DIRUI 迪瑞

PDM签审页

PDM版本：

PDM编码：

产品名称	出口_甲功试剂_甲状腺素试剂盒 T4_说明书_英文		
库存编码	1041030	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			

Thyroxine Detection Kit (Chemiluminescence Immunoassay)

【Product Name】

Thyroxine 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 thyroxine (T4) in human serum or plasma in vitro.

Thyroxine is synthesized by the thyroid, produced by thyroid follicular epithelial secretion. After release into the blood, T4 mostly combine with thyroid binding globulin, a small amount of albumin and thyroid pre-albumin binding. Thyroid hormone has a great regulation and control significance to normal cells development and differentiation, thermoregulation and the balance of various carbohydrate, fat and protein metabolism. Therefore, the detection of T4 is very important for the diagnosis or differential diagnosis of hyperthyroidism, hypothyroidism, the development process, efficacy and prognosis of thyroid function-related diseases.

Thyroxine-binding globulin levels remain relatively constant in healthy individuals, but normal pregnancy, excess estrogens, androgens, anabolic steroids, and glucocorticoids can affect thyroxine binding globulin levels, and cause inaccurate test results during thyroid function test. In these cases, the T4 level does not accurately reflect the true state of the thyroid gland. Thyroid dysfunction can cause excessiveT4 secretion (hyperthyroidism) or deficiencies (hypothyroidism). In addition, because thyroid function is directly affected by thyroid stimulating hormone, if the pituitary or hypothalamus dysfunction, it will also affect the thyroid function. Therefore, as long as there is disease occurrence of any part of thyroid-pituitary-hypothalamic system, the blood T4 level will be affected.

【Test Principle】

The thyroxine detection kit is detected by competitive method based on chemiluminescence immunoassay. The reagent consists of R1, R2 and R3.R1 is thyroxine-coated magnetic particles. R2 is acridinium ester-labeled thyroxine antibody. R3 is a buffer solution with releasing agent added; thyroxine analogues compete with the thyroxine in the sample for a limited number of acridinium ester-labeled thyroxine antibodies. The amount of thyroxine in the sample corresponds to the relative light unit (RLU) in inversely proportional.

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	Thyroxine analogues-coated magnetic particles	0.02%
	R2	Acridinium ester-labeled antibodies to thyroxine	1μg/mL
	R3	Releasing agent	2mg/mL
Calibrator (High, Low)		Thyroxine-added de-hormone human serum	See the label
Control (Level 1, Level 2)		Thyroxine-added de-hormone human serum	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 back 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 24h at 2℃～8℃. If a test is not finished within 24h, 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.
7. Note: vibration of test tube may cause hemolysis and affect the test results.

【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 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 T4 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 μg/dL.
Unit conversion: 1μg/dL=12.9nmol/L

【Reference Range】
Healthy individual with normal thyroxine function (without pregnancy): 4.5μg/dL ~ 11.5μg/dL
Pregnant women with normal thyroxine function: 6.0μg/dL ~ 12.2μg/dL
The lab should study above the 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 sample thyroxine concentration test by other ways and product test results.
3. Samples whose T4 content higher than 30ug/dL, should be diluted to the linear range for test.
4. Thyroxine measurement is different in test method, site identification, specificity and interfering factors, thus, thyroxine 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. In the sample, when homoglobin > 500mg/dL, triglyceride > 1000mg/dL, bilirubin > 20mg/dL, test results may be affected.
3. When drug in the sample up to following concentrations:methimazole0.4mg/dL, phenylbutazone15.0mg/dL, phenytoin20mg/dL, sodium salicylate 50.0mg/dL, aspirin 50.0mg/dL, perform anti-interference experiments according to the CLSIdocumentEP7-A2, the results show that the above substances may interfere with the test results.
4. The results show that the cross-reaction rate of diiodothyroid tyrosine 200μg/dL in the sample is 0.08%. The cross-reaction rate of triiodothyronine 50μg/dL is 3%. The cross-reaction rate of 3,5-diiodo-L-thyroid1000μg/dL is 0.03%. The cross-reaction rate of reversible triiodothyronine 5μg/dL is 3%. The cross-reaction rate of D-thyroxine is 70%.
5. RF in the sample may cause test results false negative 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: < 0.3μg/dL.
3. Linearity: linear range is 0.3μg/dL ~ 30μg/dL, 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】

1. Chattoraj SC, Watts NB. Endocrinology. In: Tietz NW, editor. Fundamentals of clinical chemistry. Philadelphia: WB Saunders,1987.p.584-92.
2. Reagent Water Technical Bulletin. Siemens Medical Solutions Diagnostics, 107060.
3. Clinical and Laboratory Standards Institute(CLSI). Procedures for the Handling and Processing of Blood Specimens for Common Laboratory Tests; Approved Guideline-Forth Edition. CLSI documentH18-A4; Wayne(PA):CLSI; 2010.
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. Clinical and Laboratory Standards Institute(CLSI). Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline-Third Edition. CLSI document M29-A3; Wayne(PA): CLSI; 2000.
6. Cinical and Laboratory Standards Institude (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

Temperature limit	LOT Batch code	Keep away from sunlight	Consult instructions for use	R22 S28 Danger level	EC REP Authorised Representative	REF Catalogue Number	
IVD In vitro diagnostic medical device	Use-by date	This Way Up	Biological Risk	Manufacturer	CE Comply with In Vitro Diagnostic Devices Directive (98/79/EC)		

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