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Estradiol Fast Test Kit (Immunofluorescence Assay)

REF IF1138 for Getein1100
IF5138 for Getein1160
IF3138 for Getein1180

Instructions for Use

INTENDED USE

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

SUMMARY

Estradiol 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 estradiol, which is mainly produced by the placenta in pregnant women. The concentration of estradiol in the blood changes during the menstrual cycle. Most circulating estradiol combines with sex hormone binding globulin or albumin, and about 1-3% of estradiol is free. Estradiol plays an indispensable role in the development of reproductive organs and secondary sexual characteristics. Estradiol 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 estradiol level is helpful to monitor ovulation, because estradiol level reflects the maturity of follicles; when female sexual precocity occurs, estradiol levels are often higher than normal; Continuous and dynamic detection of estradiol can also be used to monitor fetal placental function during pregnancy.

PRINCIPLE

Estradiol 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 estradiol monoclonal antibody binds with the estradiol in sample and forms a marked antigen-antibody complex. The uncombined fluorescence latex-labelled estradiol monoclonal antibody binds with the estradiol on the test line. The fluorescence intensity of the test line decreases in proportion to the amount of estradiol in sample. Fluorescent signals intensity can be analyzed by applicable device thus the estradiol 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
Estradiol test card	10 pcs	25 pcs
Disposable pipet	10 pcs	25 pcs
Sample diluent 4	10 tube	25 tube
Instructions for use	1 pc	1 pc
SD card	1 pc	1 pc

sample diluent 4 for Getein 1100/ Getein 1160/ Getein 1180 consists of:
sample diluent 4 contains 3-Morpholinepropanesulfonic acid buffer (50 mmol/L), ProClin™ 300 (0.1%).
A test card consists of:
Fluorescence latex-labelled estradiol monoclonal antibody, Fluorescence latex-labelled Chicken immunoglobulin Y natural protein, estradiol 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 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.

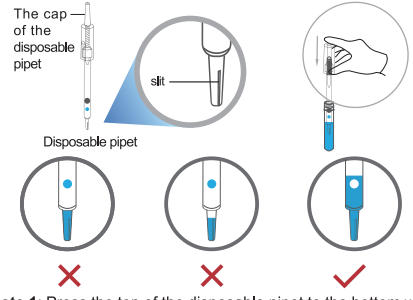
CALIBRATION

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

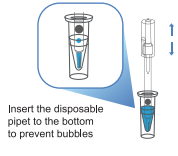
1. Before use, you must carefully read the instructions for use and operate in strict accordance with the instructions, otherwise reliable results cannot be guaranteed.
2. Test kit and sample should be brought to room temperature before testing.
3. Confirm SD card lot No. in accordance with test kit 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 4 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 4 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 instructions for use of Getein1100/Getein1160/ Getein1180.
Estradiol 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.
Estradiol Fast Test Kit (Immunofluorescence Assay) result as reported by the system (example) 1.0 pg/mL
The reported example results equal: 3.67pmol/L
Others: Measuring range of the Estradiol Fast Test Kit is 40.0 ~ 4800.0 pg/mL or 146.8~17616 pmol/L. Samples initially outside the measuring range may be diluted with 1% bovine serum albumin, measuring range can be up to 12000 pg/mL or 44040 pmol/L through dilution.

PERFORMANCE CHARACTERISTICS

1. Measuring Range 40.0-4800.0 pg/mL or 146.8-17616 pmol/L
2. Limit of Detection ≤40.0 pg/mL or ≤146.8 pmol/L
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 Estradiol was determined by testing samples from apparently healthy individuals.
Reference range of estradiol:

Group		n	95% Reference range (pg/mL)	95% Reference range (pmol/L)
Healthy men		130	<40~47	<146.8~172.5
Healthy women	Metaphaseof follicle	112	<40~126	<146.8~462.4
	Metaphase luteum	98	50-290	183.5~1064.3
	Ovulation cycle	102	95-432	348.7~1585.4
	Postmenopausal women	136	<40	<146.8

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. Caldwell JD, Gebhart VM, Jirikowski GF. Estradiol's interesting life at the cell's plasma membrane. Steroids. 2016; 111:4-11.
2. Pfaff DW, Gagnidze K, Hunter RG. Molecular endocrinology of female reproductive behavior. Mol Cell Endocrinol. 2018; 467:14-20.
3. Yen, S S C, The Human Menstrual Cycle: Neuroendocrine regulation. In Reproductive Endocrinology. Edited by Yen, S S C and Jaffe, R B Philadelphia, PA:W B Saunders Co.1911,273-308.
4. Kumar A, Banerjee A, Singh D, et al. Estradiol: A Steroid with Multiple Facets. Horm Metab Res. 2018;50(5):359-374.
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 Estradiol 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		

Thank you for using Estradiol 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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