AyoTes

AyoTes CLIA based High Sensitive Cardiac Troponin-I (hs-cTnI) Test Kit

Instructions for Use

Read the instructions for use carefully and completely before performing the assay. Always follow the instructions for use properly to avoid inaccurate or invalid test results.

INTENDED USE

This kit is intended for the in vitro quantitative determination of Cardiac Troponin-I (cTnI) in human plasma, serum and whole blood samples. Clinically, it is mainly used for auxiliary diagnosis of myocardial infarction. For professional use only.

PRINCIPLE OF THE ASSAY

AyoTes CLIA based High Sensitive Cardiac Troponin-I (hs-cTnI) Test Kit applies double antibody sandwich method. During the test, Alkaline phosphatase labeled anti-cTnI antibodies and anti-cTnI antibody coated magnetic particles are mixed with the sample. The cTnI in the sample will bind to the anti-cTnI antibodies to form an magnetic particle immunocomplex of anti-cTnI antibody - cTnI - anti-cTnI enzyme labeled antibody. After removing the unbound enzyme-labeled antibody, a chemiluminescent substrate is added. The luminescence generated by the enzyme reaction is detected and the intensity of the measured luminescence is proportional to the cTnI concentration of the sample. The cTnI concentration in the sample is calculated by Automatic Chemiluminescence Immunoassay (CLIA) Analyzer.

COMPONENTS

Components	Specification/Quantity 60 Tests/Kit	Major Components
Labeled antibody	80μL × 60	Anti-cTnI monoclonal antibody labeled by AP, Tris buffer, BSA
Coated antibody	50μL × 60	Anti-cTnI monoclonal antibody labeled by AP, PBS, BSA
Sample buffer	0.1mL × 60	NaCl solution
Calibrator 1 (CAL-1)	0.5mL × 2	Lyophilized products: BSA, Trehalose, NBS
Calibrator 2 (CAL-2)	0.5mL × 2	Lyophilized products: BSA, Trehalose, NBS
Calibrator Diluent	1.0mL × 2	Purified water
Washing solution	1.15mL× 60	Tris buffer
Substrate solution	0.2mL × 60	3-(2-spiroadamatane)-4-methoxy-4-(3-phosphoryloxy)-phenyl-1,2-dioxetane disodium salt solution
Single-use reactor	60 pieces	Polystyrene
Calibration curve card	1 sheet	Barcode, containing calibration curve and the information of calibrator target
hs-cTnI-CLIA Q1	0.5mL × 1	Lyophilized products: BSA, Trehalose, NBS
hs-cTnI-CLIA Q2	0.5mL × 1	Lyophilized products: BSA, Trehalose, NBS
Control diluent	1.0mL × 1	Purified water

Note:

1. The calibrator target value is batch-specific, please refer to label for details.
2. Calibrators are traceable to the enterprise work calibrators and are assigned the value by comparing with the listed products.
3. Mutual-use between components of kits of different batches is not allowed.

STORAGE AND STABILITY

1. Store at 2°C-8°C with shelf life for 12 months.
2. See product labels for manufacture date and expiration date.

APPLICABLE INSTRUMENT

AyoTes Auto Chemiluminescence Immunoassay (CLIA) Analyzer (Model: AT60 Smart, AT60 proB).

SAMPLE COLLECTION AND STORAGE

It's applicable to serum and plasma samples using EDTA and heparin as anticoagulants, and venous blood should be separated in 24 hours. The serum and plasma samples should not be stored for over one week at 2°C-8°C. If testing cannot be completed within one week after collecting blood, the samples should be sealed and stored at -20°C for up to 3 months, and freeze-thaw should not exceed 3 times. Avoid using severely hemolyzed and lipemic samples whenever possible.

It's also applicable to whole blood samples using EDTA as anticoagulants. Use an anticoagulant tube to collect blood or add EDTA anticoagulant to the blood collection tube in advance, and mix up and down gently for no less than 20 times. The sample should be tested immediately after collection. If the test cannot be performed within 2 hours after blood collection, the plasma should be separated for storage.

TEST PROCEDURE

1. Reagent preparation

1. The kit can only be used when it reaches room temperature after taking out from refrigerated environment.
2. Calibrator: Add 500μL of the calibrator diluent to each of calibrator 1 and calibrator 2 for reconstitution. After balancing for 30min at room temperature, please conduct the test, and the balanced calibrators should be use immediately.

2. Enter the calibration curve data

1. Before using a new batch of reagents, the calibration curve information must be entered.
2. Information contained in calibration curve card: reagent calibration curve, calibrator target information.
3. Open the instrument software, select the "Curve Adding" interface; Use the barcode scanner to scan the barcode on the calibration curve card, after scanning, click "Add", the instrument will automatically recognize and enter the information.
4. In special circumstances, if the scanner cannot read the barcode information, please enter the barcode information manually.

3. Calibration procedure

1. When using a new batch of reagents, the calibration curve data must be entered and then calibrated.
2. Calibrator 1 and Calibrator 2 shall be redrilled for calibration test.
3. Pipette 100μL well-mixed calibrator and add into corresponding sample well, put it into applicable instrument.

Note:

1. The calibration cycle is 28 days (recalibration will be performed 28 days after each calibration).
2. If the instrument displays calibration fails, please calibrate again.

4. Sample experiment

1. Injection: Load the reagent strip into the instrument, add no less than 100μL sample in the sample positions and click "Start".
2. Sample mixing: The instrument automatically aspirates 50μL sample, 50μL labeled antibody and 50μL coated antibody to mix well.
3. Incubation: Incubate the mixed sample for 10 minutes at 37°C.
4. Washing: Wash three times after incubation.
5. Testing: The instrument automatically aspirates substrate solution, blow and suck to mix well before photometry. Output concentration result by internal calculation of the instrument.

Note:

1. When using a whole blood sample, the whole blood contained in the blood collection tube can only be mixed

gently before injection (do not use the turbine agitator), then add the whole blood sample for experimentation after mixing.
2. If the sample has been loaded into the sample well for 5 minutes without testing, the results of whole blood samples will decrease due to the sample precipitation, while results of serum and plasma samples will increase due to the sample concentration.
3. When the sample result is higher than 50 ng/mL, to obtain accurate results, it is recommended to use the sample buffer to dilute and re-test. The recommendation dilution ratio is 1:10.

REFERENCE RANGE AND INTERPRETATION

1. The test results of cTnI from 176 normal people samples is 0.04 ng/mL (the 99th percentile).
2. There are some differences in reference values because of different regions and different instruments. Therefore, the normal reference value provided in Instruction for Use is for reference only. Each laboratory should determine its own reference value based on the patient population.

EXPLANATION OF TEST RESULT

The result is only for reference and patient's diagnostic result should be determined by combining with clinical diagnosis.

LIMITATIONS OF TEST METHOD

1. The test result beyond the kit test range is calculated by extending the curve and should not be used as accurate quantitative data.
2. The samples of patients who are closely exposed to rodents or have received mouse monoclonal antibody immunotherapy may contain heterophil antibody. When using detection kit containing antibody to test this type of sample, the obtained result may be abnormal.

PERFORMANCE CHARACTERISTICS

1. Appearance: The kit appearance should be neat and clean, and letter symbol identification should be clear and complete in content; the liquid components should be free of sediment or floccule.
2. Accuracy: Add pure cTnI into human source negative samples, and the recovery rate shall be within the range of 85%-115%.
3. Limit of blank (LoB): ≤ 0.02 ng/mL.
4. Liner range: Within the range of [0.02, 50] ng/mL, the correlation coefficient (r) should not be less than 0.9900.
5. Precision

1.Intra-assay precision: For test samples at concentrations of (0.04±0.004) ng/mL and (10±1) ng/mL, the intra-assay coefficient of variation (CV) should not be greater than 8.0%;
2.Inter-assay precision: For test sample at a concentration of (0.04±0.004) ng/mL, the inter-assay coefficient of variation (CV) should not be greater than 15.0%;
3. Intra-vial precision: The coefficient of variation (CV) should not be greater than 8.0%.
7. Specificity

Cross reactivity with other substances are shown below:

Cross-reactive substances	Concentration	Test concentration
cTnC	1000 ng/mL	≤ 0.02 ng/mL
cTnT	1000 ng/mL	≤ 0.02 ng/mL
sTnI	1000 ng/mL	≤ 0.02 ng/mL

8. Traceability

Provide the source, traceability process and measurement uncertainty of the calibrator etc according to the relevant regulations of GB/T21415, trace back to enterprise work calibrators and are assigned the value by comparing with the listed products.

PRECAUTIONS

1. The reagent is only used for in vitro diagnosis.
2. Store and use reagent reasonably strictly according to Instruction for Use and avoid direct exposure to sunlight.
3. For all samples, the washing solution and any waste should be disposed as infective materials.

EXPLANATION FOR IDENTIFICATION

	Use-by date		Batch code		Consult instructions for use or consult electronic instructions for use
	Contains sufficient for <n> tests		Temperature limit		Catalogue number
	Date of manufacture		Caution		Do not re-use
	Manufacturer		Keep away from sunlight		Keep dry
	In vitro diagnostic medical device				

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AyoTes

Instruction of Unassayed Quality Control

【**Product Name**】Unassayed Quality Control

【**Packaging**】 Type 1: freeze-dried powder, Q1-0.5mL×1 bottle, Q2-0.5mL×1 bottle, control diluent 1mL×1 bottle.
Type 2: Liquid, Q1 - 0.5mL×1 bottle, Q2 - 0.5mL × 1 bottle.

【**Intended use**】Used for internal quality control of in vitro diagnostic kits.

【**The principle**】Quality controls are used to objectively evaluate test methods and monitor performance within the analysis range of detection systems and are an important part of good laboratory practices.

【**Components**】Containing animal protein, antigens and other substance.

【**Storage & Stability**】

The quality control are stored at 2℃ ~ 8℃, valid for 18months. Freeze-dried quality control after redissolved, stored at 2℃～8℃, valid for 3 days. Liquid quality control after opened, stored at 2℃～8℃, valid for 7 days.

Production date and expiration date are detailed in the product label.

【**Test method**】

1. Freeze-dried Control: Prior to use, remove the Control from storage condition, dissolve with control diluent according to the bottle marked volume, stand for 30 min at room temperature, ensure the contents are completely dissolved, and then mixed for use. Follow the instructions for storage and operations, the controls can be stable during the period of validity.

2.Liquid Control: Prior to use, remove the Control from storage condition, stand at room temperature for 30 min, and then mixed for use. Follow the instructions for storage and operations, the controls can be stable during the period of validity.

3.The specific inspection operation process should refer to the relevant reagent and instrument operation manual.

【 **Interpretation of result** 】 Quality control inspection results are only used for internal quality control of laboratory testing of in vitro diagnostic reagents, to observe and control the precision of the testing process.

【**Limitations of the test method**】

1. Do not use expired products.
2. Do not use the product if it is contaminated by microorganism or turbid after resolution.
3. This product cannot be used as a standard or calibrator.
4. This product only used for in vitro diagnosis.

【**Performance of Product**】

1. Appearance: the appearance should be clean and tidy, The text symbols are clearly and completely marked. Liquid quality control have no precipitation or floccule. The freeze-dried quality control were loose and no precipitation or floccule after resolution.
2. Q1 is a low level, Q2 is a high level.

【**Precautions**】

1. The quality control are only used for monitoring and quality evaluation of clinical in vitro diagnostic reagents. They are operated by laboratory professionals, and strictly in accordance with the instructions.
2. Please store and use the product in strict accordance with the instructions and avoid direct sunlight.
3. Quality control should be treated as infectious substances.
4. This product is not required to be registered in accordance with document No. 11 of the Food and Drug Administration (2013).

【**References**】

[1] Xie kejie, Wang Kai, Zhang Lihong. Preparation and application evaluation of special protein internal quality control[J]. Laboratory medicine, 2009, 24(5):381-383.

【**Basic Information**】

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