3.0 ml, ready to use
3. **CAL | 1-5 Calibrator (Calibrator 1-5),** 5 vials, 1 ml each, ready to use;
   Concentrations: 10 – 30 – 100 – 300 – 1000 pg/ml

   Conversion: Testosterone (pg/ml) x 3.47 = pmol/l
4. **CONTROL | 1-2 Control 1 (low), Control 2 (high)**, 2 vials, 1.0 ml each, ready to use;

   Containing defined concentrations of testosterone in buffer solution
   For control values and ranges please refer to QC-Datasheet.
5. **ENZ | CONJ Enzyme Conjugate**, 1 vial, 12 ml, ready to use;
   Testosterone conjugated to horseradish peroxidase; containing <0.01% CMIT/MIT and <0.02% MIT
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.

   Avoid contact with the stop solution. It may cause skin irritations and burns.
8. **WASH | SOLN | 10x Wash Solution**, 1 vial, 50 ml (10X concentrated);
   see „Preparation of Reagents“ (4.4).

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

4.1.1 Materials required but not provided

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

4.2 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 wells must be stored at 2°C to 8°C. Take care that the foil bag is sealed tightly.

4.3 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 at least 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.

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4.4 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.

4.5 Damaged test kits

In case of any severe damage of the test kit or components, IBL-AMERICA have 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 SAMPLES

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. Blood contamination will give falsely elevated concentration values. In case of visible blood contamination, the sample should be discarded, rinse the sampling device with water, wait for 10 minutes and take a new sample.

5.1 Sample Collection

For the correct collection of saliva we are recommending to use appropriate devices made from ultra-pure polypropylene. Do not use any PE devices for sampling to avoid significant interferences. Do not use Salivette tubes for sampling. Glass tubes can be used as well, but in this case, special attention is necessary for excluding any interference caused by the stoppers. For more details please contact IBL-America.

As the Testosterone secretion in saliva as well as in serum shows an obvious episodic secretion pattern it is important to care for a proper timing of the sampling. In order to avoid arbitrary results we are recommending to collect 5 samples within a period of 2 hours (multiple sampling) preferably in the early morning of a normal day directly after waking up. As food might contain significant amounts of steroid hormones samples preferably should be taken while fasting. If fasting should be a problem the collection period should be timed just before lunch or before dinner. In the early morning Testosterone levels of males are significantly higher compared to those ones during the day. The Testosterone concentration in the morning is roughly twice as high compared to the evening concentration.

Do not chew anything during the sampling period. Any pressure to the teeth may result in falsely elevated measurements due to an elevated content of gingival liquid in the saliva sample.

5.2 Sample Storage and Preparation

Saliva samples may be stored at 2-8°C for up to one week. For longer storage, it is recommended to store the samples at ≤-20°C. Repeated thawing and freezing is not a problem, however this should be avoided to a minimum. Each sample has to be frozen, thawed, and centrifuged at least once anyhow in order to separate 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 colourless supernatant is easy to pipette. If the sample should show even a slightly red colour, it should be discarded. Blood contamination might influence the results and leads to false results. 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 staff of 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 testosterone concentrations higher than the highest calibrator (1000 pg/ml) should be diluted with the zero calibrator before assayed. The additional dilution step has to be taken into account for the calculation of the result.

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6 ASSAY PROCEDURE

6.1 General Remarks

- All reagents and specimens 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.
- 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.
- Calibrators, controls, and samples should at least be assayed in duplicates.
- 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 the 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 calibrator curve must be established for every run.

6.2 Assay procedure

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 **100 µl** of **Enzyme Conjugate** into each well.
4. Incubate for **60 minutes** at room temperature (18-25°C) on a Microplate mixer (900 rpm).

   Important Note:

   Optimal reaction in this assay is markedly dependent on shaking of the Microtiter plate!
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 for **30 minutes** at room temperature (18-25°C) without shaking in the dark.
8. Stop the reaction by adding **50 µl** of **Stop Solution** to each well.
9. Determine the optical density of each well at 450 nm. It is recommended to read the wells within 15 minutes.

6.3 Calculation of Results

1. Calculate the average absorbance values for each set of standards, controls and samples.
2. The obtained optical density 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 optical density value for each sample determine the corresponding concentration from the standard curve.
4. Automated method: The results in the IFU 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 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:

Testosterone (pg/ml) x 3.47 = pmol/l

6.3.1 Example of a Typical Calibrator Curve

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

Calibrator	Optical Density (450 nm)
Calibrator 0 (0 pg/ml)	2.869
Calibrator 1 (10 pg/ml)	2.689
Calibrator 2 (30 pg/ml)	2.209
Calibrator 3 (100 pg/ml)	1.353
Calibrator 4 (300 pg/ml)	0.713
Calibrator 5 (1000 pg/ml)	0.338

7 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 the measured 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.

8 PERFORMANCE CHARACTERISTICS

8.1 Analytical Sensitivity

The analytical sensitivity was calculated by subtracting 2 standard deviations (2SD) from the mean of at least twenty (20) replicate analyses of Calibrator 0. The analytical sensitivity of this assay is 6.1 pg/ml.

8.2 Specificity (Cross Reactivity)

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

Steroid	**% Cross reaction**
5α-Dihydrotestosterone	23.3%
Androstenedione	32.2%
Androsteron	< 0.1%
5α-Androstane	< 0.1%
5ß-Androstane-3α,17ß-diole	< 0.1%
Corticosterone	< 0.1%
11-Desoxycorticosterone	< 0.1%
Dexamethasone	< 0.1%
Estradiol	< 0.1%
Progesterone	< 0.1%
17α-Hydroxyprogesterone	< 0.1%

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Cortisol	< 0.1%
11-Desoxycortisol	< 0.1%
Cortison	< 0.1%
Estrone	< 0.1%
Pregenolone	< 0.1%
Prednisone	< 0.1%
Prednisolon	< 0.1%
Estriol	< 0.1%
Danazol	< 0.1%

8.3 Assay dynamic range

The range of the assay is between 10 – 1,000 pg/ml.

8.4 Reproducibility

8.4.1 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:

	Sample 1	**Sample 2**	**Sample 3**
Mean (pg/ml)	388.2	41.5	137.3
SD	23.47	3.38	5.89
CV (%)	6.0	8.1	4.3
n =	20	20	20

8.4.2 Inter-Assay

The inter-assay (between-run) variation was determined by duplicate measurements of three saliva samples in ten different runs.

	Sample 1	**Sample 2**	**Sample 3**
Mean (pg/ml)	49.9	88.2	282.7
SD	4.24	6.05	21.38
CV (%)	8.5	6.9	7.6
n =	10	10	10

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8.5 Recovery

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

Sample	Spiking (pg/mL)	Measured (pg/mL)	Expected (pg/mL)	Recovery (%)
1	Native	50.7	-	-
	100	152.5	150.7	101%
	200	272.9	250.7	109%
	300	361.9	350.7	103%
2	Native	15.0	-	-
	100	113.3	115	99%
	200	212.6	215	99%
	300	301.8	315	96%
3	Native	82.7	-	-
	100	212.1	182.7	116%
	200	307.6	282.7	109%
	300	406.6	382.7	106%

8.6 Linearity

Three saliva samples containing different amounts of analyte were serially diluted with Calibrator 0 and assayed. The percentage linearity was calculated by comparing the expected and measured values.

Saliva	Dilution	Measured (pg/mL)	Expected (pg/mL)	Linearity (%)
1	native	288.5	-	-
	1 : 2	150.6	144.2	104%
	1 : 4	81.7	72.1	113%
	1 : 8	41.5	36.1	115%
2	native	125.2	-	-
	1 : 2	63.8	62.6	102%
	1 : 4	37.5	31.3	120%
	1 : 8	15.4	15.6	98%
3	native	80.7	-	-
	1 : 2	41.1	40.4	102%
	1 : 4	20.2	20.2	100%
	1 : 8	10.5	10.1	104%

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9 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.

9.1 Interfering Substances

- Blood contamination in saliva samples will affect results, and usually can be seen by eye. In case of visible blood contamination, the patient should discard the sample, rinse the sampling device with water, wait for 10 minutes and take a new sample.
- Samples containing sodium azide should not be used in the assay. This can cause false results.
- The result of any immunological test system may be affected by heterophilic antibodies, anti-species antibodies or rheumatoid factors present in human samples (17-19). For example, the presence of heterophilic antibodies in samples who are regularly exposed to animals or animal products may interfere with immunological tests. Therefore, interference with this immunoassay cannot be excluded. If unplausible results are suspected, they should be considered invalid and verified by further testing.

9.2 Drug Substances

Any medication (cream, oil, pill, etc.) containing testosterone of course will significantly influence the measurement of this analyte. Any medication should be taken into account when assessing the results.

9.3 High-Dose-Hook Effect

Up to a tested concentration of 20 ng/ml testosterone, no High Dose Hook Effect was observed for the IBL-America Testosterone free in Saliva ELISA.

10 LEGAL ASPECTS

10.1 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.

10.2 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.

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11 REVISION HISTORY OF INSTRUCTIONS FOR USE

Changes from the previous version 10-03/17 to actual version 11-05/22

Cover page	Layout change
General	Editorial changes
Chapter 2	updated; editorial changes
Chapter 3	additional information
Chapter 4	updated and additional information; plate shaker at 900 rpm required (before ≥ 600 rpm)(4.2)
Chapter 5	updated: storage conditions of saliva samples
Chapter 6	updated information (6.1; 6.3); shaking during incubation at 900 rpm (before ≥600 rpm) (6.2)
Chapter 8	updated assay characteristics
Chapter 9	additional information, updates, High-Dose-Hook-Effect added (10.3)
Chapter 11	added
Chapter 13	References added

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SYMBOL

S 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

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