DIRUI 迪瑞

PDM签审页

PDM版本：

PDM编码：

产品名称	出口_骨代谢试剂_全段甲状旁腺激素测定试剂盒 iPTH_说明书		
库存编码	1056145	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			

Intact Parathormone Detection Kit (Chemiluminescence Immunoassay) Instructions

【Product Name】

Intact Parathormone 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 intact parathormone in human serum or plasma in vitro.

The intact parathormone (iPTH) is a single chain polypeptide containing 84 amino acids, with a molecular weight of about 9500da. It is synthesized in parathyroid gland and secreted into blood. Its half-life in metabolic circulation is less than 5 minutes. The intact parathormone measurement can be combined with the detection of ionic calcium to distinguish whether the function of parathyroid gland is hyperfunction or hypofunction. Therefore, by detecting the intact parathormone (iPTH), we can directly understand the secretion activity of parathyroid gland, which is mainly used in the clinical auxiliary evaluation of parathyroid function.

【Test Principle】

The intact parathormone detection kit is detected by the double antibody sandwich method based on chemiluminescence immunoassay. The reagent consists of three parts: R1, R2 and R3. R1 is the streptavidin magnetic particles, R2 is the parathormone antibody labeled with acridinium ester, R3 is the parathormone antibody labeled with biotin; the parathormone antibody labeled with acridinium ester and the parathormone antibody labeled with biotin react immunologically with the intact parathormone in the samples to form the antigen-antibody complex, and binds to magnetic particles by reaction between biotin and streptavidin. The content of intact parathormone in the samples is directly 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	parathormone antibodies labeled with acridinium ester	⩾0.1μg/mL
	R3	parathormone antibodies labeled with biotin	⩾0.2μg/mL
calibrator (high, low)		protein components supplemented with intact parathormone	see the label
control (level 1, level 2)		protein components supplemented with intact parathormone	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 reference 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 at 2℃～8℃. The calibrator and control can be stable for 28 days after reconstitution if sealed and stored at -20℃.

【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 24 hours; if the test is not finished within 24 hours, the sample should be stored at -20℃ and can be stable for 60 days.
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 freeze-dried type. Add 1.0mL purified water to reconstitute calibrators and controls, leave them for 20 minutes and mix upside down, and ensure all free-dried materials are fully dissolved before use. Fresh reconstitution calibrators and controls can be subpackaged and stored at 20 ℃ for further 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 iPTH 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 pg/mL.
Unit conversion: pg/mL x 0.106=pmol/L
pmol/L x 9.43=pg/mL

【Reference Range】
14.9 pg/mL - 56.9 pg/mL
The lab should study the above reference range and is suggested to set its own reference range due to geographical, diet and environmental 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 3.5 pg/mL -3000 pg/mL. Values below the minimum detection limit are reported that < 3.5 pg/mL and values exceed the detection limit are reported that > 3000 pg/mL.
3. For test results beyond the linear range of the reagent kit, the sample needs to be diluted to the linear range for testing.
4. The intact parathormone's measurement is different in test method, site identification, specificity and interfering factors. Thus, intact parathormone 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 confirms 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. Bilirubin, hemoglobin, triglyceride, albumin, IgG, IgM and IgA in a sample may have an impact on test results.
3. Serious hemolysis, lipemia and turbid samples used for the test may cause incorrect results.
4. High-dose biotin treatment may affect test results.
5. Samples containing high concentrations of rheumatoid factors(RF) may result in false positive or false negative results.

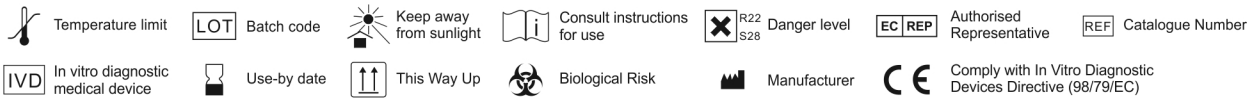
【Product Performance Indices】
1. Accuracy: the relative deviation should be within ±15% of the nominal value.
2. Minimum detection limit: should be no more than 3.5 pg/mL.
3. Linearity: linear range is 5.5 pg/mL - 3000 pg/mL; linear correlation coefficient r≥0.9900.
4. Repeatability: CV≤8.0%.
5. Between-batch 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 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 wore.
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 and repeatedly freezing and thawing calibrators and controls
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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