DIRUI 迪瑞

PDM签审页

PDM版本：

PDM编码：

产品名称	出口_甲功试剂_甲状腺过氧化物酶抗体试剂盒 A-TPO_说明书_英文		
库存编码	1041027	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			

Antibodies to Thyroid Peroxidase Detection Kit (Chemiluminescence Immunoassay)

【Product Name】

Antibodies to Thyroid Peroxidase 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 antibodies to thyroid peroxidase (A-TPO) in human serum or plasma in vitro.

Thyroid disorders are usually caused by autoimmune mechanisms and the production of autoantibodies. Thyroid peroxidase (TPO) is a membrane-linked glycoprotein that is expressed only by thyroid cells. This enzyme catalyzes the oxidation of iodide on tyrosine residues in thyroglobulin to synthesize T3 and T4, and it is one of the most important thyroid antigens.

A-TPO level measurement is a sensitive test for detecting autoimmune thyroid disease. The highest A-TPO level can be observed in Hashimoto's thyroiditis patients. In this disease, the detection ratio of A-TPO is about 90%, confirming the autoimmune origin of the disease. These autoantibodies also commonly occur(60-80%) during Graves' disease.

There is a general link between the presence of A-TPO and histological thyroiditis. However, given the large regenerative capacity of the thyroid affected by TSH, chronic thyroid disease may persist for years before the clinical manifestations of hypothyroidism become significant.

A-TPO tests can help diagnose thyroid autoimmune disorders and enable physicians to identify thyroid autoimmune disorders and non-autoimmune goiter or hypothyroidism.

【Test Principle】

A-TPO kit is based on the use of chemiluminescence immunoassay of indirect method for detection. The reagent kit comprises three parts of R1, R2 and R3. R1 is TPO-coated magnetic particles, R2 is an acridinium ester-labeled antibody to human IgG, and R3 is PBS Buffer. TPO-coated magnetic particles and acridinium ester-labeled antibody to anti-human IgG have immune reaction, with A-TPO in the sample, then form the antigen-antibody compound. The A-TPO 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	TPO-coated magnetic particles	0.01%
	R2	Acridinium ester-labeled antibodies to human IgG	0.5μg/mL
	R3	PBS buffer	20mmol/L
Calibrator (High, Low)		PBS buffer added TPO antibody	See the label
Control (Level 1, Level 2)		PBS buffer added TPO antibody	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.

【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 A-TPO 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 IU/mL.

【Reference Range】

Reference range is < 5.61 IU/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 sample A-TPO 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 the linear range.
4. A-TPO measurement is different in test method, site identification, specificity and interfering factors, thus, A-TPO 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 > 100mg/dL, triglyceride > 1000mg/dL, bilirubin > 40mg/dL, test results may be affected.
3. From test, thyroglobulin in the sample is 19000ng/mL, interference ratio is 4%.
4. 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: < 1IU/mL.
3. Linearity: linear range is 1IU/mL ~ 1000IU/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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3. H. Engler, W.F. Riesen, B. Keller. Anti-thyroid peroxidase (anti-TPO)antibodies in thyroid diseases, non-thyroidal illness and controls. Clinical validity of a new commercial method for detection of anti-TPO(thyroid microsomal) autoantibodies. ClinicaChimicaActa 225 (1994)123-136.
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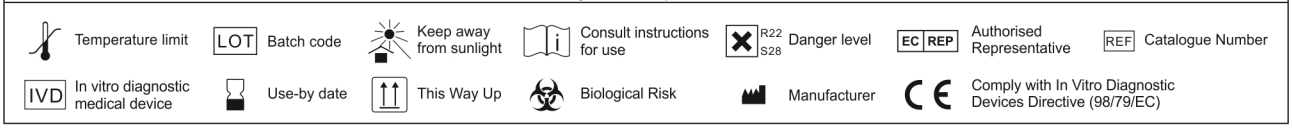
5. Lixia Zhao, Li Sun, Xiaogang Chu Chemiluminescence immunoassay Trends in Analytical Chemistry, Vol.28, No.4,2009,404-416.
6. Cinical and Laboratory Standards Institude (formerly NCCLS). Interference Testing in Clinical Chemistry; Approved Guideline-Second Edition, Wayne, PA: Clinical and Laboratory Standards Institute; 2005.CLSIEP7-A2.

【Instruction Approved & Modified Date】 03/2020

Symbol Explanation



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CE IVD

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