Estradiol (E2) Rapid Quantitative Test (Fluorescence Immunoassay)
User manual

【Product name】
Estradiol (E2) Rapid Quantitative Test (Fluorescence Immunoassay)

【Package specification】
25 Tests/kit、40 Tests/kit

【Intended use】
This kit is used for quantitative determination of estradiol in human whole blood, plasma and serum.
Estradiol is an 18 carbon steroid hormone with a molecular weight of 272D. In women, the follicular phase of the menstrual cycle is secreted by follicular intimal cells and granulosa cells. In luteal phase, there is secretion of endometrial luteal cells. It is synthesized by placenta during pregnancy. In men, estrodione in the adrenocortical reticular zone is transformed in the periphery or by sertoll cells in the testis. Serum estradiol concentration is one of the indexes to check the function of hypothalamic pituitary gonadal axis. It is mainly used for the identification of endocrine diseases before puberty and the evaluation of ovarian function in amenorrhea or abnormal menstruation. It is also one of the diagnostic indicators of male testicular or liver diseases. The increase of estradiol was found in multiple pregnancy, ovarian cancer, systemic lupus erythematosus and so on. In men, if there is feminization syndrome, breast feminization and testicular cancer, estradiol will also increase. The decrease of estradiol can be seen in pregnancy induced hypertension syndrome, ovarian cyst, hydatidiform mole, pituitary ovarian infertility and so on.

【Test principle】
The kit adopts the principle of competitive method. Take the sample to be tested, add it into the sample diluent and mix it evenly. Add the mixed sample into the sample adding hole. E2 in the sample combines with the fluorescent labeled antibody on the binding pad to form a complex. Under the action of chromatography, the complex moves forward along the nitrocellulose membrane, and the fluorescent labeled antibody that does not bind to the test line is captured by E2-BSA coated on the nitrocellulose membrane detection line. The more E2 in the sample, the fewer complexes gathered on the detection line, and the signal of fluorescent antibody is inversely proportional to the number of objects to be tested in the sample. The quantitative detection results were obtained by NIR-1000 dry fluoroimmunoassay analyser.

【Components】

Name	Quantity	Component
Test cards	25/40	It is composed of fluorescent pad (coated with fluorescent labeled E2-BSA and fluorescent labeled biotin), nitrocellulose membrane (coated with goat anti mouse IgG antibody and GSA), absorbent paper and backing.
E2 antibody lyophilized powder	25/40	Mouse anti E2 antibody （lyophilized）
Sample diluent	25/40	Phosphate buffer
ID card	1	With specific stand curve file

The components in different batches of kits cannot be used interchangeably.

【Storage conditions and validity】
The kit should be stored at 4℃~30℃, out of direct sunlight. It is valid for 18 months. The test card should be used within 15 minutes after unsealing under the environment of 15℃~30℃ and 20% ~ 90% relative humidity.
The production date, batch number and expiration date are shown in the outer package of the product.

【Applicable instruments】
NIR-1000 dry fluoroimmunoassay analyser produced by WWHS Biotech. Inc

【Sample requirements】
1. Plasma, serum and whole blood can be used as samples. The whole blood should be collected in a tube containing heparin, citrate or EDTA as the anticoagulant. If the serum procedure is used, collect blood in a tube without anticoagulant and allow clotting. Hemolyzed samples should not be used.Venous blood was collected according to routine laboratory methods to avoid hemolysis.
2. It is highly recommended to use fresh samples. After samples were collected, the detection should be completed within 4 hours at 15℃~30℃. The whole blood sample can be stored at 2℃~8℃ for 24 hours. Plasma and serum samples can be stored at 2℃~ 8℃ for 7 days, -20℃for 30 days.
3. Before testing, the sample should return to room temperature (15℃~30℃). The frozen samples should be completely thawed, rewarming and mixed evenly before use. Repeated freeze-thaw cycles should be avoided.

【Test procedure】
1. Before the test, please read the instructions completely. If the test card and sample are stored in cold storage, they should be balanced at room temperature (15-30)℃ for not less than 30min before use.
2. Start dry fluoroimmunoassay analyser and correctly select the corresponding sample type on the instrument.
3. Take out the ID card, make sure that the batch number of the ID card is consistent with that of the test card, and insert the ID card into the ID card port of the instrument.
4. Take out the test card from the aluminum foil bag and use it within 15 minutes.
5. Place the test card on a clean horizontal table and mark it horizontally.
6. Add 90μL sample diluent to the tube containing fluorescent lyophilized powder. One tube is used by one test.
7. Add 30 μL sample to the tube, mix the solution thoroughly and keep incubation for 5 minutes.
8. Apply 100 μL incubated sample to the well of the test card.
9. At 15 minutes after addition of incubated sample, insert the test card into dry fluorescent

immunoanalyzer, read and record the results then dispose of used test appropriately.

【Reference interval】

Gender	Phase	Age	2.5th percentile (pg/mL)	97.5th percentile (pg/mL)
Male	/	18-70	<9.0	85
Female	Follicular phase	18-45	12	262
	Ovulatory phase	18-45	40	396
	Luteal phase	18-45	21	381
	Menopause	46-70	<9.0	190
	Early pregnancy	22-42	145	2988
	Second trimester	21-38	1502	>3000

It is strongly recommended that each laboratory should determine its own normal and abnormal values based on population.

【Interpretation of results】

1. This reagent is only used for auxiliary detection. If the test results are abnormal, it should be reviewed in time and judged in combination with clinical symptoms.
2. For samples with E2 concentration lower than 9.00pg/mL and higher than 3000.00pg/mL, the detection results are reported as "< 9.00pg/mL" and "> 3000.00pg /mL", respectively.

【Limitations of methods】

1. Due to the limitations of immunoassay methods of antigen and antibody reaction, the results cannot be used as the only basis for clinical diagnosis, but should be evaluated with all the existing clinical and experimental data.
2. The content of triglyceride in the sample shall not exceed 15mg/ml, the content of hemoglobin shall not exceed 5mg/ml, and the content of bilirubin shall not exceed 0.5mg/ml, and the relative deviation of the test results shall not exceed ±15%。
3. When the concentration of E2 in the sample is less than 30000pg/mL, there is no hook effect.
4. HAMA effect was not produced when the concentration of human anti rat in the sample was less than 50ng/ml.
5. When RF concentration in the sample is less than 2000IU/ml, the relative deviation of the test results is within ±15%.

【Performance】

1. Limits of detection

No higher than 9.00pg /mL.

2. Accuracy

The relative deviation from the target value is within ±15%.

3. Precision

The within and between assay coefficient of variations are within 15%.

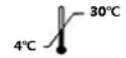
4. Linear range

Within the linear range (9.00~ 3000.00pg/mL), the linear correlation coefficient R⩾0.990.

【Precaution】

1. This kit is only used for in vitro diagnosis.
2. The test card and sample diluent are disposable and cannot be reused.
3. Please check the integrity and validity of the kit package before use, and then open the package. When it is stored at low temperature, it should be restored to room temperature (15℃ ~ 30℃) before opening the package for use. The reagents with damaged inner package and beyond the validity period cannot be used.
4. The requirements of specimen collection and storage should be strictly observed. If the specimen is turbid, it should be centrifuged and discarded before use.
5. The used kits should be treated as potential infectious substances, and all samples, reagents and potential pollutants should be disinfected and treated according to the relevant local regulations.

【Interpretation of signs】

	Temperature limit		Do not re-use
	Keep away from sunlight	IVD	In vitro diagnostic medical device
	Keep dry		Consult instructions for use

【Reference】

[1] Ho K Y, Evans W S, Blizzard R M, et al. Effects of sex and age on the 24-hour profile of growth hormone secretion in man: importance of endogenous estradiol concentrations [J]. J Clin Endocrinol Metab, 1987, 64(1):51-58.

[2] Carani, Cesare, Qin, et al. Effect of Testosterone and Estradiol in a Man with Aromatase Deficiency [J]. New England Journal of Medicine, 1997.

【Basic Information】

Registrant/Manufacturer: WWHS Biotech.Inc.

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