DIRUI 迪瑞

PDM签审页

PDM版本：

PDM编码：

产品名称	出口_甲功试剂_游离三碘甲状腺原氨酸试剂盒（三试剂）FT3_说明书		
库存编码	1041033	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 Triiodothyronine Detection Kit (Chemiluminescence Immunoassay) Instructions

【Product Name】

Free Triiodothyronine 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 triiodothyronine (FT3) in human serum or plasma in vitro.

Triiodothyronine (3,5,3'-L-triiodothyronine, T3) is a hormone that is synthesized and secreted by the thyroid gland and transformed from thyroxine (T4). In circulation, 99.7% of T3 is reversibly bound to the transporter proteins(mainly thyroxine binding globulin). The remaining small amount of T3 is not bound to the transporter proteins. This part of T3 that is not bound is free T3 (FT3).The FT3 level is directly proportional to the T3 content. The level of circulating FT3 is closely related to the state of thyroid mechanism. Clinically, it is mainly used for the auxiliary evaluation of thyroid function.

【Test Principle】

The free triiodothyronine 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 T3 antibody labeled with acridinium ester, and R3 is the triiodothyronine derivative labeled with biotin; the triiodothyronine derivative labeled with biotin and free T3 in the samples compete with the T3 antibody labeled with acridinium ester, and immune complexes bind to magnetic particles by reaction between biotin and streptavidin. The content of free triiodothyronine in samples is inversely proportional to the relative light units (RLUs) detected by the system.

The system automatically performs the following steps:

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	triiodothyronine antibodies labeled with acridinium ester	⩾20ng/mL
	R3	triiodothyronine derivatives labeled with biotin	⩾2ng/mL
calibrator (high, low)		protein components supplemented with triiodothyronine	See the label
control (level 1, level 2)		protein components supplemented with triiodothyronine	See the label

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

Note 2: different batches of calibrators and controls have different contents and batch specificity. 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 procedures.

【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 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 FT3 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) Two levels of Controls are determined on the day of testing each sample.
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 pg/mL.
Unit conversion: pg/mL×1.536=pmol/L
pmol/L×0.651=pg/mL
pg/mL×0.1=ng/dL

【Reference Range】
Reference range: 2.0pg/mL ~ 4.4pg/mL.
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 0.2pg/mL ~ 33pg/mL. Values below the minimum detection limit are reported that < 0.2pg/mL and values exceed the detection limit are reported that > 33pg/mL.
3. The Free Triiodothyronine's measurement is different in test methods, site identification, specificity and interfering factors. Thus, Free Triiodothyronine 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 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. Patients receiving high-dose biotin treatment may have an impact on test results.
3. Hemoglobin>500mg/dL, triglyceride>2000mg/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: methimidazole>4μg/mL, baotaisong>300μg/mL, phenytoin >40μg/mL, and sodium salicylate >500μg/mL. The results show that the above substances may interfere with the test results.
5. Samples containing 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: <0.2pg/mL.
3. Linearity: linear range is 0.4pg/mL ~ 33pg/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, 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 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, and National Medical Product Administration and other relevant departments.
7. Avoid freezing the reagents.
8. Samples can only be frozen once. Mix well after thawing.

【References】

1. Alessandro Pingitore, Elena GalliAcute Effects of Triiodothyronine (T3) ReplacementTherapy in Patients with Chronic Heart Failure andLow-T3 Syndrome: A Randomized, Placebo-ControlledStudy[J]. J ClinEndocrinolMetab, 2008, 93(4):1351–1358.
2. Raffaele Napoli, Vincenzo GuardasoleAcute Effects of Triiodothyronine on EndothelialFunction in Human Subjects[J].The Journal of Clinical Endocrinology Metabolism,2007,92(1):250–254.
3. Martin W. Elmlinger, Werner Kühnel,Hans-GeorgLambrechtand Michael B. Ranke1Reference Intervals from Birth to Adulthood for Serum Thyroxine (T4),Triiodothyronine (T3), free T3, free T4, Thyroxine Binding Globulin (TBG)and Thyrotropin (TSH) [J]. ClinChem Lab Med, 2001,39(10):973–979.
4. GulizKozdag, Dilek Ural. Relation between free triiodothyronine/free thyroxineratio,echocardiographic parameters and mortalityin dilated cardiomyopathy[J]. The European Journal of Heart Failure, 2005, 7(1):113– 118.
5. W. Ambrosius, R. Kazmierski,V. Gupta. Low Free Triiodothyronine Levels are Related to PoorPrognosis in Acute Ischemic Stroke[J].ClinEndocrinol Diabetes 2011,119: 139 – 143.
6. EP7-A2, Interference Testing in Clinical Chemistry; Approved Guideline-Second Edition[S].2005.

【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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