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User's Manual

Testosterone free in Saliva ELISA

IVD

CE

REF

DEM-DES6622

Σ

96 Wells

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1 INTRODUCTION

1.1 INTENDED USE

An Enzyme Immunoassay for the quantitative measurement of free active testosterone in saliva.

Measurement of testosterone is used in the diagnosis and treatment of disorders involving the male sex hormones (androgens), including primary and secondary hypogonadism, delayed or precocious puberty, impotence in males and in females hirsutism (excessive hair) and virilization (masculinization) due to tumors, polycystic ovaries, and adrenogenital syndromes.

1.2 SUMMARY AND EXPLANATION

At present, the majority of steroid hormone determinations are conducted from serum samples, even if results in the low or very low concentration range are expected, for example, in elderly patients. This is a real challenge for any diagnostic laboratory as shown by Taieb et al in 2003 [10] and others [9]. Recently there has been an official position statement of the Endocrine Society[14] stating that reliable Testosterone measurements in serum either need an extraction step or have to be done by chromatographic methods like Tandem MS or GCMS. There now is sufficient evidence that the commercial Testosterone assays are unable to quantify low concentrations in a reliable way.

Another major problem associated with the measurement of free hormone levels from serum is the episodic secretion pattern of steroid hormones. Even in 1973[1] it could be shown that steroid secretion shows a significant episodic pattern. Nevertheless, the majority of the determinations are still made from just one serum sample, resulting in non-reproducible values due to the biological variation. In general, serum measurements can only give the total steroid hormone concentration, whereas saliva testing results in the measurement of the free active hormone fraction[3,5].

So far, all attempts for a direct quantification of free Testosterone in serum or plasma samples by commercial immunoassays have failed [7].

Taking into consideration the above mentioned drawbacks of the current analytical procedures, salivary testing seems to be a reliable alternative. It has been shown in the literature[3,5,13,15] that the measurement of free salivary Testosterone gives clinically valid results even in the low concentration range. In salivary testing it is easy to compensate for the episodic secretion pattern provided multiple sampling is done (preferably 5 samples within 2 hours). The measurement of free Testosterone is done with a mixture of these 5 samples. In contrast to this, measurements from just one single saliva sample always will give arbitrary results (like in serum).

2 PRINCIPLE

The **DEMEDITEC Testosterone 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 testosterone present in the sample and a defined amount of testosterone conjugated to horseradish peroxidase compete for the binding sites of rabbit polyclonal testosterone 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 testosterone is inversely proportional to the optical density measured.

3 WARNINGS AND PRECAUTIONS

1. 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. Do not mix reagents of different lots. Do not use expired reagents.
4. The microplate contains snap-off strips. Unused wells must be stored at 2 - 8°C in the sealed foil pouch and used in the frame provided.
5. Avoid contact with Stop Solution. It may cause skin irritation and burns.
6. Pipetting of samples and reagents must be performed as quickly as possible and in the same sequence for each step.
7. Change pipette tips between samples, controls and reagents to avoid carry over contamination.
8. 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.
9. Mix the contents of the microplate wells thoroughly to ensure good test results. Do not reuse microwells.
10. Do not let wells dry during assay; add reagents immediately after completing the rinsing steps.
11. Assay reagents contain Proclin against microbial growth. In case of contact with eyes or skin, flush immediately with water.
12. All reagents should be at room temperature (21-26°C) before use. Temperature will affect the absorbance readings of the assay. However, values for the patient samples will not be affected.
13. TMB substrate has an irritant effect on skin and mucosa. In case of contact with skin or eyes, wash thoroughly with water. Please note that extreme temperature changes may cause spontaneous decay of the peroxide.

4 REAGENTS PROVIDED

1. ***Microtiterwells***, 12x8 (break apart) strips, 96 wells;
   Wells coated with an anti-Testosterone antibody (rabbit polyclonal antibody).
2. ***Standard 0,*** 1 vial, 3.0 ml, ready to use
3. ***Standard (Standard 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***, 2 vials, 1.0 ml each, ready to use;
   For control values and ranges please refer to QC-Datasheet.
5. ***Enzyme Conjugate***, 1 vial, 12 ml, ready to use;
   Testosterone conjugated to horseradish peroxidase;
6. ***Substrate Solution***, 1 vial, 22 ml, ready to use;
   contains tetramethylbenzidine (TMB).
7. ***Stop Solution***, 1 vial, 7 ml, ready to use;
   contains 2 N Hydrochloric Acid solution.
8. ***Wash Solution***, 1 vial, 50 ml (10X concentrated);
   see „Preparation of Reagents“.

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

4.1 MATERIALS REQUIRED BUT NOT PROVIDED

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

4.2 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.

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

5 SPECIMEN

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 patient should discard the sample, rinse the sampling device with water, wait for 10 minutes and take a new sample.

5.1 Specimen 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. 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 Demeditec Diagnostics. 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 Specimen 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 separate the mucins by centrifugation. Upon arrival of the samples at the lab the samples have to 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 slighty 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 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 Specimen Dilution

Samples expected to contain testosterone concentrations higher than the highest calibrator (1000 pg/ml) should be diluted with the zero calibrator before 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 Standard 0 (mix thoroughly)
b) Dilution 1:100: 10 µl of dilution a) + 90 µl Standard 0 (mix thoroughly).

6 ASSAY PROCEDURE

Each run must include a standard curve.

1. Prepare a sufficient number of microplate wells to accommodate calibrators, controls and patient samples.
2. Dispense **100 µl** of each ***Standard, 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 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 beating 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.

6.1 CALCULATION OF RESULTS

1. Calculate the average absorbance values for each set of standards, controls and patient 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 standard 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 standard curve. Samples with concentrations higher than that of the highest standard 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

6.2 Example of Typical Standard Curve

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

Standard	Absorbance Units
Standard 0 (0 pg/ml)	2.267
Standard 1 (10 pg/ml)	2.040
Standard 2 (30 pg/ml)	1.721
Standard 3 (100 pg/ml)	1.019
Standard 4 (300 pg/ml)	0.592
Standard 5 (1000 pg/ml)	0.299

7 EXPECTED NORMAL VALUES

In order to determine the normal range of salivary Testosterone, saliva samples from children, adult male and adult female apparently healthy subjects were collected in the morning and analyzed using the DEMEDITEC Testosterone free in Saliva ELISA kit. The following ranges are calculated with the results of this study.

The concentrations are given in pg/ml.

	Men ♂			Women ♀		
Age Group Years	**Range (5 - 95%)**	**Median pg/ml**	**n**	**Range (5 - 95%)**	**Median pg/ml**	**n**
15 – 55	45.9 –113.1	79.5	65	13.1 – 44.9	29	435
>55	34.5 – 95.7	65.1	31	11.0 – 36.6	23.8	108

	Children		
Age Group Years	**Range (5 - 95%)**	**Median pg/ml**	**n**
< 11	0.5 – 20.7	32.2	8

The results alone should not be the only reason for therapy. The results should be correlated to other clinical observations and diagnostic tests. Since testosterone levels show diurnal cycles, we recommend that the samples should be obtained at the same time each day. Because of differences which may exist between laboratories and location with respect to population, laboratory technique and selection of reference group, it is important for each laboratory to establish the appropriateness of adopting the reference range suggested here.

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 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 DEMEDITEC directly.

9 PERFORMANCE CHARACTERISTICS

9.1 Sensitivity

The lowest analytical detectable level of testosterone that can be distinguished from the Zero Standard is 2.2 pg/ml at the 2SD confidence limit.

9.2 Specificity

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

Steroid	% Cross reaction
Testosterone	100%
5α-Dihydrotestosterone	23.3%
Androstenedione	1.6%
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%
Cortisol	< 0.1%
11-Desoxycortisol	< 0.1%
Cortison	< 0.1%
Estrone	< 0.1%
Pregenolone	< 0.1%
Prednisone	< 0.1%
Prednisolon	< 0.1%
Prednisone	< 0.1%
Danazol	< 0.1%

9.3 Reproducibility

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)	61.0	90.8	216.4
SD	5.92	6.58	12.0
CV (%)	9.7	6.6	5.6
n =	20	20	20

Inter-Assay

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

Mean (pg/ml)	54.3	74.3	275.5
SD	4.37	5.49	19.5
CV (%)	8	7.4	7.0
n =	8	8	8

9.4 Recovery

Using the Calibrator Matrix six spiking solutions were prepared (A = 2000 pg/ml, B = 4000 pg/ml, C = 6000 pg/ml, D = 500 pg/ml, E = 1000 pg/ml and F = 2000 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 Testosterone 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	61.8	-	-
	153.3	158.7	96.6
	259.0	258.7	100.1
	365.0	358.7	101.8
2	74.0	-	-
	164.6	170.3	96.6
	270.4	270.3	100.0
	345.4	370.3	93.3
3	30.9	-	-
	49.4	54.3	91.0
	76.6	79.3	96.6
	109.0	129.3	84.3

Sample	**Measured (pg/ml)**	**Expected (pg/ml)**	**Recovery (%)**
4	87.3	-	-
	105.8	107.9	98.0
	125.8	132.9	94.7
	195.6	182.9	106.9
5	71.1	-	-
	85.6	92.5	92.5
	94.5	117.5	80.4
	154.9	167.5	92.5
6	74.7	-	-
	87.9	95.9	91.6
	140.3	120.9	116.0
	168.4	170.9	98.5

9.5 Linearity

Six saliva samples containing different amounts of analyte were serially diluted with zero standard and assayed with the DEMEDITEC ELISA. Four native samples were serially diluted, and two samples were spiked with testosterone and then serially diluted up to 1:8. The percentage recovery was calculated by comparing the expected and measured values for testosterone.

		Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6
Concentration	**(pg/ml)**	224	205	106.7	66.6	91.1	133.7
Average %	**Recovery**	97	103	99	81	113	103
Range of	**from**	91	98	89	74	112	94
Recovery %	**to**	105	107	104	87	115	117

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

Until now no substances (drugs) are known influencing the measurement of Testosterone in a saliva sample.

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SYMBOLS USED WITH 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	Consultez le Mode d'emploi	Consulte las Instrucciones	Consulti le istruzioni
IVD	In vitro diagnostic device	In-vitro-Diagnostikum	Diagnostic in vitro	Diagnóstico in vitro	Diagnostica in vitro
REF	Catalogue number	Katalog-Nr.	Référence	No de catálogo	No. di Cat.
LOT	Lot. No. / Batch code	Chargen-Nr.	No. de lot	Número de lote	Lotto no
	Contains sufficient for <n> tests/	Ausreichend für "n" Ansätze	Contenu suffisant pour "n" tests	Contenido suficiente para <n> ensayos	Contenuto sufficiente per "n" saggi
	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
Content	Content	Inhalt	Contenu	Contenido	Contenuto
Volume/No.	Volume / No.	Volumen/Anzahl	Volume/Numéro	Volumen/Número	Volume/Quantità
Microtiterwells	Microtiterwells	Mikrotiterwells	Plaques de micro-titration	Pocillos de la Microplaca	Micropozzetti
Antiserum	Antiserum	Antiserum	Antisérum	Antisuero	Antisiero
Enzyme Conjugate	Enzyme Conjugate	Enzymkonjugat	Conjugué enzymatique	Conjugado enzimático	Tracciante enzimatico
Enzyme Complex	Enzyme Complex	Enzymkomplex	Complexe enzymatique	Complex enzimático	Complesso enzimatico
Substrate Solution	Substrate Solution	Substratlösung	Solution substrat	Solución de sustrato	Soluzione di substrato
Stop Solution	Stop Solution	Stopplösung	Solution d'arrêt	Solución de paro	Soluzione d´ arresto
Zero Standard	Zero Standard	Nullstandard	Standard 0	Standard 0	Standard zero
Standard	Standard	Standard	Standard	Calibrador	Standard
Control	Control	Kontrolle	Contrôle	Control	Controllo
Assay Buffer	Assay Buffer	Assaypuffer	Tampon d'essai	Tampón de ensayo	Tampone del test
Wash Solution	Wash Solution	Waschlösung	Solution de lavage	Solución de lavado	Soluzione di lavaggio
1N NaOH	1N NaOH	1N NaOH	1N NaOH	1N NaOH	1N NaOH (idrossido di sodio 1N)
1 N HCl	1 N HCl	1 N HCl	1N HCl	1 N HCl	
Sample Diluent	Sample Diluent	Probenverdünnungs-medium	Solution pour dilution de l'échantillon		Diluente dei campioni
Conjugate Diluent	Conjugate Diluent	Konjugatverdünnungs-medium	Solution pour dilution du conjugué		Diluente del tracciante

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
Antiserum	Anti-soro	Antiserum	Antiserum	Αντιορός
Enzyme Conjugate	Conjugado enzimático	Enzymkonjugat	Enzymkonjugat	Συζευγμένο ενζυμο
Enzyme Complex	Complexo enzimático	Enzymkompleks	Enzymkomplex	Σύμπλοκο ενζύμου
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
Assay Buffer	Tampão de teste	Assay buffer	Assay Buffer	Ρυθμιστικό Διάλυμα Εξέτασης
Wash Solution	Solução de lavagem	Vaskebuffer	Tvätt lösning	Διάλυμα πλύσεως
1N NaOH	1N NaOH	1N NaOH	1N NaOH	1N NaOH
1 N HCl	1 N HCl	1 N HCl	1 N HCl	1 N HCl
Sample Diluent				
Conjugate Diluent				