PDM签审页

PDM版本：

PDM编码：

产品名称	出口_甲功试剂_促甲状腺素试剂盒 TSH_说明书_英文		
库存编码	1041026	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			

Thyroid Stimulating Hormone Detection Kit (Chemiluminescence Immunoassay)

【Product Name】

Thyroid Stimulating Hormone 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 Thyroid Stimulating Hormone (TSH) in human serum or plasma in vitro.

TSH is a foreign body dimer that is covalently linked by two glycoprotein subunits. The TSH alpha subunit is similar to the alpha subunit of follicle stimulating hormone (FSH), human chorionic gonadotropin (hCG), and luteinizing hormone (LH). TSH is synthesized and secreted by the anterior pituitary gland and its synthesis and secretion process is regulated by a negative feedback mechanism of free triiodothyronine and free thyroxine; tripeptide and TSH-releasing hormone (TRH) in the hypothalamus may also stimulate TSH generation.TSH can combine with specific thyroid cell receptors and has mainly two physiological roles. The first is to stimulate cell regeneration and overgrowth; the other is to stimulate thyroid to synthesize and secrete triiodothyronine and thyroxine. Determination of TSH concentration in circulating system makes a great significance on the assessment of thyroid function. The detection of primary (thyroid), secondary (pituitary) and tertiary(hypothalamic) hypothyroidism in the differential diagnosis, the item is the most advantageous clinical test indicators. In patients with primary hypothyroidism, TSH concentration continues to rise; but in patients with secondary and tertiary hypothyroidism, TSH concentration continues to decrease.

【Test Principle】

TSH Detection Kit is detected by double antibody sandwich method based on Chemiluminescence immunoassay. The reagent kit comprises three parts of R1, R2 and R3. R1 is a streptavidin-coated magnetic particle, R2 is an acridinium ester-labeled TSH antibody, and R3 is a biotin-labeled TSH antibody. Acridinium ester, biotin-labeled TSH antibody react with the sample to be tested in the thyroid stimulate immune reaction, and then form the antigen-antibody compound. The TSH content in a sample is proportional to the relative light unit (RLU) detected by the system.

The system automatically performs the following steps:

- Put sample and reagent into the cuvette, incubate at 37℃;
- Separate magnetic particles, and rinse with washing buffer;
- Add acid trigger reagent and alkaline trigger reagent to stimulate chemiluminiscence reaction.

【Main Components】

Composition		Main Components	Content
Reagent	R1	Streptavidin-coated magnetic particles	0.01%
	R2	Acridinium ester-labeled TSH antibody	1μg/mL
	R3	Biotin-labeled TSH antibody	1μg/mL
Calibrator (High, Low)		Bovine serum added TSH	See the label
Control (Level 1, Level 2)		Bovine serum added TSH	See the label

Note 1: The components in different batches of kits are not interchangeable.

Note 2: Different batches of Calibrators and Controls have different contents and batch specificity. The Calibrator fixed values and the target values of Controls are detailed in the bottle label.

Note 3: The necessary materials not provided are Acid Trigger Reagent, Alkaline Trigger Reagent, and Washing Buffer. The tests are carried out according to the instrument user manual and the instructions of the above reagents.

Note 4: Calibrators can be traced to national standard material.

【Storage Conditions & Shelf Life】

1. The reagent kit shall be stored at 2℃～8℃, away from sunlight, kept airtight and upright. For the shelf life refer to the label.
2. After being used for the first time, the reagent 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 preparation

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 the reagents by hand. Visually inspect the reagent bottle bottom, to guarantee magnetic particles divided or resuspended. For detailed operation steps refer to the instrument user manual.

3. Calibration
When using new batches of reagents, the TSH determination item needs to be re-calibrated and the calibration information registration card scanned (support manual input registration). By measuring low and high Calibrators, each calibration point on the pre-input main calibration curve is adjusted to a new calibration curve.
In the following cases, it should be calibrated again:
♦ Use the reagent kit of a new batch number.
♦ Replace trigger reagent with that of a new batch number.
♦ When the QC repeated results are not within the prescribed range.
4. QC
1) Two levels of Controls are determined on the day of testing a sample each time.
2) Controls 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 μIU/mL.
Unit conversion: 1μIU/mL=1mIU/L

【Reference Range】
Reference range is 0.55μIU/mL～4.78μIU/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
2. There is no direct comparability between sample TSH concentration tested by other ways and product test results.
3. Test results outside the reagent kit linear range should be tested again after diluting samples to the linear range.
4. When TSH concentration is up to 3000μIU/mL, there is no high dose hook effect.
5. TSH measurement is different in test method, site identification, specificity and interfering factors, thus, TSH 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 t 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. In the sample, when homoglobin > 100mg/dL, triglyceride > 1000mg/dL, bilirubin > 40mg/dL, test results may be affected.
3. RF in the sample may cause test result false positive or false negative.

【Product Performance Indices】
1. Precision: test national standard material, the relative deviation between concentration test value and nominal value should be within± 10%.
2. Minimum detection limit: < 0.01μIU/mL.
3. Linearity: linear range is 0.01μIU/mL～150μIU/mL, linear correlation coefficient r≥0.9900.
4. Repeatability:CV≤8.0%.
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】

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2. Marsden P, McKerron CG. Serum Triiodothyronine Concentration in the Diagnosis of Hyperthyrodism. Clin Endocrinol 1975; 4:183-189.
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4. Centers for Disease Control. 1988. Update: Universal precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus and other bloodborne pathogens in healthcare settings. MMWR, 37:377-82, 387-8.
5. Passing H, Bablok W, et al. A General Regression Procedure for Method Transformation. J Clin Chem Clin Biochem 1988; 26:783-790.
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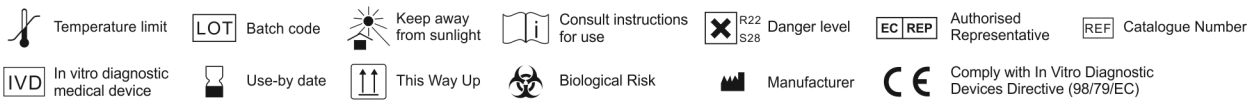
7. Cinical and Laboratory Standards Institude (formerly NCCLS).Interference Testing in Clinical Chemistry; Approved Guideline-Second Edition, Wayne, PA: Clinical and Laboratory Standards Institute; 2005. CLSI document EP7-A2.

【Instruction Approved & Modified Date】03/2020

Symbol Explanation



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