TESTO

infinosis™

Testosterone (FIA)

REF: IN027707 Σ 25

Intended use
The Infinosis™ TESTO is a fluorescence immunoassay (FIA) for the in vitro quantitative determination of Testosterone (TESTO) in human serum or plasma. For professional use only.

Summary
References[1-6]
Testosterone is a steroid from the androstane class containing a keto and a hydroxyl group at positions three and seventeen respectively. Testosterone is the primary sex hormone and anabolic steroid in males. In male humans, testosterone plays a key role in the development of male reproductive tissues such as testes and prostate, as well as promoting secondary sexual characteristics such as increased muscle and bone mass, and the growth of body hair. In addition, testosterone in both sexes is involved in health and well-being, including moods, behaviour, and in the prevention of osteoporosis. Insufficient levels of testosterone in men may lead to abnormalities including frailty and bone loss.

Test principle
Competitive principle. Total duration of assay: **10 minutes**
Sample is added to the sample well of the test, the fluorescence-labeled detector TESTO antibodies bind to TESTO antigens in blood specimen and form immune complexes. As the complexes migrate on the nitrocellulose matrix by capillary action, it can't be captured by TESTO antigens that have been immobilized on test strip, otherwise the excess unbound fluorescence-labeled detector TESTO antibodies are captured. Thus the more TESTO in blood, the less unbound fluorescence-labeled antibodies accumulated on test strip. Signal intensity of detector TESTO antibodies reflect the amount of antigens and are processed in the instrument for infinosis™ tests to determine the TESTO concentration in blood.

Reagents
Materials provided
- **Test Cartridge**, 25 pcs, individually packaged
- **ID Chip** or **QR code of Calibration Curve**, 1 pcs
- **Sample Buffer,** 1 x 3.0 mL
- **Detector Tube (lyophilized):** 25 tubes
- **IFU**, 1 copy

Materials required (but not provided)
- infinosis™ FIA analyzer
- TESTO control (DiaSino control is recommended)
- Specimen collection containers
- Transfer pipette set (100 µL size)
- Centrifuge (for plasma and serum only)
- Timer

Precautions and warnings
- For in vitro diagnostic use only.
- Carefully follow the instructions and procedures described in this instructions before testing.
- The test cartridge should remain in its original sealed pouch until ready to use. Do not use it if the pouch is damaged or the seal is broken.
- Do not use reagents beyond the labeled expiry date.
- Do not mix or use components from kits with different Lots.
- Don't use Test Cartridge if its Lot does not match with ID Chip that is inserted onto the instrument.
- The infinosis™ TESTO should be used only in conjunction with the instrument for infinosis™ tests.
- The tests should be applied by professionally trained staff working in certified laboratories at some remove from the patient and clinic at which the sample is taken by qualified medical personnel.
- infinosis™ TESTO assay is single use only. Do not reuse it.
- The Test Cartridge and instrument for infinosis™ tests should be used away from vibration and magnetic field. During normal usage, the Test Cartridge may generate slight vibration, which should be regarded as normal.
- Use separate clean pipette tips and buffer tubes for different specimens. The pipette tips and detector buffer tubes should be used for one specimen only.
- Do not smoke, eat, or drink in areas in which specimens or kit reagents are handled.
- Blood specimens, used test cartridges, pipette tips and sample buffer tubes are potentially infectious. Proper laboratory safety techniques, handing and disposal methods should be followed in accordance with standard procedures and relevant regulations observed by microbiological hazard materials.
- The results should be interpreted by the physician along with clinical findings and other laboratory test results.

Incident report
Any suspected serious incidents related to this assay shall be immediately reported to DiaSino, DiaSino's Authorized Representative in the EU, and the national competent authorities of the Member States where the users and/or patients are located.

Storage and stability
- Store the test kit at 2-30°C, the stability is up to the expiration date printed on package.
- Store all the other components at 2-30°C, the stability is up to the expiration date printed on package.
- Test cartridge and sample buffer should be used within 1 hour after opening the pack.

Specimen collection and preparation
- The test can be performed with either serum or plasma.
- Collect serum samples in accordance with correct medical practices.
- Using standard phlebotomy procedure, collect a venipuncture whole blood specimen using a blood collection tube. If collecting plasma use a blood collection tube containing suitable anticoagulant (EDTA recommended).
- Separate the serum/plasma from blood as soon as possible to avoid hemolysis.
- Test should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 3 days. For long-term storage, specimens should be kept below -20°C.

Quality control
- Quality control tests are a part of the good testing practice to confirm the expected results and validity of the assay and should be performed at regular intervals.
- The control tests should be performed immediately after opening a new test lot to ensure the test performance is not altered.
- Quality control tests should also be performed whenever there is any question concerning the validity of the test results.
- Control materials are provided on demand with infinosis™ tests. For more information regarding obtaining the control materials, contact DiaSino Laboratories Co., Ltd for assistance.

Test setup
- Ensure that the lot number of the cartridge matches that of the sample buffer, and the ID Chip.
- If the sealed cartridge and sample buffer have been stored in refrigerator, place them at room temperature (18-25 °C) at least 30 minutes before measurement.
- Turn on the instrument for infinosis™ tests.
  Refer to the *'instrument for infinosis™ tests Operation Manual'* for the complete information and operating instructions.

Test procedure
1. Insert ID Chip into the instrument for infinosis™ tests or Scan the QR code to read the calibration curve.
2. Using a pipette to transfer **100 µL** of **Sample Buffer**, and **50 µL** of **Sample** (Human plasma/serum) to the **Detector Tube (lyophilized)**.
3. Close the lid of the sample mixing tube and mix the sample thoroughly for 60 seconds (1 minute) by tapping or inverting the tube.
4. Pipette out **100 µL** of **sample mixture** and load it onto the sample well on the cartridge.
5. Leave the sample-loaded cartridge at room temperature for **10 minutes.**
6. Insert the sample-loaded cartridge into the cartridge holder of instrument for infinosis™ tests.
   Ensure proper orientation of the cartridge before pushing it all the way inside the cartridge holder.
7. Press **"Test"** button on the instrument for infinosis™ tests.
8. Instrument for infinosis™ tests will start scanning the sample-loaded cartridge immediately.
9. Read the test result on the display screen of the instrument for infinosis™ tests.
10. Print out the testing results when press **"Print"** button on the instrument for infinosis™ tests.

IVD CE

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Limitations - interference
- The assay is unaffected by icterus (bilirubin < 513 µmol/L or < 30 mg/dL), hemolysis (Hb < 0.372 mmol/L or < 0.600 g/dL), lipemia (Intralipid < 1000 mg/dL) and biotin (< 123 nmol/L or < 30 ng/mL).
- Criterion: Recovery within ± 10 % of initial value (concentration range > 1-15 ng/mL), recovery within ± 15 % of initial value (concentration range > 0.5-1 ng/mL) and recovery of ± 0.075 ng/mL (concentration range of 0.150-0.500 ng/mL).
- Samples should not be taken from patients receiving therapy with high biotin doses (i.e. > 5 mg/day) until at least 8 hours following the last biotin administration.
- No interference was observed from rheumatoid factors up to a concentration of 1000 IU/mL.
- In isolated cases, elevated testosterone levels can be seen in samples from female patients with end stage renal disease (ESRD).
- Implausible elevated testosterone values in women should be verified by an extraction method or a validated LC-MS/MS tandem method.[6]
- In rare cases, interference due to extremely high titers of antibodies to analyte-specific antibodies, streptavidin or ruthenium can occur. These effects are minimized by suitable test design.
- For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

Calculation
The analyzer automatically calculates the analyte concentration of each sample (either in nmol/L, ng/mL or µg/L).

Conversion factors:
ng/mL x 3.47 = nmol/L
ng/mL x 100 = ng/dL
nmol/L x 0.288 = ng/mL

Measuring range
0.15-15 ng/mL (defined by the lower detection limit and the maximum of the master curve). Values below the detection limit are reported as < 0.15 ng/mL. Values above the measuring range are reported as > 15 ng/mL.

Lower detection limit
0.15 ng/mL
The detection limit represents the lowest analyte level that can be distinguished from zero. It is calculated as the value lying two standard deviations above that of the lowest standard (master calibrator, standard 1+2 SD, repeatability study, n=21).

Expected values

Male > 18 years	1.49-10.36 ng/mL
Female > 18 years	< 1.08 ng/mL

Measurement with the DiaSino Testosterone assay on 118 healthy male serum samples from test subjects in China yielded the above values (2.5th-97.5th percentile): the average level is around 8.50 ng/mL.

Specific performance data
Representative performance data are given below. Results obtained in individual laboratories may differ.

Precision
Intra-assay
Determined by using 10 tests in the same batch to test with TESTO control, CV ≤ 15%

Inter-assay
Determined by using 3 tests in 3 random and continuous batches to test with TESTO control, CV ≤ 20%

Method comparison
A comparison of the infinosis™ TESTO assay (y) with the Roche Elecsys TESTO II (x) using 118 clinical samples gave the following correlation:

Linear regression
y = 0.9876x + 0.0409
r = 0.9509

Analytical specificity
The following substances were tested for cross reactivity of the assay:

Substance	Concentration (ng/mL)	Cross-reactivity (%)
Estradiol	1000	< 0.160
Estrone	1000	< 0.004
Androstenedione	100	< 3.00
Progesterone	1000	n.d
DHEA-S	50000	< 0.003
Cortisol	1000	< 0.01
Cortisone	2000	n.d
Ethisterone	1000	< 2.40

Functional sensitivity
0.20 ng/mL
The functional sensitivity is the lowest analyte concentration that can be reproducibly measured with an intermediate precision CV of ≤ 20 %.

References

1. "Understanding the risks of performance-enhancing drugs". Mayo Clinic. Retrieved December 30, 2019.
2. Mooradian AD, Morley JE, Korenman SG (February 1987). "Biological actions of androgens". Endocrine Reviews. 8 (1): 1–28. doi:10.1210/edrv-8-1-1. PMID 3549275.
3. Gaviglio CM, Crewther BT, Kilduff LP, Stokes KA, Cook CJ. Rela- tionship between pregame concentrations of free testosterone and out- come in rugby union. Int J Sports Physiol Perform. 2014;9(2):324–31.
4. Crewther BT, Thomas AG, Stewart-Williams S, Kilduff LP, Cook CJ. Is salivary cortisol moderating the relationship between salivary testosterone and hand-grip strength in healthy men? Eur J Sport Sci. 2017;17(2):188–94.
5. Crewther BT, Sanctuary CE, Kilduff LP, Carruthers JS, Gaviglio CM, Cook CJ. The workout responses of salivary-free testosterone and cortisol concentrations and their association with the subsequent competition outcomes in professional rugby league. J Strength Cond Res. 2013;27(2):471–6.
6. Rosner W, Auchus RJ, Azzis R, et al. Position Statement: Utility, Limitations, and Pitfalls in Measuring Testosterone: An Endocrine Society Positions Statement. J Clin Endocrinol Metab 2007;92(2):404-413.

Symbols

IVD In vitro diagnostic medical device	30°C / 2°C Temperature limit	Consult instructions for use	REF Catalog number
LOT Batch code	Date of manufacture	Use-by date	Σ Contains sufficient for <n> tests
Manufacturer	Do not re-use	Do not use if package is damaged and consult instructions for use	CE European Conformity
EC REP Authorized representative in the European Community			

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