EC Declaration of Conformity

according to the Directive 98/79/EC
(applicable to IVD Devices of NOT Annex Ⅱ and NOT self-test)

Manufacturer	Guangdong Wesail Biotech Co., Ltd. 2F, Building 1, 5 Hualian Street, Songshan Lake Science and Technology Industrial Park, Songshan Lake, 523808 Dongguan, Guangdong, China
European Representative	Lotus NL B.V. Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
Product/s	High Sensitivity Cardiac Troponin I Test Kit (Immunofluorescence) REF No.: BA0010 Model: 20 tests/kit
Basic UDI-DI	697384100A00103K
UDI-DI	6973841000857
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.
GMDN Code	54010
EMDN Code	W0102160703
Classification	Others/General
Conformity Assessment Route	Annex Ⅲ, except point 6, of Directive

Applicable Standards

EN ISO 18113-1:2011	EN ISO 18113-2:2011	EN ISO 15223-1:2016
EN 13612:2002	EN ISO 23640:2015	EN 13641:2002
EN 13975:2003	EN ISO 17511:2003	EN ISO 14971:2012
ISO 14971:2019	EN ISO 13485:2016	ISO 15198:2004

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

Signed this Day/ 30th of Month/ June of Year/ 2021, Place (Dongguan), China

Signature (on behalf of the manufacturer)

Name of authorized signatory: **Dong Yu**

Position held in the company: **General Manager**

Company Seal/Stamp:

EU DECLARATION OF CONFORMITY

According to Art. 17 of Regulation (EU) 2017/746 on in vitro diagnostic medical devices

Manufacturer:	Guangdong Wesail Biotech Co., Ltd. 2F, Building 1, 5 Hualian Street, Songshan Lake Science and Technology Industrial Park, Songshan Lake, 523808 Dongguan, Guangdong, China
European Representative:	MedPath GmbH Mies-van-der-Rohe-Strasse 8 80807 Munich, Germany
Product or trade name:	Immunofluorescence Analyzer
Product Model	WS-Si1500
Basic UDI-DI	697384100B15004T
UDI-DI	6973841000826
Intended Use	The instrument is used in conjunction with WESAIL reagents and is used for qualitative or quantitative and quantitative analysis of human samples to be tested.
GMDN Code	48014
EMDN Code	W0201020103
Classification acc. to IVDR Ax. VIII:	Class A, rule 5
Applied Standard & Common Specification:	EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 18113-1:2011, EN ISO 18113-3:2011, EN 13612:2002, EN ISO 15223-1:2021, EN ISO 23640:2015, EN 62366-1:2015, IEC 61010-2-101:2018, EN IEC 61326-1:2021, EN IEC 61326-2-6:2021
Conformity assessment procedure:	Article 17 + Ax. II + Ax. III
CE certificate No.:	N.A.

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR). All supporting documentations are retained under the premises of the manufacturer.

Signed this Day/ 15th of Month/ January of Year/ 2021, Place Dongguan , China

Signature (on behalf of the manufacturer)

Name of authorized signatory: Dong Yu

Position held in the company: General Manager

Company Seal/Stamp:

UDI-DI: 06973841000826

Go back to the list

Manufacturer details

Version 1 (Current) | Last update date: 2021-06-30

Actor/Organisation name	Guangdong Wesail Biotech Co., Ltd. [EN]
Actor ID/SRN	CN-MF-000008828
Address	2F, Building 1, 5 Hualian Street, Songshan Lake Science and Technology Industrial Park, Songshan Lake, 523808 Dongguan, Guangdong, China Dongguan
Country	China
Telephone number	+86-769-22890969
Email	Registration.Wesail@wesailbio.com

Manufacturer details
Basic UDI-DI details
Certificates
UDI-DI details

Basic UDI-DI details

Version 1 (Current) | Last update date: 2023-10-23

Applicable legislation	IVDR (REGULATION (EU) 2017/746 on in vitro diagnostic medical devices)
Basic UDI-DI/EUDAMED DI / Issuing entity	697384100B15004T / GS1
Kit	No
Authorised representative	DE-AR-000000087 - MedPath GmbH - 8 Mies-van-der-Rohe-Strasse Munich - Germany
Risk class	Class A
Companion diagnostic	No
Near patient testing	No
Patient self testing	No
Professional testing	Yes
Reagent	No
Instrument	Yes
Device model	WS-Si1500
Device name	Immunofluorescence Analyzer

Manufacturer details
Basic UDI-DI details
Certificates
UDI-DI details

Tissues and cells

Presence of human tissues and cells or their derivatives	No
Presence of animal tissues and cells or their derivatives	No
Presence of cells or substances of microbial origin	No

Information on substances

Presence of a substance which, if used separately, may be considered to be a medicinal product	No
Presence of a substance which, if used separately, may be considered to be a medicinal product derived from human blood or human plasma	No

Certificates

There is no reference to this Basic UDI-DI in any certificate, because:

- It does not require a certificate or
- It requires only a certificate that does not reference the Basic UDI-DI (e.g. a QMS certificate) or
- The required certificate(s) referencing this Basic UDI-DI is(are) not registered yet.

Manufacturer details

Basic UDI-DI details

Certificates

UDI-DI details

UDI-DI details

Version 1 (Current) | Last update date: 2023-10-23

UDI-DI code / Issuing entity	06973841000826 / GS1
Status	On the EU market
UDI-DI from another entity (secondary)	-
Nomenclature code(s)	W0201020103: Automated immunochemistry analysers - moderate to high routine (throughput > 250 and <= 700 test/h)
Name/Trade name(s)	Immunofluorescence Analyzer [EN]
Reference / Catalogue number	WS-Si1500
Direct marking DI	Yes
Quantity of device	1
Type of UDI-PI	Serial number Manufacturing date
Additional Product description	-
Additional information url	-

Manufacturer details

Basic UDI-DI details

Certificates

UDI-DI details

Labelled as single use	No
Maximum number of reuses	-
Need for sterilisation before use	No
Device labelled as sterile	No
New device	No
Member state of the placing on the EU market of the device	Germany

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 108683 0001 Rev. 01

Holder of Certificate: **Guangdong Wesail Biotech Co., Ltd.**
2F, Building 1, 5 Hualian Street
Songshan Lake Science and Technology Industrial Park
Songshan Lake
523808 Dongguan, Guangdong
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Design and Development, Production and Distribution of In Vitro Diagnostic Reagents for Immunochemistry.**
Design and Development, Production, Distribution and Servicing of In Vitro Diagnostic Instruments for Immunochemistry.

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 108683 0001 Rev. 01

Report No.: GZ2355001 / GZ2355001_CN

Valid from: 2023-10-13
Valid until: 2026-10-12

Date, 2023-09-19

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 108683 0001 Rev. 01

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

Guangdong Wesail Biotech Co., Ltd.
2F, Building 1, 5 Hualian Street, Songshan Lake Science and Technology Industrial Park, Songshan Lake, 523808 Dongguan, Guangdong, PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production of In Vitro Diagnostic Reagents for Immunochemistry.
Distribution of In Vitro Diagnostic Reagents and Instruments for Immunochemistry.

Guangdong Wesail Biotech Co., Ltd.
Room 201, Building 10, 19 Alishan RD, Songshan Lake Science and Technology Industrial Park, Songshan Lake, 523808 Dongguan, Guangdong, PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production and Servicing of In Vitro Diagnostic Instruments for Immunochemistry.

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

24077

Cardiac Troponin I Test Kit (Immunofluorescence) Control

[Product Name]
Generic Name: Cardiac Troponin I Test Kit (Immunofluorescence) Control

[Package Specification & REF ID]
Level 1, Level 2: 1×0.25 mL/bottle (reconstitution volume) (BD0011)

[Intended Use]
This product can be used for quality control of the Cardiac Troponin I Test Kit (Immunofluorescence) manufactured by Guangdong Wesail Biotech Co., Ltd.

[Principle]
The Cardiac Troponin I (cTnI) contained in this quality control material can specifically binds with the antibody in the cassette, and form a fluorescent complex. By detecting the content of the complex, the quantitative experimental results of the quality control material can be determined.

[Components]

Composition	Main ingredients	Specification
Control Level 1	cTnI antigen, BSA, phosphate buffer	1×0.25 mL/bottle(reconstitution volume)
Control Level 2	cTnI antigen, BSA,phosphate buffer	1×0.25 mL/bottle(reconstitution volume)
Target Value Card	/	1 copy

The components in different batch of kits are not interchangeable. The target range of the quality control product is the target value ± 3 standard deviations (SD). The target range is batch-specific, please refer to the target value information on the Target Value Card for details.

[Storage and Stability]
The Control should be sealed and stored at a temperature of 2°C to 8°C, and the validity period is 18 months.
After reconstitution, the Control should be stored in the shady place at a temperature of 2°C to 8°C and has a shelf life of 24 hours. It is recommended to use it all at once.
The production batch number, production date and expiration date are shown on the label.

[Applicable Instrument]

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

[Test Procedure]

1. Before using the Control, equilibrate to room temperature and then open the bottle cap.
2. Take 250 μL ultrapure water and slowly add it to the Control bottle, avoiding the lyophilized powder sticking to the tip during this period.
3. Tighten the bottle cap. Gently shake and invert the Control to dissolve the powder completely and ensure thorough mixing. Avoid applying excessive force to prevent bubble formation or loosening of the bottle cap.
4. Take 60 μL of the reconstituted Control for sample addition. For specific operating procedures, please refer to the instructions of Cardiac Troponin I Test Kit (Immunofluorescence) from Guangdong Wesail Biotech Co., Ltd.

[Interpretation of Test Results]

The target value and target range of each batch of Control are different. Before use, please carefully read this Instruction for Use and the target value information provided on the Target Value Card. Test the Control on the quality control detection system, and the test results should fall within its target range. Possible errors include: quality issues with the cassette, operational errors, instrument abnormalities, etc.

[Limitations of Test Method]

1. The Control is suitable for Cardiac Troponin I Test Kit (Immunofluorescence) of Guangdong Wesail Biotech Co., Ltd.
2. This product is not a calibration material and cannot be used for instrument calibration.

[Product Performance Index]

1. Expected results: The assay results should be within the target range.
2. Homogeneity: CV≤15.0%.

[Precautions]

1. Lyophilized Control should be brought to room temperature before reconstitution by using ultrapure water. The amount of ultrapure water added during reconstitution must be accurate.
2. When reconstituting the lyophilized Control, gently invert the vial until the lyophilized powder is fully mixed, avoiding the generation of foam. Do not use a vortex mixer.
3. The Control should not contain fibrin and other impurities.
4. The reconstituted Control should be used up at one time, avoid freezing and thawing.
5. Strictly follow the instructions regarding the cassette operating procedures.
6. This product cannot be used after the expiry date.
7. This product cannot be used as a standard material.
8. After reconstitution, it cannot be used for detection when caking or flocs appear.
9. When the values fall outside the target value range for the specific batch, please verify if the reagents have expired or if there were errors in the procedure that caused the result deviation.
10. Please strictly adhere to the storage conditions and use the product within its expiration date.
11. Biosafety warning: experimental waste, disposable items and other materials should be treated as potential infectious substances, and appropriate preventive measures should be taken.

[References]

1. Panteghini M, Apple F S, Christenson R H, et al. Proposals from IFCC Committee on Standardization of Markers of Cardiac Damage (C-SMCD): Recommendations on use of biochemical markers of cardiac damage in acute coronary syndromes[J]. Scandinavian Journal of Clinical & Laboratory Investigation, 1999, 59(s230):103-112.
2. Wu A H. National Academy of Clinical Biochemistry Standards of Laboratory Practice: ecommendations for the use of cardiac markers in coronary artery diseases[J]. Clin Chem, 1999, 45.
3. J Ravkilde. Risk stratification in acute coronary syndrome using cardiac troponin I[J]. clinical chemistry, 2000, 46(4):443.
4. Pradip Datta, Kimberley Foster, Amitava Dasgupta. Comparison of Immunoreactivity of Five Human Cardiac Troponin I Assays toward Free and Complexed Forms of the Antigen: Implications for Assay Discordance[J]. Clinical Chemistry, 1999, 45(12):2266-9.
5. Reiffert S U, Jaquet K, Heilmeyer L M G, et al. Stepwise Subunit Interaction Changes by Mono- and Bisphosphorylation of Cardiac Troponin I [J]. Biochemistry, 1998, 37(39):13516-13525.

Guangdong Wesail Biotech Co., Ltd.

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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
EC REP	Authorized representative in the European Community
IVD	*In Vitro* Diagnostic Medical Device
LOT	Batch Code
	Use-by date
2°C 8°C	Temperature Limitation
CE	CE Mark
REF	Catalogue number
	Biological risks
	Do not re-use
Σ	Contains Sufficient for <n> Tests
	Date of manufacture

SYMBOL	DESCRIPTION
	Keep Away From Sunlight
	Consult instructions for use
	Keep Dry

16327

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 immuno-fluorescence 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]

1. Cummins P, Perry V. Troponin I from human skeletal and cardiac muscles. Biochem J 1978;171:251-259.
2. Mair J, Genser N, Morandell D, et al. Cardiac troponin I in the diagnosis of myocardial injury and infarction. Clinica Chimica Acta 1996;245:19-38.
3. Expert consensus group for joint detection of biomarkers of acute nontraumatic chest pain. Expert consensus on joint detection of biomarkers for acute nontraumatic chest pain [J] Chinese Journal of Emergency Medicine, 2015,24(009): 940-951.
4. Galvani M, Ottani F, Ferrini D, et al. Prognostic influence of elevated values of cardiac troponin I in patients with unstable angina. Circulation 1997;95:2053-2059.
5. Missov ED, De Marco T. Clinical insights on the use of highly sensitive cardiac troponin assays. Clin Chem Acta 1999;284:175-185.
6. Antman EM, Tanasijevic MJ, Thompson B, et al. Cardiac-specific troponin I levels to predict the risk of mortality in patients with acute coronary syndromes. N Engl J Med 1996;335:1342-1349.
7. Antman EM, Fox KM. Guidelines for the diagnosis and management of unstable angina and non-Q-wave myocardial infarction: Proposed revisions. Am Heart J 2000;139:461-475.
8. Wu AH. Early detection of acute coronary syndromes and risk stratification by multimarker analysis. Biomark Med. 2007Jun;1(1): 45-57.
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SYMBOL	DESCRIPTION
	Manufacturer
EC REP	Authorized representative in the European Community
IVD	*In Vitro* Diagnostic Medical Device
LOT	Batch Code
	Use-by date
2°C 30°C	Temperature Limitation
CE	CE Mark
REF	Catalogue number
	Biological risks
	Do not re-use
Σ	Contains Sufficient for <n> Tests
	Date of manufacture
	Keep Away From Sunlight
	Consult instructions for use
	Keep Dry

TECHNICAL DATA BOOKLET

Hand-held Immunofluorescence analyzer

DESCRIPTION

Handheld Immunofluorescence Analyzer is designed to work with WESAIL parameters. During testing, the analyte in the sample are captured in the detection and control zones on the strip. The analyzer scans these zones with excitation light, detects the emitted fluorescence, and converts it into an electrical signal. The signal intensity is proportional to the analyte concentration and is calculated automatically by the analyzer.

TECHNICAL DATA

Model	WS-Si1500
Methodology	Immunofluorescence assay
Weight	~1 Kg
Display	5.5-inch touchscreen
Incubator	Built-in incubator precisely maintains 18.5°C
Scancer	Built-in barcode scaner
Printer	Detachable thermal printer
Connection	USB, RS-232, LIS compatible
Power	Rechargeable Battery
Storage	100,000 test results
Input Supply	100-240VAC, 50/60Hz
Operation	Temperature 5°C-40°C,
Optional	Carrying Bag

FEATURES

- Wi-Fi Connection with LIS
- Built in incubator internal temperature control, always 18.5 temperature inside.
- Built in Barcode scanning for reagent barcode and sample barcode.
- Big color touch screen
- Built in battery
- Dispatchable Printer

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