High Sensitivity Cardiac Troponin I Test Kit (Immunofluorescence)

(For *In Vitro* Diagnostic Use Only)

[Product Name] High Sensitivity Cardiac Troponin I Test Kit (Immunofluorescence)

[Package Specification& REF ID]

20 tests/kit(BA0010), 50 tests/kit(BA0011)

[Intended Use]

This kit applies to the quantitative determination of cardiac troponin I (cTnI) in human serum, plasma and whole blood in vitro, and is mainly used for the auxiliary diagnosis of acute myocardial infarction in clinic.

Troponin I is a key regulatory protein of striated muscle tissue, which is related to muscle contraction. Three isoforms of troponin I have been identified so far, among which cardiac troponin I (cTnI) has high myocardial tissue specificity, is a highly sensitive marker of myocardial injury that can distinguish skeletal muscle disease and myocardial injury[1,2]. When myocardial infarction occurs, the serum cTnI level increases at about 3-6 hours, peaks at 12-16 hours, and continues to increase for 4-10 days[2,3]. Elevated cTnI levels are also found in patients with unstable angina pectoris (UAP) and congestive heart failure (CHF)[4,5]. cTnI is also a mature indicator to predict the short-term, medium-term and even long-term prognosis of patients with acute coronary syndrome (ACS)[6,7]. In general, the rise of cTnI level indicates the existence of myocardial injury. If clinical result indicate that it is not myocardial ischemia, we have to consider other causes of cardiac injury.

Currently the common clinical test methods include enzyme-linked immunosorbent assay (ELISA), chemiluminescence immunoassay (CLIA), electrochemiluminescence (ECL), fluoroimmunoassay (FIA), etc.

[Principle]

The kit is based on the principle of the lateral flow fluorescence immunoassay utilizing an immuno-sandwich format. When the sample is added to the sample port, the sample first passes through the sample pad, and then cTnI in the sample specifically binds to the fluorescent-conjugated cTnI monoclonal antibody on the conjugate pad to form a fluorescent complex. When the fluorescence complex flows to the test band, it will bind to the cTnI monoclonal antibody pre-coated on the nitrocellulose membrane and will be fixed on the test band. The antigen content in the complex is proportional to the fluorescence intensity of the test band. When the free fluorescence complex reaches the control band, the complex will specifically bind to the goat IgG pre-coated on the control band and therefore will be fixed on it. The immunofluorescence analyzer converts the received fluorescence signal value into electrical signal value, and automatically converts the concentration of cTnI in the sample (ng/mL) by substituting the T/C value (T/C peak area) into the preset calibration curve.

[Components]

The kit consists of the Reagent

Reagent:

Composition	Main ingredients/information	20 tests/kit		50 tests/kit	
		BA0010		BA0011	
		Quantity	Specification	Quantity	Specification
Test Cassette	Nitrocellulose membrane (cTnI monoclonal antibody, goat IgG), conjugate pad (fluorescent conjugated cTnI monoclonal antibody), sample pad, absorbent pad	20	Individual package	50	Individual package

Certificate of conformity/ calibrate card	Product information (item name, item code, batch number, production date, expiration date), calibration curve	1 copy	----	1 copy	----
Product insert	/	1 copy	----	1 copy	----

The components in different batch of Reagent kits are not interchangeable.

[Storage and Stability]

The Reagent kit should be store at room temperature (2-30℃ or 35.6-86℉) in a dry shady place. Avoid direct sunlight. 18 months of shelf life (production date to expiration date).

The test cassette should be used within half an hour as long as the aluminum foil bag is opened, and used immediately when the room temperature exceeds 25℃ or in an environment with high humidity.

The kit can be transported for 30 days at the temperature of -20 °C to 45 °C.

[Applicable Instrument]

Immunofluorescence analyzers: WS-Si1000, WS-Si1500 and WS-Mi6000 produced by Guangdong Wesail Biotech Co., Ltd.

[Sample Requirements]

1. Applicable to the following sample:

   Fresh venous serum, heparin plasma or whole blood samples, fasting blood collection is unnecessary.
2. Precautions during sample collection:

2.1 The sample shall be protected against hemolysis and free of fibrin and other impurities;

2.2 White blood cells or platelets should be avoided when collecting plasma samples.

2.3 Before testing, the serum/plasma samples should be centrifuged at room temperature (15°C~25°C) for 10 minutes at 1,300g~2,000g (generally 3,500~4,000rpm), which can be configured according to the Instructions for Use of the centrifuge.

3. Hematocrit value:

   If the whole blood sample is used for detection, its hematocrit value should be in the range of 0.30-0.62.
4. Storage and preparation of samples:

4.1 The whole blood sample at room temperature should be used within 4 hours and, if it cannot be tested within 4 hours, it should be timely transferred for storage at 2°C~8°C. The samples that are not detected within 24 hours should be discarded and the blood has to be drawn again.

Sample type	Storage condition	Storage time
Plasma/Serum	≤-20 ℃	30 days
Plasma/Serum	2 ℃～8 ℃	24 hours
Plasma/Serum	15 ℃～30 ℃	8 hours
Whole Blood	Room temperature	4 hours

4.2 The sample can only be frozen and thawed once after thawing.

[Test Procedure]

Before the test, you are required to thoroughly read the relevant operating instructions for this reagent and the immunofluorescence analyzers.

Model of Analyzer	Steps	Details	Notes
WS-Si1000	Preparation	1.1 Power on the analyzer and incubator, allow them to preheat and perform self-checking respectively. 1.2 After the self-check of the analyzer is completed, insert the calibrate card into the corresponding scanning area of the analyzer, click the QR code icon to identify and import the item information. 1.3 Set the incubator to 8 minutes, 18.5°C.	The samples and kits must be restored to room temperature before testing
	Sample addition	2.1 Pipette 60 μL sample into the sample port of the cassette , insert the cassette into the incubator immediately, and the incubator will count down for 8 minutes.	Avoid sample overflow the sample port
	Detection	3.1 The incubator will automatically alarm at the last 10 seconds of incubation. Pull out the cassette immediately and insert it into the analyzer which will automatically recognize the QR code information on the cassette and display it in the test interface. After confirming the information is correct, select sample type and click “Test”, and the analyzer will automatically scan the cassette. 3.2 The analyzer will convert the scanned signal value through the preset calibration curve, and display the test results in the test interface. 3.3 Click “Print” to print results.	It has to be inserted into the analyzer for detection immediately after incubation
WS-Si1500; WS-Mi6000	Preparation	1.1 Power on the analyzer, allow it to preheat and perform self-checking. 1.2 After the self-check of the analyzer is completed, put the calibrate card in the corresponding scanning area, click "import" and the analyzer will identify and import the QR code information. 1.3 Insert the cassette, the analyzer will automatically identify the item information, and then eject the cassette, exposing the sample port. Select sample type in the test interface.	The samples and kits must be restored to room temperature before testing
	Sample addition	2.1 Pipette 60 μL sample to the sample port, then immediately insert the cassette into the analyzer, and the incubation time will automatically count down.	Avoid sample overflow the sample port
	Detection	3.1 After incubation, automatic detection is performed. The analyzer will convert the scanned signal value through the preset calibration curve, and display the test results in the test interface. 3.2 Click “Print” to print results.	/

[Quality Control Procedure]

Periodic quality control shall be carried out to ensure the effectiveness and accuracy of test results.

The analyzer's optical parts and moving parts are validated by the quality control card.

Periodic validation is performed on the validity and accuracy of reagent test results by using the Cardiac troponin I Control from Guangdong Wesail Biotech Co., Ltd.

The kit does not contain the Cardiac troponin I Control and the quality control card, if necessary, please contact the manufacturer.

[Reference Range]

1. Considering the differences in geography, race, gender and age, laboratories are recommended to establish their own reference intervals according to their own conditions.
2. The High Sensitivity Cardiac Troponin I test kit (immunofluorescence) from Guangdong Wesail Biotech Co., Ltd. was used to test apparently healthy people aged 18-80, including 199 males and 212 females. No significant difference was observed between different ages and genders. Based on the treatment by non-parametric method, the 99th percentile was taken as the upper limit of reference interval, and the reference interval of normal population was confirmed in the range of 0 ng/mL to 0.080 ng/mL.

[Interpretation of Test Results]

1. The detection range of samples is 0.020 ng/mL-100.000 ng/mL. For the samples exceeding the upper detection limit the results are reported "＞100.000 ng/mL", or less than the lower detection limit the results are reported "＜0.020 ng/mL".
2. When the test kit expires, the immunofluorescence analyzer will directly report "kit failure".
3. When the control line exceeds the acceptable value set in the analyzer or the test cassette expires, the immunofluorescence analyzer will report "invalid detection".
4. The test results of the kit are for clinical reference only and cannot be taken alone as the basis for diagnosis or exclusion of cases. For the purpose of diagnosis, the test results should be used in combination with clinical examination, medical history and other examination results.
5. It is not recommended to dilute the sample for detection when the sample concentration is greater than 100.000 ng/mL.

[Limitations of Test Method]

1. The following may lead to false positive results: influence of cross reaction of similar antibody components in blood (such as high concentration of heterophile antibody or rheumatoid factor); some non-specific components in blood having similar epitopes which can be captured by the fluorescent conjugated antibodies.
2. The following may lead to false negative results: antigenic determinants blocked by some unknown components fail to bind with antibodies; unstable cTnI antigens that gradually degenerate with time and temperature are not recognized by the antibody. Effective test results require a good test cassette and the proper sample storage environment.
3. Other factors may also lead to errors in cTnI test result, including technical reasons, operational errors and other factors related to the sample. For the abnormal results caused by such factors, it is required to repeat the detection and avoid non-standard use process.
4. Interferent: Since this product implements chromatography on the nitrocellulose membrane using fluorescently-labeled antibody and quantifies cTnI in the sample through fluorescence detection at the corresponding position, the presence of hemolysis or high concentration of triglyceride, cholesterol, bilirubin, rheumatoid factor and HAMA in the sample will affect its chromatography on the nitrocellulose membrane or the normal reaction of antigen and antibody, resulting in wrong detection results. This product therefore must not be used for detection when the sample contains any of the following interferents exceeding the specific concentration:
   Lipid blood: with triglyceride exceeding 15 mg/mL;
   High cholesterol: with cholesterol exceeding 400 mg/dL;
   Jaundice: with bilirubin exceeding 40 mg/L;
   Hemolysis: with hemoglobin exceeding 6 mg/mL;
   Rheumatoid factor: with rheumatoid factor exceeding 200 IU/mL;
   HAMA: with HAMA exceeding 200 ng/mL

[Product Performance Index]

1. The limit of detection shall not be greater than 0.020 ng/mL.
2. Accuracy: When tested with the national standard substances/enterprise reference, the relative deviation between the test result and the calibration concentration shall not exceed ±15.0%.
3. Linearity: Within the range of [0.020, 80.000] ng/mL, the correlation coefficient (r) of linear regression shall not be less than 0.9900.
4. Repeatability: The intra-batch coefficient of variation (CV) shall not be greater than 10.0% when tested with the enterprise reference.
5. Inter-batch variation: The inter-batch coefficient of variation (CV) shall not be greater than 15.0% when tested with the enterprise reference.
6. Specificity: The detection value should be less than 0.080 ng/mL when tested with cTnI specific references (1000 ng/mL cTnT, 1000 ng/mL cTnC and 1000 ng/mL sTnI).
7. The sample concentration is up to 500.000 ng/mL, and no high-dose hook effect is observed.

[Precautions]

1. This product is used for in vitro testing only.
2. Do not test the samples with high fat chyle, jaundice, severe hemolysis and high rheumatoid factor.
3. Product performance cannot be guaranteed when other sample types, or sample collection and processing methods are used.
4. Do not use the test kit with damaged package, unclear mark or beyond expiry date.
5. Please operate in strict accordance with the instructions, and the test cannot be stopped halfway once the test starts. The test that is stopped halfway cannot be resumed. If retesting is required, a new test cassette must be used for retesting.
6. Retesting is required for an invalid result.
7. A corresponding calibrate card is provided for each batch of cassettes and must be updated in time.
8. Test cassettes, which are disposable, should be handled as biological products after use according to relevant regulations.
9. The desiccant in the aluminum foil bag cannot be taken internally.
10. Biosafety warning: clinical samples, test wastes, disposable articles and other materials exposed in the test shall be handled as potential infectious substances, and corresponding preventive measures shall be taken.
11. The test results cannot serve as the absolute basis for diagnosis, and should be interpreted by the doctors according to clinical characteristics and other test results.
12. Due to methodology or antibody specificity, testing the same sample with kits from different manufacturers may produce different test results. Therefore, direct comparison should not be conducted among different kits.

[References]

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Guangdong Wesail Biotech Co., Ltd.

Address: 2F, Building 1, 5 Hualian Street, Songshan Lake Science and Technology Industrial Park, Songshan Lake, 523808 Dongguan, Guangdong, China

Tel : 400-900-1339

E-mail : customer@wesailbio.com

Website: http://en.wesailbio.com

Lotus NL B.V.

Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

E-mail : peter@lotusnl.com

SYMBOL	DESCRIPTION
	Manufacturer
	Authorized representative in the European Community
	*In Vitro* Diagnostic Medical Device
	Batch Code
	Use-by date
	Temperature Limitation
	CE Mark
	Catalogue number
	Biological risks
	Do not re-use
	Contains Sufficient for <n> Tests
	Date of manufacture
	Keep Away From Sunlight
	Consult instructions for use
	Keep Dry