PDM签审页

PDM版本：

PDM编码：

产品名称	出口_性激素试剂_雌二醇测定试剂盒 E2_说明书_英文		
库存编码	1041535	版本号	20200330
成品尺寸	210×297mm	单位	mm
印刷色	单色	允差	±2mm
材质	80g胶版纸，双面印刷		
备注			
设计			
审核			
批准			

Estradiol Detection Kit (Chemiluminescence Immunoassay)

【Product Name】
Estradiol Detection Kit (Chemiluminescence Immunoassay)

【Package Specification】

Package Specification	Reagent Kit Composition
1×50 Tests/kit	1×Reagent, 1×Calibrator (High), 1×Calibrator (Low), 1×Control (Level 1), 1×Control (Level 2)
1×50 Tests/kit (without Calibrator and Control)	1×Reagent
2×50 Tests/kit	2×Reagent, 1×Calibrator (High), 1×Calibrator (Low), 1×Control (Level 1), 1×Control (Level 2)
2×50 Tests/kit (without Calibrator and Control)	2×Reagent
1×100 Tests/kit	1×Reagent, 1×Calibrator (High), 1×Calibrator (Low), 1×Control (Level 1), 1×Control (Level 2)
1×100 Tests/kit (without Calibrator and Control)	1×Reagent
2×100 Tests/kit	2×Reagent, 1×Calibrator (High), 1×Calibrator (Low), 1×Control (Level 1), 1×Control (Level 2)
2×100 Tests/kit (without Calibrator and Control)	2×Reagent
4×100 Tests/kit	4×Reagent, 2×Calibrator (High), 2×Calibrator (Low), 2×Control (Level 1), 2×Control (Level 2)
4×100 Tests/kit (without Calibrator and Control)	4×Reagent
1×200 Tests/kit	1×Reagent, 1×Calibrator (High), 1×Calibrator (Low), 1×Control (Level 1), 1×Control (Level 2)
1×200 Tests/kit (without Calibrator and Control)	1×Reagent
2×200 Tests/kit	2×Reagent, 1×Calibrator (High), 1×Calibrator (Low), 1×Control (Level 1), 1×Control (Level 2)
2×200 Tests/kit (without Calibrator and Control)	2×Reagent

【Intended Use】
For quantitative determination of estradiol (E2) in human serum or plasma in vitro.
Estradiol is mainly produced by follicles and placentas in the female ovary, and adrenal and male testes may also be produced in small quantities. Estradiol is one of the strongest biological activity of female hormone, its physiological effects mainly promote the growth and development of female genital organs, prompting the development of secondary sexual characteristics. Changes in estradiol levels may show different pathologies. In general, estradiol is mainly secreted by the sheath cells and granulosa cells and the corpusluteum during follicular development in non pregnant women. In pregnancy, estradiol is mainly secreted by the placenta. Elevated female estradiol levels in women may be due to primary or secondary ovarian hyperactivity. Very high levels of estradiol were observed during ovulation induction assisted reproductive therapy or during pregnancy. The decrease in estradiol levels may be due to two factors: reduced ovarian synthesis (primary ovarian dysfunction and menopause); dysfunction of the hypothalamus-pituitary axis (secondary ovarian dysfunction). In the male body, estradiol levels are usually low. Elevated levels of estradiol in males can cause male females to manifest themselves.

【Test Principle】
Estradiol Detection Kit is tested by the competitive method based on chemiluminescence immunoassay. The reagent consists of three parts: R1, R2 and R3, R1 is magnetic particle coated with estradiol analogue, R2 is acridinium ester labeled estradiol antibody,R3 is buffer solution added with releasing agent; The estradiol analogue competes with the estradiol in the sample for a limited number of acridinium ester labeled estradiol antibodies. The content of estradiol in the sample is inversely proportional to the relative light unit (RLU) detected by the system.
The system automatically performs the following steps:
1. Put sample and reagent into the cuvette, incubate at 37℃;
2. Separate magnetic particles, and then add Washing Buffer to wash them;
3. Add acid trigger reagent and alkaline trigger reagent to stimulate chemiluminiscence reaction.

【Main Components】

Composition		Main Components	Content
Reagent	R1	Estradiol analogue-coated magnetic particles	0.01%
	R2	Acridinium ester-labeled estradiol antibody	0.5μg/mL
	R3	Releasing agent	0.5μg/mL
Calibrator (High, Low)		Hormone-free human serum supplemented with estradiol	/
Control (Level 1, Level 2)		Hormone-free human serum supplemented with estradiol	/

Note 1: Each component of different batch kits cannot be exchanged.
Note 2: Calibrator and Control contents are different in different batches. For the Calibrator fixed value and Control target value refer to the bottle label.
Note 3: Essential unprovided materials: Acid Trigger Reagent, Alkaline Trigger Reagent, Washing Buffer/Concentrated Washing Buffer. Perform the test according to the instrument user manual or reagent instructions for use.
Note 4: Calibrator can be traced to national standard material.

【Storage Conditions & Shelf Life】
1. The reagent kit shall be sealed, stored upright in a dry and dark place at 2℃~8℃, and for the shelf life refer to the label.
2. After being used for the first time, it can be stable for 28 days if stored on the instrument or at 2℃～8℃. The calibrator and control after being opened for the first time can be stable for 28 days at 2℃～8℃.

【Date of Manufacture& Expiry Date】 See the label.

【Applicable Instrument】
CM Series Chemiluminescence Immunoassay Analyzer and CSM Series Integrated System

【Sample Requirements】
1. Specimens for tests are serum or plasma.
2. Adopt correct medical technology to collect samples.
3. Serious hemolysis，lipemia and turbid samples cannot be used for tests.
4. Samples can be stable for 48h at 2℃～8℃. If a test is not finished within 48h, freeze samples at -20℃ or lower temperature.
5. Samples can only be frozen once. Mix well after thawing.
6. Before putting a sample in the system, ensure that the sample is without fibrous protein or other particles, and bubbles.

【Test Method】
1. Reagent preparing
R1, R2 and R3 are all ready-to-use reagents, which can be used directly. Mix the reagents before loading them into the system. Visual inspection of the bottom of the kit ensures that all magnetic particles have been dispersed and re-suspended to avoid bubbles.
Calibrator and control are ready-to-use and can be used directly. Before use, mix calibrator and control, balance them to room temperature and use them.
2. Test procedure
Before loading reagents on the system, mix all reagents. Visually inspect the reagent bottle bottom to guarantee magnetic particles are divided or resuspended. For detailed operation steps refer to the instrument user manual.
3. Calibration
When using new batches of reagents, the estradiol determination item needs to be re-calibrated and the calibration information registration card scanned (support manual input registration). By measuring high and low Calibrators, each calibration point on the pre-input main calibration curve is adjusted to a new calibration curve.
Re-calibrate when the following situations happen:
- Use the reagent kit of a new batch number.
- Replace with new batch trigger reagent.
- Control repeat results are not within the regulated range.

4. QC
1) Test two levels of control on the day of testing samples.
2) Control must be tested when performing calibration. All calibrators and controls should be disposed of regarding as samples.
3) Take the following measures when control results are not within the lab regulated acceptable range.
- ♦ Ensure the reagent used has not expired.
- ♦ Ensure required maintenance is executed.
- ♦ Ensure test procedures are performed strictly following the instructions.
- ♦ Use new control to re-test.
- ♦ Use new calibrator to re-calibrate.
- ♦ Ask local technicians or distributor for help if necessary.

5. Calculation on test results
The instrument can calculate each sample concentration automatically, the unit is pg/mL.
Unit conversion: 1pg/mL=3.67pmol/L

【Reference Range】

Test samples		Reference Range
Male		< 39.8pg/mL
Female	Follicular phase	19.5 ~ 144.2pg/mL
	Middle of cycle	63.9 ~ 356.7pg/mL
	Luteal phase	55.8 ~ 214.2pg/mL
	Postmenopausal	< 32.2pg/mL

The lab should study the above reference range. The lab is suggested to set its own reference range due to geographical, patient dietary habit and environmental factors.

【Interpretation of Test Results】
1. Test results are not the only one as diagnosis index of clinical indications. Clinical significance is analyzed specifically combined with other test indices and clinical manifestation.
2. There is no direct comparability between the sample's estradiol concentration test by other ways and product test results.
3. Test results outside the reagent kit linear range should be tested again after diluting samples to linear range.
4. Estradiol measurement is different in test method, site identification, specificity and interfering factors, thus, estradiol test results are different for a specified sample; Inspectors should indicate the test method when supplying a laboratory test report to doctors. No direct comparability between test results obtained from different test methods. Direct cross use may lead to misinterpretation of its clinical significance; in the continuous monitoring of the efficacy of patients, before the method can be changed halfway, it is necessary to go through a full parallel experiment between the old and new methods and confirm its feasibility.

【Limitations of Test Method】
1. Patients of frequent exposure to animals and animal serum products and those who have used antibodies for in vivo diagnosis and treatment may contain heterophilic antibodies, which may lead to false positive or false negative.
2. Homoglobin > 250mg/dL, triglyceride > 1000mg/dL, bilirubin > 20mg/dL, in a sample may have an impact on the test results.
3. The experimental results showed that in the sample, the cross-reactivity rate of estrone 0.05μg/mL is 0.4%, the cross-reactivity rate of estriol 0.05μg/mL is 0.8%, the cross-reactivity rate of 17β-estradiol-17-cyclopentanepropionate 0.1μg/mL is 0.06%; the cross-reactivity rate of 17-β-estradiol-17-pentanoate 0.1μg/mL is 0.13%; the cross-reactivity rate of progesterone 0.05μg/mL is 0.001%. The cross-reactivity rate of testosterone 0.1μg/mL is 0.001%. The cross-reactivity rate of dihydrotestosterone 0.1μg/mL is 0.001%; the cross-reactivity rate of and rostenedione 0.1μg/mL is 0.001%; the cross-reactivity rate of cortisol 0.1μg/mL is 0.001%, the cross-reactivity of nandrolone 0.1μg/mL is 0.001%; the cross-reactivity of danazol 0.1μg/mL is 0.001%; the cross-reactivity of dexamethasone 0.1μg/mL is 0.001%.
4. Rheumatoid factor (RF) in samples may lead to false positive or false negative results.

【Product Performance Indices】
1. Accuracy: test national standard material, the relative deviation should be within the nominal value ±10%.
2. Minimum detection limit: < 15pg/mL.
3. Linearity: Linear range is 15pg/mL ~ 3000pg/mL, linear correlation coefficient r≥0.9900.
4. Repeatability: CV≤8%.
5. Between-batch difference: CV≤15.0%.

【Matters Needing Attention】
1. This product is only used for in vitro diagnosis.
2. Considering the possible evaporation effect, the samples, calibrators and controls on board should be analyzed/measured within 2 hours.
3. Please treat the samples as dangerous substances that may be infected with HIV, HBV, HCV, etc. To avoid or reduce the risk of infection, disposable gloves and eye/face protective items should be worn.
4. If the reagent enters the eye or mouth by mistake, or touches the skin, please rinse it with water quickly and receive medical treatment if necessary.
5. Samples and waste liquids are potentially biologically contagious. Operators should abide by laboratory safety regulations and treat waste liquids in accordance with local medical wastes, infectious wastes and industrial wastes.
6. Clinical samples should be treated as infectious samples, and operate according to the relevant laboratory specifications and requirements promulgated by the Health and Planning Commission, the Ministry of Science and Technology, and National Medical Products Administration and other relevant departments.
7. Avoid freezing the reagents.

【References】

1. Mean F, Pellaton M, Magrini G. Study on the binding of dihydrotestosterone, testosterone and oestradiol with sex hormone binding globulin. Clinica Chimica Acta. 1977; 80:171-180.
2. Boscato LM and Stuart MC. Heterophilic Antibodies: A Problem for All Immunoassays.Clin Chem. 1988; 34:27-33.
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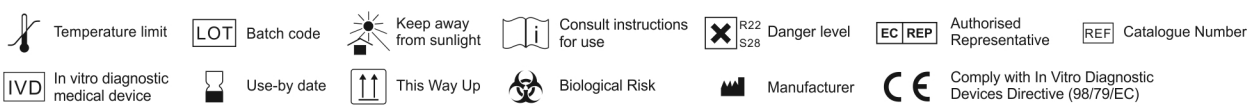
4. Zhao LX, Sun L, Chu XG. Chemiluminescence immunoassay. Trends in Analytical Chemistry. 2009; 28:404-415.
5. Xin TB, Liang SX, Wang X, et al. Determination of estradiol in human serum using magnetic particles-based chemiluminescence immunoassay. Original Research Article. 2008; 627:277-284.
6. Bouve J, Boever D, Leyseele D, et al. Improvement of assay sensitivity in immunoassay: chemiluminescence immunoassay for estradiol as a model. Analytica Chimica Acta. 1991; 255:417-422.
7. Chaisuwan N, Xu H, Wu GY, et al. A highly sensitive differential pulse anodic stripping voltammetry for determination of 17differential pulsusing CdSe quantum dots based on indirect competitive immunoassay. Biosensors and Bioelectronics. 2013; 46:150-154.
8. Clinical and Laboratory Standards Institute (formerly NCCLS). Interference Testing in Clinical Chemistry; Approved Guideline-Second Edition. Wayne, PA: Clinical and Laboratory Standards Institute; 2005.CLSIEP7-A2.

【Instruction Approved & Modified Date】 03/2020

Symbol Explanation



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