CE IVD

E2
Fast Test Kit
(Immunofluorescence Assay)

User Manual

INTENDED USE

E2 Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of E2 in human serum, plasma samples. E2 tests are used to measure ovarian function. For professional and laboratory use.

SUMMARY

Estradiol (E2) is a kind of steroid hormone, which is the most important and biologically active hormone in estrogen. For non-pregnant women, it is mainly secreted by ovarian follicles and corpus luteum; The adrenal cortex and male testicular interstitial cells can also produce a small amount of E2, which is mainly produced by the placenta in pregnant women. The concentration of E2 in the blood changes during the menstrual cycle. Most circulating E2 combines with sex hormone binding globulin or albumin, and about 1-3% of E2 is free. E2 plays an indispensable role in the development of reproductive organs and secondary sexual characteristics. E2 determination can monitor ovarian function and is a very useful indicator for evaluating various menstrual abnormalities. It has a high guiding significance in analyzing sexual development, causes of amenorrhea, infertility and menopause; Dynamic monitoring of E2 level is helpful to monitor ovulation, because E2 level reflects the maturity of follicles; Female precocious puberty, E2 levels are often higher than normal; Continuous and dynamic detection of E2 can also be used to monitor fetal placental function during pregnancy.

PRINCIPLE

E2 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 E2 monoclonal antibody binds with the E2 in sample and forms a marked antigen-antibody complex. The uncombined fluorescence latex-labelled E2 monoclonal antibody binds with the E2 on the test line. The fluorescence intensity of the test line decreases in proportion to the amount of E2 in sample. Fluorescent signals intensity can be analyzed by applicable device thus the E2 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
E2 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	/	/
Sample diluent	10/tube	25/tube	1 box	1 box
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

Sample diluent for Getein 1100/ Getein 1160/ Getein 1180 consists of:
Sample diluent contains 3-Morpholinepropanesulfonic acid buffer (50 mmol/L), ProClin™ 300 (0.1%).
Sample diluent for Getein 1200/ Getein 1600 consists of:
Sample diluent contains 3-Morpholinepropanesulfonic acid buffer (50 mmol/L), ProClin™ 300 (0.1%) (25 mL/bottle for Getein 1200, 30 mL/bottle for Getein 1600),
-Box with pipette tips (96 tips/box),
-Mixing plate (1 piece/box).
A test card consists of:
Fluorescence latex-labelled E2 monoclonal antibody, Fluorescence latex-labelled Chicken immunoglobulin Y natural protein , E2 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℃ 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 8 hours after collection. Stable in plasma and serum for 2 days when stored at 2~8°C and 3 months when stored at -20°C.
4. Refrigerated or frozen sample should reach room temperature before testing. Avoid multiple freeze-thaw cycles.

CALIBRATION

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.

For Getein 1100:
(1)Confirm SD card lot No. in accordance with test kit lot No. Perform calibration using the SD card when necessary.
(2)Select the corresponding model on the analyzer according to the sample type (see the instructions of analyzer for details).
(3)Remove the test card from the sealed pouch before use. Horizontally place the test card.
(4)Deliver **100 μL** of sample into one tube of sample diluent using **disposable pipet**, mix gently and thoroughly.
Note: Use the matching **disposable pipet** of the kit.
(5)**Wait 5~10 minutes.** Then drop **100 μL** of sample mixture into the sample port "S" on the test card.
Note: It is recommended to wait for 5-10 minutes after mixing the samples, and the results of early or overtime testing are inaccurate.
(6)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)Confirm SD card lot No.in accordance with test kit lot No. Perform calibration using the SD card when necessary.
(2)Select the corresponding model on the analyzer according to the sample type (see the instructions of analyzer for details).
(3)Enter testing interface of Getein1160/Getein1180.
(4)Remove the test card from the sealed pouch before use. Horizontally place the test card.
(5)Deliver **100 μL** of sample into one tube of sample diluent using **disposable pipet**, mix gently and thoroughly.
Note: Use the matching **disposable pipet** of the kit.
(6)**Wait 5~10 minutes.** Then drop **100 μL** of sample mixture into the sample port "S" on the test card.
Note: It is recommended to wait for 5-10 minutes after mixing the samples, and the results of early or overtime testing are inaccurate.
(7)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 the sample diluent at the correct position.
(3)Place samples on 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

Getein1100/Getein1160/Getein1180/Getein1200/Getein1600 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/Getein1200/ Getein1600.
E2 Fast Test Kit (Immunofluorescence Assay) results are provided in pg/mL.
Results in pg/mL may be converted to pmol/mL as shown with an example below.

E2 Fast Test Kit (Immunofluorescence Assay) result as reported by the system (example)	1.0 pg/mL
The reported example results equal:	3.67pmol/mL

Others: Measuring range of the E2 Fast Test Kit is 40.0 ~ 4800.0 pg/mL. Samples initially outside the measuring range may be diluted with 1% bovine serum albumin, measuring

range can be up to 12000 pg/mL through dilution.

PERFORMANCE CHARACTERISTICS

1.Measuring Range	40.0-4800.0 pg/mL
2.Limit of Detection	≤40.0 pg/mL
3.Within-Run Precision	≤15%
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. 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 E2 was determined by testing samples from apparently healthy individuals.
Reference range of E2:

Group		n	95% Reference range (pg/mL)
Healthy men		130	<40~47
Healthy women	Metaphase of follicle	112	<40~126
	Metaphase luteum	98	50-290
	Ovulation cycle	102	95-432
	Postmenopausal women	136	<40

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

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5. Hall JE. Polycystic ovarian disease as a neuroendocrine disorder of the female reproductive axis. Endocrinol Metab Clin North Am. 1993;22(1):75-92.6. EN ISO 18113-1:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
7. 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 E2 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 E2 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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Getein Biotech, Inc.
Add.: No.9 Bofu Road, Luhe District, Nanjing, 211505, China
Tel: +86-25-68568508
Fax: +86-25-68568500
E-mail: tech@getein.com.cn
overseas@getein.com.cn
Website: www.getein.com

EC REP CMC Medical Devices & Drugs S.L.
Add.: C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain
Tel: +34951214054

Catalogue number	Applicable instrument	Package specification
IF1074-10T	Getein 1100	10 T/kit
IF1074-25T	Getein 1100	25 T/kit
IF5074-10T	Getein 1160	10 T/kit
IF5074-25T	Getein 1160	25 T/kit
IF3074-10T	Getein 1180	10 T/kit
IF3074-25T	Getein 1180	25 T/kit
IF4074-48T	Getein 1200	2*24 T/kit
IF4074-96T	Getein 1200	2*48 T/kit
IF2074-48T	Getein 1600	2*24 T/kit
IF2074-96T	Getein 1600	2*48 T/kit