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Testosterone Fast Test Kit (Immunofluorescence Assay)

User Manual

INTENDED USE

Testosterone Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of Testosterone in human serum and plasma. Testosterone tests are used to assist in the diagnosis of female polycystic ovary syndrome and male testosterone insufficiency. For professional and laboratory use.

SUMMARY

Testosterone, one of the main sex hormones in the human body, is a steroid hormone with 19 carbon atoms synthesized from cholesterol. About 90% of male testosterone comes from leydig cells, and the rest is produced in adrenal cortex and other tissues; Testosterone in women synthesized by ovarian stromal cells,portal cells and adrenal cortex reticular zone, account for about 50% of total. The remaining 50% is mainly converted from androstenedione in liver, fat, skin and other tissues. It is the precursor of estradiol synthesis in the ovary, and has a certain role in maintaining the female gonadal function. Testosterone exists in blood in two forms: bound and free. The binding state is mainly bound with sex hormone binding protein, albumin and other proteins, accounting for 97%~99%; Free testosterone accounts for 1%~3%, which is the main form of biological activity in vivo. Detection of female testosterone can assist in the diagnosis of polycystic ovary syndrome (PCOS), masculinized tumors in women, congenital adrenal hyperplasia and adrenal tumors. Detection of male testosterone content can assist in the diagnosis of diseases with insufficient testosterone production, such as congenital testicular dysplasia, chromosomal abnormalities, and in addition, it can assist in the diagnosis of hypopituitarism, cirrhosis.

PRINCIPLE

Testosterone Fast Test Kit (Immunofluorescence Assay) is a lateral flow immunoassay in a competitive design. After the sample has been applied to the test strip, the fluorescence latex-labelled testosterone monoclonal antibody binds with the testosterone in sample and forms a marked antigen-antibody complex. The uncombined fluorescence latex-labelled testosterone monoclonal antibody binds with the testosterone on the test line. The fluorescence intensity of the test line decreases in proportion to the amount of testosterone in sample. Fluorescent signals intensity can be analyzed by applicable device thus the testosterone in sample be detected quantitatively.

APPLICABLE DEVICE

Getein 1100 Immunofluorescence Quantitative Analyzer
Getein 1160 Immunofluorescence Quantitative Analyzer
Getein 1180 Immunofluorescence Quantitative Analyzer

CONTENTS

Materials provided	Getein 1100/ Getein 1160/ Getein 1180	
	10 T/kit	25 T/kit
Testosterone test card	10 pcs	25 pcs
Disposable pipet	10 pcs	25 pcs
Sample diluent	10 tube	25 tube
User manual	1 pc	1 pc
SD card	1 pc	1 pc

Sample diluent for Getein 1100/ Getein 1160/ Getein 1180 consists of:
Sample diluent contains Carbonate buffer (50 mmol/L), ProClin™ 300 (0.1%).
A test card consists of:
Fluorescence latex-labelled testosterone monoclonal antibody, Fluorescence latex-labelled Chicken immunoglobulin Y natural protein, testosterone antigen and Goat anti chicken immunoglobulin Y polyclonal antibody.

Note:

1. The standard curve data can be written to RFID card in the kit. According to the function of RFID card, we define it as "Standard Curve Data Card", short for "SD Card".
2. Do not mix or interchange different batches of kits.

STORAGE AND STABILITY

Realtime stability:
Store the kit at 4~30°C with a valid period of 24 months. The test kits are stable until the expiry date printed on the labels.
In-use stability:
For the test card of Getein 1100/Getein 1160/Getein 1180: Use the test card within 1 hour once the foil pouch is opened.

PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. Handle all specimens as potentially infectious. The foil bag is nondegradable. Proper handling and disposal methods should be followed in accordance with local regulations.

SPECIMEN COLLECTION AND PREPARATION

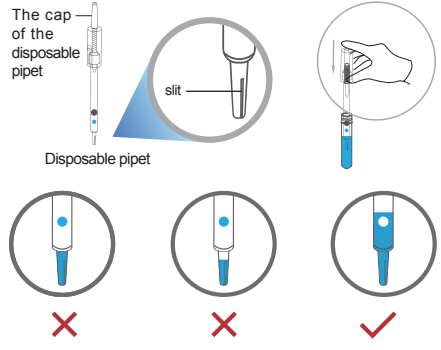
1. This test can be used for **plasma and serum samples**.
2. Heparin, sodium citrate or EDTA can be used as the anticoagulant for plasma samples.
3. It is recommended to test the sample within 8 hours after collection. Stable in plasma for 7 days when stored at 2~8°C and 6 months when stored at -20°C.
4. Refrigerated or frozen sample should reach room temperature before testing. Avoid multiple freeze-thaw cycles.

CALIBRATION AND TRACEABILITY

1. Calibration: The regression equation fitting the concentration value of the working calibrator with the reaction signal value is written into the SD card in advance. Before detection, the SD card is written into the instrument, which can automatically read the calibration curve information in the SD card. During detection, the content of analyte can be calculated by substituting the obtained signal value into the regression equation.
   Calibration Frequency: A new calibration is required when using a new reagent lot or a new instrument.

TEST PROCEDURE

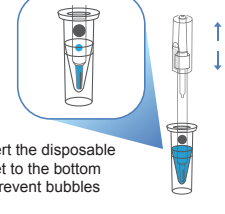
1. Before use, you must carefully read the instructions for use and operate in strict accordance with the instructions, otherwise reliable results cannot be guaranteed.
2. Test kit and sample should be brought to room temperature before testing.
3. Confirm SD card lot No. in accordance with test kit lot No. Perform calibration using the SD card when necessary.
4. Select the corresponding model on the analyzer according to the sample type (see the instructions of analyzer for details).
5. Remove the test card from the sealed pouch before use. Horizontally place the test card.
6. Deliver **100 μL** of sample into one tube of sample diluent using **disposable pipet**, mix gently and thoroughly. (Samples must be added using the disposable pipet in the kit to avoid incorrect results).



Note 1: Press the top of the disposable pipet to the bottom with your finger during sampling. Ensure that the slit is fully submerged in the sample.
Note 2: Throughly press the disposable pipette only once to take a sample, not repeatedly.

7. Insert the disposable pipet into the sample diluent tube to mix the sample by pushing the cap at the top of the disposable pipet for 4-6 times and wait 5~10 minutes.

Note 3: Insert the disposable pipet to the bottom of tube to prevent bubbles.
Note 4: It is recommended to wait for 5-10 minutes after mixing the samples, and the results of early or overtime testing are inaccurate.



8. Deliver the sample mixture by pushing the cap at the top of the disposable pipet and dispense the sample mixture into the sample port “S” on the test card.

For Getein 1100:

Reaction time: **15 minutes**. Insert the test card into Getein 1100 and press "ENT" button (click on “Start” icon for Android Getein 1100) after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein 1160/Getein 1180:

Insert the test card into Getein 1160/Getein 1180 immediately after sample loading. The analyzer will count down the reaction time (15 minutes) and automatically test the card after reaction time is elapsed. The result will be shown on the screen and printed automatically.

RESULTS

Getein1100/Getein1160/Getein1180 can scan the test card automatically and display the result on the screen. For additional information, please refer to the user manual of Getein1100/Getein1160/ Getein1180.

Testosterone Fast Test Kit (Immunofluorescence Assay) results are provided in ng/mL.

Results in ng/mL may be converted to nmol/mL as shown with an example below.

Testosterone Fast Test Kit (Immunofluorescence Assay) result as reported by the system (example) 1.00 ng/mL

The reported example result equals: 3.47 nmol/mL

Others: Measuring range of the Testosterone Fast Test Kit is 0.10 ~ 16.00 ng/mL. Samples initially outside the measuring range may be diluted with 1% bovine serum albumin, upper limit can be up to 48.00 ng/mL through dilution.

PERFORMANCE CHARACTERISTICS

1. Measuring Range 0.10 ~ 16.00 ng/mL
2. Limit of Detection ≤0.10 ng/mL
3. Within-Run Precision ≤10%
4. Between-Run Precision ≤15%

LIMITATIONS

1. The test results of this kit are only for clinical reference and cannot be used as the basis for confirming or excluding cases alone. In order to achieve the purpose of diagnosis, this test result should be used in combination with clinical examination, medical history and other examination results.
2. Do not use the test card if the foil pouch or the cartridge is damaged.
3. Do not open pouches until performing the test.
4. Patient samples may contain heterophilic antibodies (e.g. human anti-mouse antibodies (HAMA) and rheumatoid factors) that could react in immunoassays to give a falsely elevated or depressed result. This assay has been designed to minimize interference from heterophilic antibodies. Nevertheless, complete elimination of this interference from all patient specimens cannot be guaranteed.
5. Triglyceride and bilirubin in the sample may interfere with the test results, and the maximum allowable concentrations are 18 g/L and 0.1 g/L respectively.

EXPECTED VALUE

The expected normal value for Testosterone was determined by testing samples from apparently healthy individuals.

Reference range of Testosterone:

Group	n	95% Reference range
		（ng/mL）
Healthy men	260	1.75-7.81
Healthy women	280	0.10-0.75

Expected values may vary with age, sex, sample type, diet and geographical location. Each laboratory should verify the transferability of the expected values to its own population, and if necessary, determine its own expected values according to good laboratory practice.

REFERENCES

1. Payne AH, Hales DB. Overview of steroidogenic enzymes in the pathway from cholesterol to active steroid hormones. Endocr Rev. 2004 Dec;25(6):947-70. doi: 10.1210/er.2003-0030. PMID: 15583024.
2. RICHARD, Sharpe M. Intratesticular Factors Controlling Testicular Function[J]. Biol Reprod，1984,30（1）：29-49
3. EN ISO 18113-1:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
4. EN ISO 18113-2:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on Testosterone Fast Test Kit (Immunofluorescence Assay) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN ISO 15223-1:2021.

Key to symbols used			
	Manufacturer		Use-by date
	Do not re-use		Date of manufacture
	Consult *instructions for use* or consult electronic *instructions for use*	LOT	Batch code
	Temperature limit	IVD	*In vitro* diagnostic medical device
	Contains sufficient for <n> tests	EC REP	Authorized representative in the European Community/European Union
CE	CE mark		Do not use if package is damaged and consult *instructions for use*
REF	Catalogue number		Keep dry
	Keep away from sunlight		Caution

Thank you for using Testosterone Fast Test Kit (Immunofluorescence Assay). Please read this user manual carefully before operating to ensure proper use. Please report any product problems or adverse events to the below manufacture or authorized representative in the European Community in time.

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Catalogue number	Applicable instrument	Package specification
IF1073-10T	Getein 1100	10 T/kit
IF1073-25T	Getein 1100	25 T/kit
IF5073-10T	Getein 1160	10 T/kit
IF5073-25T	Getein 1160	25 T/kit
IF3073-10T	Getein 1180	10 T/kit
IF3073-25T	Getein 1180	25 T/kit