

Free Testosterone ELISA

REF CAN-FTE-260

IVD

Effective Date: May 21, 2024

Version: IVD-9.0

1. INTENDED PURPOSE & USE

For the quantitative measurement of Free Testosterone in human serum by an ELISA (Enzyme-Linked Immunosorbent Assay).

This kit is intended for professional use only and is for laboratory use only. For *in vitro* diagnostic use only. Intended to be used manually but may be adaptable to open automated analyzers. The user is responsible for validating the performance of this kit with any automated analyzers.

2. LIMITATIONS RELATED TO INTENDED PURPOSE & USE

- This test is not intended to be used for screening purposes.
- This test is not intended for home testing or self-testing.
- The kit is calibrated for the determination of free testosterone in human serum. The kit is not calibrated for the determination of free testosterone in other specimens of human or animal origin.
- The results obtained with this kit shall never be used as the sole basis for a clinical diagnosis and for therapeutic decisions.
- Although common interfering substances have been evaluated with this test, other substances that have not been evaluated such as drugs and the occurrence of heterophilic antibodies in individuals regularly exposed to animals or animal products have the potential of causing interferences.

3. SUPPLEMENTAL INFORMATION

Testosterone is a C-19 steroid secreted from the testis and the adrenal cortex in men and from the adrenal cortex and ovaries in women. Testosterone is also produced by peripheral tissues from androstenedione, which is of little physiological significance in men; in women however, about half of the circulating testosterone is derived from this origin. Testosterone measurements are used mainly for clinical evaluation of hypogonadism in males and hyperandrogenic states in females.

Testosterone circulates in the blood bound to three proteins: sex hormone binding globulin (60–80%), albumin and cortisol binding globulin. Only about 1–2% of the total circulating testosterone remains unbound or free. Even though it is still under investigation, most researchers accept the free testosterone determination as a measure of the biologically active fraction. Free testosterone determinations are recommended to overcome the influences caused by variations in transport proteins on the total testosterone concentration.

4. PRINCIPLE OF THE TEST

The Free Testosterone ELISA is a competitive immunoassay. Competition occurs between free testosterone present in calibrators, controls, specimen samples and an enzyme-labelled antigen (HRP conjugate) for a limited number of anti-free testosterone antibody binding sites on the microplate wells. After a washing step that removes unbound materials, the TMB substrate (enzyme substrate) is added which reacts with HRP to form a blue-coloured product that is inversely proportional to the amount of free testosterone present. Following an incubation, the enzymatic reaction is terminated by the addition of the stopping solution, converting the colour from blue to yellow. The absorbance is measured on a microplate reader at 450 nm. A set of calibrators is used to plot a calibrator curve from which the amount of free testosterone in specimen samples and controls can be directly read.

The DBC free testosterone kit utilizes a highly specific rabbit anti-testosterone polyclonal antibody at a low binding capacity (Keq x concentration) to keep minimum disturbances of the testosterone-protein equilibrium. The other components in the test system are also optimized in order to not alter the original free testosterone concentration.

5. PROCEDURAL CAUTIONS AND WARNINGS

- This kit is for use by trained laboratory personnel (professional use only). For laboratory *in vitro* use only.
- Practice good laboratory practices when handling kit reagents and specimens. This includes:
 - Do not pipette by mouth.
 - Do not smoke, drink, or eat in areas where specimens or kit reagents are handled.
 - Wear protective clothing and disposable gloves.
 - Wash hands thoroughly after performing the test.
 - Avoid contact with eyes; use safety glasses; in case of contact with eyes, flush eyes with water immediately and contact a doctor.
- Users should have a thorough understanding of this protocol for the successful use of this kit. Reliable performance will only be attained by strict and careful adherence to the instructions provided.
- Do not use the kit beyond the expiry date stated on the label.
- If the kit reagents are visibly damaged, do not use the test kit.
- Do not use kit components from different kit lots within a test and do not use any component beyond the expiration date printed on the label.
- All kit reagents and specimens must be brought to room temperature and mixed gently but thoroughly before use. Avoid repeated freezing and thawing of specimens.
- When the use of water is specified for dilution or reconstitution, use deionized or distilled water.
- Immediately after use, each individual component of the kit must be returned to the recommended storage temperature stated on the label.
- A calibrator curve must be established for every run.
- It is recommended to all customers to prepare their own control materials or serum pools which should be included in every run at a high and low level for assessing the reliability of results.
- The controls (included in kit) must be included in every run and their results must fall within the ranges stated in the quality control certificate; a failed control result might indicate improper procedural techniques or pipetting, incomplete washing, or improper reagent storage.
- When dispensing the substrate and stopping solutions, do not use pipettes in which these liquids will come into contact with any metal parts.
- The TMB Substrate is sensitive to light and should remain colourless if properly stored. Instability or contamination may be indicated by the development of a blue colour, in which case it should not be used.
- Do not use grossly hemolyzed, grossly lipemic, icteric or improperly stored serum.
- Samples or controls containing azide or thimerosal are not compatible with this kit, they may lead to false results.
- Samples values above the measuring range of the kit should be reported as >60 pg/mL and shall not be diluted and retested. Dilution will alter the equilibrium between free testosterone and serum proteins, leading to false results.
- Avoid microbial contamination of reagents.
- To prevent the contamination of reagents, use a new disposable pipette tip for dispensing each reagent, sample, calibrator, and control.
- To prevent the contamination of reagents, do not pour reagents back into the original containers.
- Kit reagents must be regarded as hazardous waste and disposed of according to local and/or national regulations.
- Consumables used with the kit that are potentially biohazardous (e.g., pipette tips, bottles or containers containing human materials) must be handled according to biosafety practices to minimize the risk of infection and disposed of according to local and/or national regulations relating to biohazardous waste.
- This kit contains 1 M sulfuric acid in the stopping solution component. Do not combine acid with waste material containing sodium azide or sodium hypochlorite.

- The use of safety glasses, and disposable plastic, is strongly recommended when manipulating biohazardous or bio-contaminated solutions.
- Proper calibration of the equipment used with the test, such as the pipettes and absorbance microplate reader, is required.
- If a microplate shaker is required for the assay procedure, the type and speed of shaker required is stated in the REAGENTS AND EQUIPMENT NEEDED BUT NOT PROVIDED section. Both the type and speed of shaker used can influence the optical densities and test results. If a different type of shaker and/or speed is used, the user is responsible for validating the performance of the kit.
- Do not reuse the microplate wells, they are for SINGLE USE only.
- To avoid condensation within the microplate wells in humid environments, do not open the pouch containing the microplate until it has reached room temperature.
- When reading the microplate, the presence of bubbles in the wells will affect the optical densities (ODs). Carefully remove any bubbles before performing the reading step.

6. SAFETY CAUTIONS AND WARNINGS

6.1 BIOHAZARDS

The reagents should be considered a potential biohazard and handled with the same precautions applied to blood specimens. All human specimens should be considered a potential biohazard and handled as if capable of transmitting infections and in accordance with good laboratory practices.

Human serum that is used in the preparation of the calibrators and controls has been tested by approved methods and found to be negative for the presence of HBsAg and antibodies to HCV and HIV 1/2. However, no test method can offer complete assurance that any viable pathogens are absent. Therefore, these components should be considered a potential biohazard and handled with the same precautions as applied to any blood specimen, following good laboratory practices.

6.2 CHEMICAL HAZARDS

Avoid direct contact with any of the kit reagents. Specifically avoid contact with the TMB Substrate (contains tetramethylbenzidine) and Stopping Solution (contains sulfuric acid). If contacted with any of these reagents, wash with plenty of water and refer to SDS for additional information.

7. SPECIMEN COLLECTION, STORAGE AND PRE-TREATMENT

7.1 Specimen Collection & Storage

Approximately 0.1 mL of serum is required per duplicate determination. Collect 4–5 mL of venous blood into an appropriately labelled tube and allow it to clot. Centrifuge at room temperature and carefully transfer the serum into a new storage tube or container. Serum samples may be stored at 2–8°C for up to 24 hours or at -10°C or lower if the analyses are to be done at a later date.

Consider all human specimens as possible biohazardous materials and take appropriate precautions when handling.

7.2 Specimen Pre-Treatment

Specimen pre-treatment is not required.

8. REAGENTS AND EQUIPMENT NEEDED BUT NOT PROVIDED

- Calibrated single-channel pipette to dispense 25 µL.
- Calibrated multi-channel pipettes to dispense 50 µL, 100 µL and 150 µL.
- Calibrated multi-channel pipettes to dispense 350 µL (if washing manually).
- Automatic microplate washer (recommended).
- Disposable pipette tips.
- Distilled or deionized water.
- Calibrated absorbance microplate reader with a 450 nm filter and an upper OD limit of 3.0 or greater.
- A 37°C incubator.

9. REAGENTS PROVIDED

1. **MPL** **Microplate**

Contents:	One anti-free testosterone polyclonal antibody-coated 96-well (12x8) microplate in a resealable pouch with desiccant.
Format:	Ready to Use
Storage:	2–8°C
Stability:	Unopened: Stable until the expiry date printed on the label. After Opening: Stable for four weeks.

2. **HRP** **CONJ** **CONC** **HRP Conjugate Concentrate**

Contents:	One bottle containing Free Testosterone-Horse Radish Peroxidase (HRP) conjugate in a protein-based buffer with a non-mercury preservative.
Format:	Concentrated; Requires Preparation
Volume:	0.3 mL/bottle
Storage:	2–8°C
Stability:	Unopened: Stable until the expiry date printed on the label. After Opening: Stable for four weeks.

X51 **Dilute 1:51 Before Use**

Preparation of HRP Conjugate Working Solution:	Dilute 1:51 in assay buffer before use (e.g., 40 µL of conjugate concentrate in 2 mL of assay buffer). If the whole plate is to be used dilute 240 µL of conjugate concentrate in 12 mL of assay buffer. Discard any that is left over.
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3. **CAL** **A – F** **Calibrator A – F**

Contents:	Six bottles of calibrator containing specified free testosterone concentrations. Human serum-based buffer with a non-mercury preservative. Prepared by spiking buffer with defined quantities of testosterone.
	Listed below are approximate concentrations, please refer to vial labels for exact concentrations. Concentrations: 0, 0.1, 1, 5, 20, 60 pg/mL.
Format:	Ready to Use
Volume:	0.5 mL/bottle
Storage:	2–8°C
Stability:	Unopened: Stable until the expiry date printed on the label. After Opening: Stable for four weeks.

4. **CONTROL** **1 – 2** **Control 1 – 2**

Contents:	Two bottles of control containing different free testosterone concentrations. Human serum-based buffer with a non-mercury preservative. Prepared by spiking buffer with defined quantities of testosterone. Refer to the QC certificate for the target values and acceptable ranges.
Format:	Ready to Use
Volume:	0.5 mL/bottle
Storage:	2–8°C
Stability:	Unopened: Stable until the expiry date printed on the label. After Opening: Stable for four weeks.

5. ASY BUFF Assay Buffer


Contents:	One bottle containing a protein-based buffer with a non-mercury preservative.
Format:	Ready to Use
Volume:	15 mL/bottle
Storage:	2–8°C
Stability:	Unopened: Stable until the expiry date printed on the label. After Opening: Stable for four weeks.

6. TMB SUB TMB Substrate

Contents:	One bottle containing tetramethylbenzidine and hydrogen peroxide in a non-DMF or DMSO containing buffer.
Format:	Ready to Use
Volume:	16 mL/bottle
Storage:	2–8°C
Stability:	Unopened: Stable until the expiry date printed on the label. After Opening: Stable for four weeks.

7. STOP Stopping Solution

Contents:	One bottle containing 1M sulfuric acid.
Format:	Ready to Use
Volume:	6 mL/bottle
Storage:	2–8°C
Stability:	Unopened: Stable until the expiry date printed on the label. After Opening: Stable for four weeks.
Safety:	Refer to product SDS.

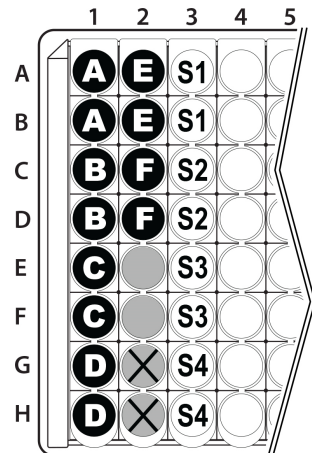


Warning





8. WASH BUFF CONC Wash Buffer Concentrate

Contents:	One bottle containing buffer with a non-ionic detergent and a non-mercury preservative.
Format:	Concentrated; Requires Preparation
Volume:	50 mL/bottle
Storage:	2–8°C
Stability:	Unopened: Stable until the expiry date printed on the label. After Opening: Stable for four weeks. Following Preparation: The wash buffer working solution is stable for 2 weeks following preparation, assuming Good Laboratory Practices are adhered to. To prevent microbial growth, prepare the wash buffer working solution in a clean container and store under refrigerated conditions (2-8°C) when not in use.
Preparation of Wash Buffer Working Solution:	<div style="border: 1px solid black; padding: 2px; display: inline-block;">X10 Dilute 1:10 Before Use</div> Dilute 1:10 in distilled or deionized water before use. If the whole microplate is to be used dilute 50 mL of the wash buffer concentrate in 450 mL of distilled or deionized water.

10. RECOMMENDED ASSAY LAYOUT



Legend

-  Calibrators
-  Control 1
-  Control 2
-  Samples

11. ASSAY PROCEDURE

Specimen Pre-Treatment: None
All kit components, controls and specimen samples must reach room temperature prior to use. Calibrators, controls, and specimen samples should be assayed in duplicate. Once the procedure has been started, all steps should be completed without interruption.
<ol style="list-style-type: none"> After all kit components have reached room temperature, mix gently by inversion. Prepare the HRP Conjugate Working Solution and Wash Buffer Working Solution (See section 9. <i>Reagents Provided</i> section, 2. <i>HRP Conjugate Concentrate</i> and 8. <i>Wash Buffer Concentrate</i>). Plan the microplate wells to be used for calibrators, controls, and samples. See section 10. <i>Recommended Assay Layout</i>. Remove the strips from the microplate frame that will not be used and place them in the bag with desiccant. Reseal the bag with the unused strips and return it to the refrigerator. Pipette 25 µL of each calibrator, control, and specimen sample into assigned wells. Pipette 100 µL of the HRP Conjugate Working Solution into each well (the use of a multi-channel pipette is recommended). Gently shake the microplate frame for 10 seconds to mix the contents of the wells. Incubate the microplate inside a 37°C incubator for 1 hour. Wash the microplate wells with an automatic microplate washer (preferred) or manually as stated below. <i>Automatic:</i> Using an automatic microplate washer, perform a 3-cycle wash using 350 µL/well of Wash Buffer Working Solution (3 x 350 µL). One cycle consists of aspirating all wells then filling each well with 350 µL of Wash Buffer Working Solution. After the final wash cycle, aspirate all wells and then tap the microplate firmly against absorbent paper to remove any residual liquid. <i>Manually:</i> For manual washing, perform a 3-cycle wash using 350 µL/well of Wash Buffer Working Solution (3 x 350 µL). One cycle consists of aspirating all wells by briskly emptying the contents of the wells over a waste container, then pipetting 350 µL of Wash Buffer Working Solution into each well using a multi-channel pipette. After the final wash cycle, aspirate all wells by briskly emptying the contents over a waste container and then tap the microplate firmly against absorbent paper to remove any residual liquid. Pipette 150 µL of TMB Substrate into each well (the use of a multi-channel pipette is recommended). Incubate the microplate inside at 37°C incubator for 10-15 minutes (or until calibrator A attains dark blue colour for desired OD). Pipette 50 µL of Stopping Solution into each well (the use of a multi-channel pipette is recommended) in the same order and speed as was used for addition of the TMB Substrate. Gently tap the microplate frame to mix the contents of the wells. Measure the optical density (absorbance) in the microplate wells using an absorbance microplate reader set to 450 nm, within 20 minutes after addition of the Stopping Solution.

12. CALCULATIONS

- Calculate the mean optical density for each calibrator, control and specimen sample duplicate.
- Use a 4-parameter or 5-parameter curve fit with immunoassay software to generate a calibrator curve.
- The immunoassay software will calculate the concentrations of the controls and specimen samples using the mean optical density values and the calibrator curve.

13. QUALITY CONTROL

When assessing the validity of the test results, the following criteria should be evaluated:

- The calibrator A mean optical density meets the acceptable range as stated in the QC Certificate.
- The calibrator with the highest concentration meets the % binding acceptable range as stated in the QC Certificate. % Binding = (OD of calibrator/OD of calibrator A) x 100.
- The values obtained for the kit controls are within the acceptable ranges as stated in the QC certificate.
- The results of any external controls that were used meet the acceptable ranges.

14. TYPICAL DATA

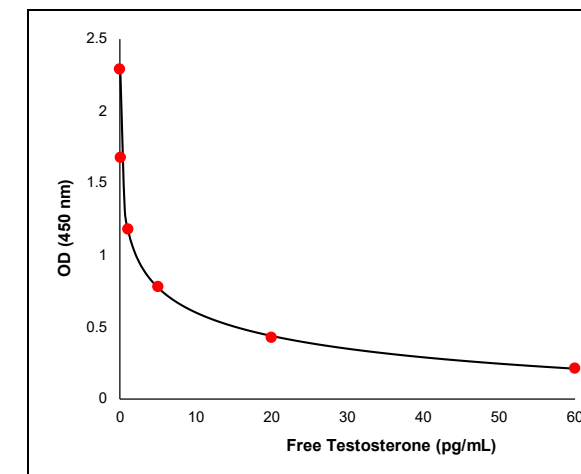
14.1 TYPICAL TABULATED DATA

Sample data only. **Do not** use to calculate results.

Calibrator	Mean OD (450 nm)	% Binding	Value (pg/mL)
A	2.292	100	0
B	1.680	73	0.1
C	1.181	52	1
D	0.780	34	5
E	0.426	19	20
F	0.214	9	60
Unknown	1.066	-	1.59

14.2 TYPICAL CALIBRATOR CURVE

Sample curve only. **Do not** use to calculate results.



15. PERFORMANCE CHARACTERISTICS

15.1 SENSITIVITY

The limit of detection (LoD) was determined from the analysis of 64 replicates of a low value sample and from the LoB.

LoD = LoB + 1.645σS,

where σS is the standard deviation of the low value sample. σS was determined to be 0.0093 based on 64 measurements of a low value sample.

LoD = 0.0025 + (1.645*0.0093) = 0.018 pg/mL.

15.2 SPECIFICITY (CROSS-REACTIVITY)

The following compounds were tested for cross-reactivity with testosterone cross-reacting at 100%.

Compound	% Cross-Reactivity
Testosterone	100
5α-DHT	3.5
Androstenedione	0.17
Progesterone	0.007
Androsterone	0.075
Aldosterone	< 0.008
Cholesterol	< 0.0001
Cortisone	0.0025
DHEA	0.071
DHEAS	0.0014
17β-Estradiol	0.15
Estrinol	< 0.008
Pregnenolone	0.028

15.3 PRECISION

Intra-Assay Precision

Five samples were assayed 24 times each on the same calibrator curve.

The results (in pg/mL) are tabulated below:

Sample	Mean	CV%
1	2.24	6.7
2	3.81	6.4
3	13.6	6.0
4	13.7	5.9
5	23.7	4.8

Inter-Assay Precision

Three samples were assayed twenty times in duplicate over a period of greater than ten days. The results (in pg/mL) are tabulated below:

Sample	Mean	CV%
1	3.53	8.1
2	13.8	11.5
3	23.3	6.9

15.4 EFFECT OF SEX HORMONE BINDING GLOBULIN (SHBG)

The purpose of this study was to investigate a possible interference caused by the binding of SHBG to the free testosterone-HRP conjugate. A charcoal-stripped human serum pool was spiked precisely with SHBG at concentrations ranging from 6.25–200 µg/mL and was assayed with the DBC Free Testosterone ELISA Kit. Results tabulated below (in pg/mL):

SHBG Added	OD 450 nm	Percent B/Bo (%)
0	2.37	100.0
6.25	2.37	99.9
12.5	2.34	98.7
50	2.36	99.5
200	2.27	95.6

The results showed % binding values between 95–100% (Bo = unspiked serum) even at higher than normal SHBG levels. In conclusion, the results showed that there was no significant binding by SHBG on the free testosterone-HRP conjugate.

15.5 COMPARATIVE STUDIES

The DBC Free Testosterone ELISA Kit (y) was compared with a competitor's Free Testosterone Coated Tube RIA Kit (x). The comparison of 60 serum samples yielded the following linear regression results: y (DBC) = 0.9362x (competitor) + 3.8794, r = 0.97

16. REFERENCE RANGES

The results of an expected range study with apparently normal healthy subjects yielded the following results (all values are reported in pg/mL). Each laboratory shall establish their own reference ranges.

Cohort Group; Gender/Age	N	95% Confidence Range	Absolute Range
Males / < 13	44	–	ND–1.6
Males / 13–19	37	–	ND–22.3
Males / 20–39	120	9.1–32.2	–
Males / 40–59	120	5.7–30.7	–
Males / ≥ 60	120	5.9–27.0	–
Females / < 13	63	–	ND–1.3
Females / 13–19	17	–	0.2–2.0
Females / 20–39	120	0.1–6.3	–
Females 40–59	120	0.2–4.1	–
Females / ≥ 60	60	0.5–3.9	–

17. LITERATURE

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18. SYMBOLS GLOSSARY

Symbol	Definition	Symbol	Definition
	Catalogue number		Manufacturer
	Batch code		Date of manufacture
	In vitro diagnostic medical device		Biological risks
	Unique Device Identifier		Consult instructions for use
	Dilute 1:# Before Use		Prescription only: Device restricted to use by or on the order of a physician
	Quantity		Keep away from sunlight
	Use-by date		Authorized representative in the European Community/ European Union
	Do not re-use		Temperature limit
	Caution		Contains sufficient for <n> tests
	Lyophilized		For Research Use Only. Not for use in diagnostic procedures.
The definitions of symbols used for kit component names are described in the <i>Reagents Provided</i> section.			

19. CHANGE HISTORY

Previous Version:	8.1 (COMB)	New Version:	IVD-9.0
Changes:	<p>New IFU format with numbered headings.</p> <p>HEADING Removal of country-specific regulatory information.</p> <p>1. INTENDED PURPOSE & USE Change From: For the direct quantitative determination of Free Testosterone by an enzyme immunoassay in human serum. To: For the quantitative measurement of Free Testosterone in human serum by an ELISA (Enzyme-Linked Immunosorbent Assay).</p> <p>Addition: This kit is intended for professional use only and is for laboratory use only. For <i>in vitro</i> diagnostic use only. Intended to be used manually but may be adaptable to open automated analyzers. The user is responsible for validating the performance of this kit with any automated analyzers.</p> <p>2. LIMITATIONS RELATED TO INTENDED PURPOSE & USE 1 and 2 added.</p>		

5. PROCEDURAL CAUTIONS AND WARNINGS

Additional cautions and warnings added. Some previous limitations added to this section.

9. REAGENTS PROVIDED

Addition of symbols for all components and safety information if applicable.

In-use stability statement added for all components.

Control low and high now called control 1 and 2, respectively.

10. RECOMMENDED ASSAY LAYOUT

New section added.

11. ASSAY PROCEDURE

Component names revised to match symbol definitions.

13. QUALITY CONTROL

New section added.

17. SYMBOLS GLOSSARY

Addition of symbols and definitions.

18. CHANGE HISTORY

New section added.

19. GENERAL INFORMATION

Addition of product complaints, warranty and limitation of liability sections.
Removal of EC REP information.

Build: v1.3D

20. GENERAL INFORMATION



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Tel: (519) 681-8731
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www.dbc-labs.com

Product Complaints

In the case of product complaints, the user shall submit in writing to the distributor or manufacturer a description of the complaint and provide accompanying data and/or information.

Warranty

DBC guarantees that the product is free of defects and will perform within the product specifications when the product is used prior to the expiration date, according to the intended purpose and use, and according to the instructions for use provided with the product. Any deviations from the intended purpose and use, instructions for use, modifications to kit components or use beyond the expiration date will invalidate any warranty claims.

Limitation of Liability

DBC liability in all circumstances whether in tort (including negligence) or at common law, and for any damage or loss, including but not limited to loss of profit and loss of sales, suffered whether direct, indirect, consequential, incidental or special is limited to the purchase price of the product(s) in question.