PDM签审页

PDM版本：

PDM编码：

产品名称	出口_甲功试剂_游离甲状腺素试剂盒（三试剂）FT4_说明书		
库存编码	1041032	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			

Free Thyroxine Detection Kit
(Chemiluminescence Immunoassay) Instructions

【Product Name】

Free 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 free thyroxine (FT4) in human serum or plasma in vitro.

Thyroxine (3,5,3',5'-tetraiodothyronine, T4) is a hormone secreted by thyroid follicular epithelial cells with a molecular weight of about 777Da. T4 is released into the blood circulation through thyroid secretion and exists in two forms: binding state and free state. Normally, there is a dynamic balance between two forms. Only free T4 (FT4) can enter the target cell and bind to the receptor to exert its physiological function. FT4 is the active part of thyroid hormone in circulating blood and has biological activity. The level of FT4 is closely related to the state of thyroid hormone, and it is mainly used for the auxiliary evaluation of thyroid function.

【Test Principle】

The free thyroxine detection kit is detected by the competitive method based on chemiluminescence immunoassay. The reagent consists of three parts: R1, R2 and R3. R1 is the streptavidin magnetic particles, R2 is the thyroxine antibody labeled with acridinium ester and R3 is the thyroxine derivative labeled with biotin; the thyroxine derivative labeled with biotin and free T4 in the samples compete with the T4 antibody labeled with acridinium ester, and immune complexes bind to magnetic particles by reaction between biotin and streptavidin. The content of free thyroxine in the samples is inversely proportional to the relative light units (RLUs) detected by the system.

The system automatically performs the following system:

1. Place the sample and reagent into the cuvette and incubate at 37℃;
2. Separate the magnetic particles and then wash them with washing buffer;
3. Add Acid Trigger Reagent and Alkaline Trigger Reagent to stimulate the chemiluminescence reaction.

【Main Components】

Composition		Main Components	Content
reagent	R1	streptavidin magnetic particles	⩾0.03%
	R2	thyroxine antibodies labeled with acridinium ester	⩾200ng/mL
	R3	thyroxine derivatives labeled with biotin	⩾2ng/mL
calibrator (high, low)		protein components supplemented with thyroxine	See the label
control (level 1, level 2)		protein components supplemented with thyroxine	See the label

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

Note 2: do not use calibrators and controls mixed from different lots. Fixed values of calibrators and target values of controls are detailed in the calibration and control information registration card.

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

Note 4: calibrators are traced back to the company's internal measurement procedure.

【Storage Conditions & Shelf Life】

1. The reagent kit should 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 at 2℃~8℃. The calibrator and control can be stable for 28 days after opened if sealed and stored 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. The sample type for tests is serum or plasma.
2. Adopt correct medical technology to collect samples.
3. Serious hemolysis, lipemia and turbid samples cannot be used for tests.
4. The sample can be stored at 2℃～8℃for 48 hours; if the test is not finished within 48 hours, freeze the sample at -20℃ or lower.
5. Before putting the sample into 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 reagent's bottom ensures that all magnetic particles have been separated and re-suspended to avoid bubbles.

Calibrators and controls are ready-to-use reagents, which can be used directly. Mix calibrators and controls, balance them to room temperature and use.

2. Test procedure

Before loading reagents on the system, mix all reagents. Visually inspect the reagent bottle bottom to guarantee magnetic particles are separated or re-suspended. For detailed operation steps refer to the instrument user manual.

3. Calibration

When using new batches of reagents, recalibrate the FT4 item and

scan the calibration information registration card(manual input registration is supported). By measuring low and high calibrators, each calibration point on the pre-input main calibration curve is adjusted to a new calibrated curve.

In the following cases, recalibration is recommended:

♦ Use the reagent kit with a new batch number.

♦ Replace trigger reagent with a new batch number.

♦ When the QC results are not within the prescribed range.

4. QC

1) Regarding the frequency of QC, please follow the regulations or requirements of the government.

2) Controls must also be determined when calibration is performed. All calibrator and control samples are treated equally to patients' samples.

3) If the quality control results are not within the acceptable range prescribed by the laboratory, the following measures can be taken.

♦ Ensure the reagent used has not expired.

♦ Ensure required maintenance is executed.

♦ Ensure test procedures are performed strictly following the instructions.

♦ Use a new control to re-test.

♦ Use a new calibrator to re-calibrate.

♦ Ask local technicians or distributor for help if necessary.

5. Calculation of test results

The instrument will automatically calculate the concentration of each sample in ng/dL.

Conversion formula: ng/dL×12.872=pmol/L

pmol/L×0.77688=ng/L

pmol/L×0.077688=ng/dL

【Reference Range】

Reference range 0.93ng/dL ~ 1.7ng/dL.

The lab should study the above reference range and is suggested to set its own reference range due to geography, diet, environment factors, etc.

【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. The detection range is 0.1ng/dL~12ng/dL. Values below the minimum detection limit are reported that < 0.1ng/dL and values exceed the detection limit are reported that >12ng/dL.

3. The free thyroxine's measurement is different in test methods, site identification, specificity and interfering factors. Thus, free 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 among 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, 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. High-dose biotin treatment may have an impact on the test results.

3. Hemoglobin>500mg/dL, triglyceride>3000mg/dL and bilirubin>20mg/dL in a sample may have an impact on the test results.

4. Anti-interference experiments are carried out according to the CLSI document EP7-A2 when drugs in the samples reach the following concentrations: methimazole >0.4mg/dL, phenytoin >500mg/dL, sodium salicylate 7500mg/dL and aspirin >7500mg/dL. The results showed that the above substances might interfere with the test results.

5. Samples containing high concentrations of rheumatoid factors(RF) may result in false positive or false negative results.

【Product Performance Indices】

1. Accuracy: the relative deviation should be within ±15%.

2. Limit of detection: should be<0.1ng/dL.

3. Linearity: linear range is 0.2ng/dL ~ 12ng/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, samples, calibrators and controls on board should be analyzed/measured within 2 hours.

3. Please treat 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 eyes or the 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, industrial wastes, etc.

6. Clinical samples should be treated as infectious samples, and operate according to the relevant laboratory specifications and requirements promulgated by National Health Commission, Ministry of Science and Technology, National Medical Products Administration and other relevant departments.

7. Avoid freezing the reagents.

8. Samples can only be frozen once. Mix well after thawing.

【References】

1. Angela M. Inzerillo, MoneZaidi, Christopher L.-H. Huang.Calcitonin: Physiological Actions and Clinical Applications[J].Journal of Pediatric Endocrinology&Metabolism 2004, 17:931-40.

2. Paul L. Munson, Philip F. Hirsc. Importance of calcitonin in physiology, clinical pharmacology, and medicine[J].Bone and Mineral, 1992,16(3):162-165.

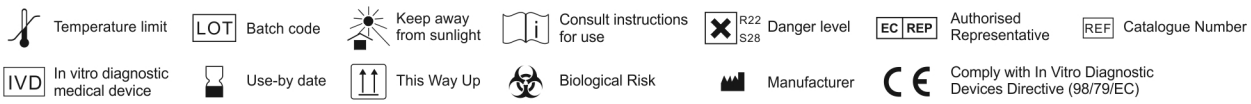
3. Jin Shixin. Biosynthesis and Physiological Effects of Calcitonin[J]. Chinese Journal of Osteoporosis, 2003, 9(4):381-383.

4. Shan Fengling, Lu Hankui. Application of Serum Calcitonin in Clinical Diagnosis and Treatment of Medullary Thyroid Carcinoma [J]. Medical Review, 2017(2).

5. EP05-A3,Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline-Third Edition [S].2014.

【Instruction Approved & Modified Date】 03/2020

Symbol Explanation



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