



Cortisol Fast Test Kit (Immunofluorescence Assay)

IF1110 for Getein 1100
IF5110 for Getein 1160
IF3110 for Getein 1180
IF2110 for Getein 1600
IF4110 for Getein 1200



Instructions for Use

INTENDED USE

Cortisol Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of cortisol in human serum and plasma samples. It is mainly used for auxiliary evaluation of Adrenal cortex function. For professional and laboratory use.

SUMMARY

Cortisol is a type of steroid hormone that belongs to glucocorticoids. It is mainly synthesized by adrenal cortex in the zona fasciculata. About 90% of cortisol is combined with corticosteroid combined with globulin (CBG) in the blood, and 5%~10% free cortisol is discharged from urine. Cortisol can maintain the balance and stability of the physiological function of the body, and has a very important role in metabolism of protein, fat, and sugar. When stress reaction occurs, the body can quickly secrete cortisol into blood to maintain stability of blood sugar and blood pressure.

Overproduction of cortisol may lead to Cushing's syndrome, which mostly starts with obesity, with a moon face and centripetal obesity. There are purple striae in the lower abdomen and inner thighs, and the face shows sanguine temperament, women have menstrual disorders or amenorrhea, and men have decreased sexual desire. A lack of cortisol could cause Addison's disease. Clinical manifestations include fatigue, weight loss, loss of appetite, hypoglycemia, hypotension, and darkening of skin color. Therefore, measuring cortisol levels can help doctors diagnose Cushing's syndrome or Addison's disease, as well as monitor treatment.

Testing the level of cortisol in serum/plasma can determine whether the adrenal glands are dysfunctional. Clinically, the secretion of cortisol is closely related to the function of human adrenal gland, which plays an important role in the metabolism of water, salt, protein, sugar and fat.

PRINCIPLE

Cortisol 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 cortisol monoclonal antibody binds with the cortisol in sample and forms a marked antigen-antibody complex. The uncombined fluorescence latex-labelled cortisol monoclonal antibody binds with the cortisol antigen on the test line. The fluorescence intensity of the test line decreases in proportion to the amount of cortisol in sample. Fluorescent signals intensity can be analyzed by applicable device thus the cortisol in sample be detected quantitatively.

APPLICABLE DEVICE

Getein 1100 Immunofluorescence Quantitative Analyzer
Getein 1160 Immunofluorescence Quantitative Analyzer
Getein 1180 Immunofluorescence Quantitative Analyzer
Getein 1200 Immunofluorescence Quantitative Analyzer
Getein 1600 Immunofluorescence Quantitative Analyzer

CONTENTS

Materials provided	Getein 1100/ Getein 1160/ Getein 1180		Getein 1200/ Getein 1600	
	10 T/kit	25 T/kit	2*24 T/kit	2*48 T/kit
Cortisol test card	10 pcs	25 pcs	24 test cards in 1 cartridge, and 2 cartridges in 1 box	48 test cards in 1 cartridge, and 2 cartridges in 1 box
Disposable pipet	10 pcs	25 pcs	/	/
User manual	1 pc	1 pc	1 pc	1 pc
SD card	1 pc	1 pc	1 pc in each cartridge	1 pc in each cartridge

A test card consists of:

Fluorescence latex-labelled cortisol monoclonal antibody, Fluorescence latex-labelled Chicken immunoglobulin Y natural protein, cortisol antigen and Goat anti chicken immunoglobulin Y polyclonal antibody.

Materials required for Getein 1200/1600:

- 1) Box with pipette tips: 96 tips/box
- 2) Mixing plate: 1 piece/box

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. For test card of Getein 1200/Getein 1600: The valid period after opening is 7 days, it is recommended to put the cartridge back to the foil bag and reseal along the entire edge of zip-seal if not used up.

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 4 hours after collection. Stable in plasma and serum 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

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).

For Getein 1100:

- (1) Remove the test card from the sealed pouch before use. Horizontally place the test card.
- (2) Deliver 100 µL of serum/plasma into the sample port "S" on the test card.
- (3) 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:

- (1) Remove the test card from the sealed pouch before use. Horizontally place the test card.
- (2) Deliver 100 µL of serum/plasma into the sample port "S" on the test card.
- (3) 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.

For Getein 1200/Getein 1600:

- (1) Insert the test card cartridge into the analyzer, each test card cartridge for Getein 1200/Getein 1600 contains a specific SD card which can calibrate automatically.
- (2) Place samples on the sample holder, insert the holder and select the right test item, Getein 1200/Getein 1600 will perform the testing and print the result automatically.

Notes:

Make sure insertion of the test card cartridge and the sample are correct and complete.

RESULTS

Getein 1100/Getein 1160/Getein 1180/Getein 1200/Getein 1600 can scan the test card automatically and display the result on the screen. For additional information, please refer to the instructions for use of Getein 1100/Getein 1160/ Getein 1180/ Getein 1200/Getein 1600.

Cortisol Fast Test Kit (Immunofluorescence Assay) results are provided in nmol/L.

Results in nmol/L may be converted to ug/dL as shown with an example below.

Cortisol Fast Test Kit (Immunofluorescence Assay) result as reported by the system (example)	11 nmol/L
The reported example results equal:	0,4 µg/dL

Others: Measuring range of the Cortisol Fast Test Kit is 11-1655 nmol/L.

PERFORMANCE CHARACTERISTICS

1. Measuring Range 11-1655 nmol/L
2. Limit of Detection ≤11 nmol/L
3. Within-Run Precision ≤15%
4. Between-Run Precision ≤20%

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. Getein 1200/ Getein 1600 test card cartridge, keep dry and put back to the foil bag for 7 days if not used up.
5. 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.
6. 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 Cortisol was determined by testing samples from apparently healthy individuals.

Reference range of cortisol:

Group	n	95% Reference range (nmol/L)
Healthy human	275	185-624

Expected values may vary with age, 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

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DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on Cortisol 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		Batch code
	Temperature limit		In vitro diagnostic medical device
	Contains sufficient for <n> tests		Authorized representative in the European Community/European Union
	CE mark		Do not use if package is damaged and consult instructions for use
	Catalogue number		

Thank you for using Cortisol Fast Test Kit (Immunofluorescence Assay). Please read this instructions for use 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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