



Declaration of Conformity



according to Directive 98/79/EC, on in vitro diagnostic medical devices

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Authorized Representative (Name, Address)	Lotus NL B.V. Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.		
Medical device	Description :		FIA8000 Quantitative Immunoassay Analyzer FIA8600 Quantitative Immunoassay Analyzer Cardiac Troponin I Fast Test Kit One Step Test for cTnI (Colloidal Gold) cTnI Rapid Test (Colloidal Gold Assay) One Step Test for NT-proBNP (Colloidal Gold) One Step Test for NT-proBNP/cTnI (Colloidal Gold) One Step Test for CK-MB/cTnI/Myo (Colloidal Gold) One Step Test for hs-CRP+CRP (Colloidal Gold) One Step Test for D-Dimer (Colloidal Gold) One Step Test for PCT (Colloidal Gold) One Step Test for β 2-MG (Colloidal Gold) One Step Test for mAlb (Colloidal Gold) One Step Test for NGAL (Colloidal Gold) One Step Test for CysC (Colloidal Gold) One Step Test for HCG+ β (Colloidal Gold) One Step Test for HbA1c (Colloidal Gold) One Step Test for PCT/CRP (Colloidal Gold) One Step Test for CK-MB/cTnI/H-FABP (Colloidal Gold) One Step Test for H-FABP (Colloidal Gold) One Step Test for CK-MB/cTnI (Colloidal Gold) One Step Test for CK-MB (Colloidal Gold) One Step Test for TSH (Colloidal Gold) One Step Test for T4/T3 (Colloidal Gold) One Step Test for T3 (Colloidal Gold) One Step Test for T4 (Colloidal Gold) One Step Test for 25-OH-VD (Colloidal Gold) One Step Test for FOB (Colloidal Gold) One Step Test for <i>H. pylori</i> (Colloidal Gold) One Step Test for SAA (Colloidal Gold) Getein1100 Immunofluorescence Quantitative Analyzer Getein1600 Immunofluorescence Quantitative Analyzer Getein1180 Immunofluorescence Quantitative Analyzer Getein1200 Immunofluorescence Quantitative Analyzer Cardiac Troponin I Fast Test Kit (Immunofluorescence Assay) NT-proBNP Fast Test Kit (Immunofluorescence Assay) hs-CRP+CRP Fast Test Kit (Immunofluorescence Assay) NT-proBNP/cTnI Fast Test Kit (Immunofluorescence Assay) CK-MB/cTnI/Myo Fast Test Kit (Immunofluorescence Assay) D-Dimer Fast Test Kit (Immunofluorescence Assay)

		PCT Fast Test Kit (Immunofluorescence Assay) β2-MG Fast Test Kit (Immunofluorescence Assay) mAlb Fast Test Kit (Immunofluorescence Assay) NGAL Fast Test Kit (Immunofluorescence Assay) CysC Fast Test Kit (Immunofluorescence Assay) CK-MB Fast Test Kit (Immunofluorescence Assay) CK-MB/cTnI Fast Test Kit (Immunofluorescence Assay) HCG+β Fast Test Kit (Immunofluorescence Assay) HbA1c Fast Test Kit (Immunofluorescence Assay) PCT/CRP Fast Test Kit (Immunofluorescence Assay) CK-MB/cTnI/H-FABP Fast Test Kit (Immunofluorescence Assay) H-FABP Fast Test Kit (Immunofluorescence Assay) 25-OH-VD Fast Test Kit (Immunofluorescence Assay) TSH Fast Test Kit (Immunofluorescence Assay) T3 Fast Test Kit (Immunofluorescence Assay) T4 Fast Test Kit (Immunofluorescence Assay) 25-OH-VD Fast Test Kit (Immunofluorescence Assay) FOB Fast Test Kit (Immunofluorescence Assay) <i>H. pylori</i> Fast Test Kit (Immunofluorescence Assay) SAA Fast Test Kit (Immunofluorescence Assay) LH Fast Test Kit (Immunofluorescence Assay) FSH Fast Test Kit (Immunofluorescence Assay) AMH Fast Test Kit (Immunofluorescence Assay) PRL Fast Test Kit (Immunofluorescence Assay) CK-MB Control cTnI Control Myo Control NT-proBNP Control D-Dimer Control CRP Control PCT Control β2-MG Control mAlb Control NGAL Control CysC Control H-FABP Control HbA1c Control HCG+β Control CK-MB/cTnI/Myo Control CK-MB/cTnI Control NT-proBNP/cTnI Control TSH Control T4/T3 Control T3 Control T4 Control		
	Classification of products according to directive	:	Others	
	Batch/serial No. Type, production term (if applicable)	:		



Applicable coordination standards:	EN ISO 14971:2012	EN ISO 23640:2015	EN ISO 13485:2016
	EN 13612:2002	EN ISO15223-1:2012	EN ISO 18113-2:2011
	EN 1041:2008	EN ISO 18113-1:2011	EN ISO 18113-3:2011
	IEC 61010-1:2010	IEC 61010-2-081:2015	IEC 61010-2-101:2015
	IEC 61326-1:2013	IEC 61326-2-2:2013	

Signatory representative declares herein the above mentioned device meets the basic requirements of the European Parliament and the Council's in vitro diagnostic medical devices directive: 98/79/EC Annex III. This declaration of conformity is based on European Parliament and the Council's 98/79/EC directive Annex III. The compiled technical file and quality system document according to 98/79/EC directive Annex III are testified and the quality system certificate has issued by TÜV Rheinland (Shanghai) Co., Ltd.

General Manager: Enben Su

Nha Trang, 25th, Jul, 2019

(place and date of issue)

(name and signature or equivalent
marking of authorized person)



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: Getein Biotech, Inc.
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基蛋生物科技股份有限公司
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沿江工业开发区
博富路9号
邮编: 211505

Holds Certificate No: **MD 728432**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Design & Development, Manufacture and Distribution of Chemiluminescence Immunoassay, Biochemistry Assay, Point of Care Assay (including Colloidal Gold Assay, Immunofluorescence Assay, Dry Chemistry Assay). Design & Development, Manufacture and Distribution of Analyzers in use of Chemiluminescence Immunoassay, Biochemistry Assay, Point of Care Assay (including Colloidal Gold Assay, Immunofluorescence Assay, Dry Chemistry Assay).
研发, 生产和销售化学发光法试剂, 生化试剂, 即时诊断 (包括胶体金法, 免疫荧光法, 干式化学法) 试剂。
研发, 生产和销售用于化学发光法试剂, 生化试剂, 即时诊断 (包括胶体金法, 免疫荧光法, 干式化学法) 试剂配套使用的分析仪。



For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2020-05-29

Latest Revision Date: 2020-07-22

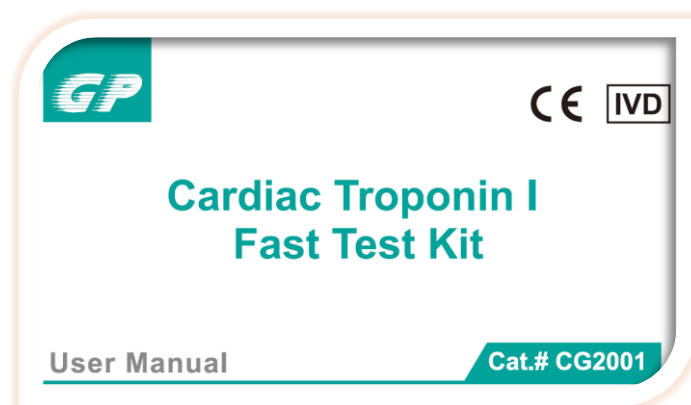
Effective Date: 2020-07-26

Expiry Date: 2023-07-25

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Utilizare

Cardiac Troponin Fast Test Kit se folosește pentru determinarea calitativă și semi-cantitativă *in vitro* a Troponinei I cardiacă (cTnI) în ser, plasmă sau sânge integru. Acest test este prevăzut ca un ajutor în diagnosticarea leziunilor miocardice, ca Infarctul Miocardic Acut, Anghina Instabilă, Miocardită Acută și Sindromul Coronarian Acut.

Principiu

Testul utilizează anticorpi monoclonali de cTnI anti-uman conjugați cu aur coloidal și alți anticorpi monoclonali de cTnI anti-uman căpușiți în linia de test. După ce proba a fost aplicată pe banda de testare, anticorpii monoclonali de cTnI anti-uman marcați cu aur coloidal se leagă cu cTnI din probă și formează un complex de anticorpi-antigeni marcați. Prin acțiune capilară, acest complex se mișcă spre zona de detecție a test cardului, după care este capturat pe linia de test de către anticorpi monoclonali de cTnI anti-uman. În rezultat apare o linie roșie purpurie. Intensitatea culorii liniei de testare crește proporțional cu cantitatea de cTnI din probă.

Conținut

Un kit conține:

1. 25 de test-carduri Getein cTnI în pungă sigilată cu desicant.
2. 1 Pipetă de unică folosință.
3. 1 Instrucțiune.
4. 1 Card colorimetric standard.
5. 1 Buffer pentru sânge integru.

Un test card conține:

Un corp de plastic și o bandă de reactiv care e alcătuită dintr-un strat pentru probă, un strat de aur coloidal (acoperit cu anticorpi monoclonali anti-cTnI uman marcați cu aur), membrană de nitroceluloză (linia de test este acoperită cu un alt anticorp monoclonal anti-cTnI uman, iar linia de control este acoperită cu anticorpi IgG anti-șoarece de iepure), hârtie absorbantă și căpușeală.

Bufferul pentru sânge integru conține: soluție salină tamponată cu fosfat, proteine, detergent, conservant și stabilizator.

Notă: Nu amestecați sau schimbați testele din loturi diferite.

Păstrare și Stabilitate

Păstrați test-cardul la temperatura de 4 ~ 30°C, cu un termen de valabilitate de 24 luni. Utilizați testul în timp de o oră după ce ai deschis folia pungi. Bufferul se păstrează la temperatura de 0 ~ 30°C, cu un termen de valabilitate de 24 luni. Pentru rezultate mai bune, recomandăm să păstrați Bufferul la temperatura de 0 ~ 8°C.

Precauții

1. Se utilizează doar pentru diagnosticare in vitro.
2. Doar pentru utilizare profesională.
3. Nu folosiți kit-ul după expirarea termenului de valabilitate de pe cutie.
4. Nu utilizați testul dacă folia pungii este deteriorată.
5. Nu deschideți folia pungii cu test decât dacă sunteți gata să realizați testul.
6. Nu reutilizați test cardul.
7. Nu reutilizați pipeta.
8. Lucrați cu probele ca și cum ar fi potențiale infecții.
9. Citiți cu atenție instrucțiunea înainte de utilizare.

Colectarea și pregătirea probelor

1. Acest test poate fi utilizat pentru probele de ser, plasmă și sînge integru . Pentru probele de plasmă și sînge integru se folosește în calitate de anticoagulant Heparina, EDTA sau Citratul de Sodium. Probele trebuie să fie lipsite de hemoliză.
2. Recomandăm utilizarea serului sau plasmăi pentru mai bune rezultate.
3. Serul sau plasma poate fi folosit direct. Pentru probele de sînge integru se adaugă bufferul din kit înainte de testare.
4. Dacă procesul de testare este amînat, probele de ser sau plasmă pot fi păstrate la temperatura de 2 ~ 8°C pînă la 7 zile sau pînă la 6 luni la temperatura de -20°C. Probele de sînge integru pot fi păstrate pînă la 3 zile la temperatura de 2 ~ 8°C.
5. Probele refrigerate sau înghețate trebuiesc omogenizate și lăsate să atingă temperatura camerei înainte de testare. Evitați ciclurile multiple de înghețare- dezghețare.
6. Nu utilizați probele inactivate termic.
7. Volumul probei: 80 µl .

Procedura de testare

1. Colectați proba conform instrucțiunii.
2. Test-cardul , proba și reagenții trebuie să atingă temperatura camerei înainte de testare.
3. Îndepărtați testul din punga sigilată imediat înainte de testare. Etichetați testul pentru al putea identifica cu pacientul.
4. Așezați test-cardul pe o masă curată amplasată orizontal.
5. Utilizînd pipeta, picurați 80 µl din probă (3 picături cu pipeta de unică folosință) în portul destinat probei de pe test-card. (Pentru proba de sînge integru- adăugați o picătură de Buffer în după ce a-ți picurat 80 µl din probă).
6. Citiți vizual rezultatul în timp de 15 minute. Pentru o interpretare semi-cantitativă a rezultatelor utilizați cardul colorimetric standard.

Rezultatele testului

Negativ: O singură linie roșie- purpurie în zona de control (C) a test-cardului fără nici o altă linie se consideră un rezultat negativ valid, indicînd o concentrație de cTnI în probă sub limită.

Pozitiv: O singură linie roșie- purpurie în zona de control (C) a test-cardului și încă una în zona liniei de testare este un rezultat pozitiv valid. Intensitatea culorii roșu-purpuriu din linia de test ajută la interpretarea vizuală semi-cantitativă, conform cardului colorimetric standard.

Intensitatea culorii	Concentrația de referință(ng/ml)
-	<0,3
+ -	0,3 ~ 1
+	1~ 5
++	5 ~ 15

+++	15 ~ 30
++++	30 ~ 50
++++	>50

Invalid: Dacă în timp de 15 minute nu apare nici o bandă de culoare pe linia de control (C) sau pe linia de test, rezultatul se declară invalid. Testul trebuie de repetat, iar dacă se repetă situația, încetați să utilizați testele din acest lot și contactați furnizorul.

Valori așteptate

Valorile normale așteptate au fost determinate cu probe de la 500 de pacienți aparent sănătoși. Probabilitatea ca la o persoană sănătoasă concentrația de cTnI să fie sub 0,3 ng/ml este de 99% .

O concentrație de cTnI sub 0,3 ng/ml se consideră normală. Se recomandă ca fiecare laborator să-și stabilească propriile valori așteptate pentru populația pe care o deservește.



Cardiac Troponin I Fast Test Kit

User Manual

Cat.# CG2001

INTENDED USE

Cardiac Troponin I Fast Test Kit is intended for *in vitro* qualitative and semi-quantitative determination of cardiac Troponin I (cTnI) in serum, plasma or whole blood. This test is used as an aid in the diagnosis of myocardial injury such as Acute Myocardial Infarction (AMI), Unstable Angina, Acute Myocarditis and Acute Coronary Syndrome (ACS).

SUMMARY

Troponin, a molecular complex that is bound to the thin filament (actin) of striated muscle fibers, acts with intracellular calcium to control the interaction of the thin filament with the thick filament (myosin), thus regulating muscle contraction. Troponin consists of three subunits: T, which connects the troponin complex and tropomyosin (another cardiac muscle regulatory protein); I, which prevents muscle contraction in the absence of calcium; and C, which binds calcium. Cardiac Troponin I (MW 22.5 kDa) and the two skeletal muscle isoforms of Troponin I have considerable amino acid sequence homology, but cTnI contains an additional N-terminal sequence and is highly specific for myocardium.

Clinical studies have demonstrated the release of cTnI into the blood stream within hours following acute myocardial infarctions (AMI) or ischemic damage. Elevated levels of cTnI are detectable in blood within 4 to 6 hours after the onset of chest pain, reaching peak concentrations in approximately 8 to 28 hours, and remain elevated for 3 to 10 days following AMI. Due to the high myocardial specificity and the long duration of elevation, cTnI has become an important marker in the diagnosis and

evaluation of patients suspected of having an AMI.

The current guideline of The Joint European Society of Cardiology/ American College of Cardiology Committee support the use of cTnI as a preferred marker of myocardial injury. Several major studies have shown that cTnI is also a predictor of cardiac risk in patients with unstable angina. The American College of Cardiology and the American Heart Association's current guidelines recommend using troponin results when making treatment decisions regarding unstable angina and non-ST segment elevation MI (NSTEMI).

PRINCIPLE

The test uses an anti-human cTnI monoclonal antibody conjugated with colloidal gold and another anti-human cTnI monoclonal antibody coated on the test line. After the sample has been applied to the test strip, the gold-labelled anti-human cTnI monoclonal antibody binds with the cTnI in sample and forms a marked antigen-antibody complex. This complex moves to the test card detection zone by capillary action. Then marked antigen-antibody complex is captured on the test line by the anti-human cTnI monoclonal antibody resulting in a purplish red streak appears on the test line. The color intensity of the test line increases in proportion to the amount of cTnI in sample.

CONTENTS

A kit contains:

1. Getein cTnI test card in a sealed pouch with desiccant 25
2. Disposable pipet 25
3. User manual 1
4. Standard colorimetric card 1
5. Whole blood buffer 1

A test card consists of:

A plastic shell and a reagent strip which is composed of a sample pad, a colloid gold pad (coated with gold-labelled anti-human cTnI monoclonal antibody), nitrocellulose membrane (the test line is coated with anti-human cTnI monoclonal antibody, and the control line is coated with rabbit anti-mouse IgG antibody), absorbent paper and liner.

Whole blood buffer composition:

Phosphate buffered saline, proteins, detergent, preservative, stabilizer.

Note: Do not mix or interchange different batches of kits.

STORAGE AND STABILITY

Store the test card at 4~30°C with a valid period of 24 months. Use the test card within 1 hour once the foil pouch is opened. Store the whole blood buffer at 0~30°C with a valid period of 24 months.

Store the whole blood buffer at 2~8°C for better results.

PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. For professional use only.
3. Do not use the kit beyond the expiration date.
4. Do not use the test card if the foil pouch is damaged.
5. Do not open pouches until ready to perform the test.
6. Do not reuse the test card.
7. Do not reuse the pipet.
8. Handle all specimens as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.
9. Carefully read and follow user manual to ensure proper test performance.

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for **serum, plasma or whole blood samples**. **Heparin, EDTA or sodium citrate** should be used as the anticoagulant for plasma and whole blood. Samples should be free of hemolysis.
2. Suggest using serum or plasma for better results.
3. Serum or plasma can be used directly. For whole blood sample, whole blood buffer must be added before testing.
4. If testing will be delayed, serum and plasma samples may be stored up to 7 days at 2~8°C or stored at -20°C for 6 months before testing (whole blood sample may be stored up to 3 days at 2~8°C).

- Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
- Do not use heat-inactivated samples.
- SAMPLE VOLUME: 80 µl.**

TEST PROCEDURE

- Collect specimens according to user manual.
- Test card, sample and reagent should be brought to room temperature before testing.
- Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
- Put the test card on a clean table, horizontally placed.
- Using sample transfer pipette, deliver **80 µl** of sample (or 3 drops of sample when using disposable pipet) into the sample port on the test card (for whole blood sample, one drop of whole blood buffer must be added after loading 80 µl sample on the test card).
- Read the results visually in 15 minutes.** For semi-quantitative interpretation of results, please refer to the standard colorimetric card.

TEST RESULTS

Negative: A single purplish red band appears at the control area (C) without any other band at test line is a valid negative result, indicating the concentration of cTnI in the sample is below the cut-off value.

Positive: A single purplish red band appears at the control area (C) and a purplish red colored band appears in test line is a valid positive result. The intensity of the purplish red color in the test line helps to read the semi-quantitative result visually according to the standard colorimetric card:

Color intensity	Reference Concentration (ng/ml)
—	<0.3
+ —	0.3~1
+	1~5
++	5~15
+++	15~30
++++	30~50
++++	>50

Invalid: If no colored band appears in the control area (C) in 15 minutes, the test result is invalid. The test should be repeated and if the same situation happened again, please stop using this batch of products and contact your supplier.

EXPECTED VALUE

The expected normal value for Troponin I was determined by testing samples from 500 apparently healthy individuals. The 99th percentile of the concentration for cTnI is 0.3 ng/ml, (The probability that value of a normal person below 0.3 ng/ml is 99%). cTnI concentration less than 0.3 ng/ml can be estimated as normal.

It is recommended that each laboratory establish its own expected values for the population it serves.

LIMITATIONS

As with all diagnostic tests, a definitive clinical diagnosis should not be made based on the result of a single test. The test results should be interpreted considering all other test results and clinical information such as clinical signs and symptoms.

REFERENCES

- Mauro Pantaghini; Undefined International Federation of Clinical Chemistry and Laboratory Medicine (IFCC). Scientific Division Committee on Standardization of Markers of Cardiac Damage. Clin Chem Lab Med, 1998, 36:887~893.
- Antman EM, Anbe DT, Armstrong PW, et al. ACC/AHA guidelines for the management of patients with ST-elevation myocardial infarction: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee to Revise the 1999 Guidelines for the Manage 2004).
- EN ISO 18113-1:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
- EN ISO 18113-2:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use (ISO18113-2:2011).

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on Cardiac Troponin I Fast Test Kit are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN 980:2008 and International Standard ISO 15223 – 1: 2012.

Key to symbols used			
	Manufacturer		Expiration date
	Do not reuse		Date of manufacture
	Consult instructions for use		Batch code
	Temperature limitation		In vitro diagnostic medical device
	Sufficient for		Authorized representative in the European Community
	CE mark		Do not use if package is damaged

Thank you for purchasing Cardiac Troponin I Fast Test Kit. Please read this user manual carefully before operating to ensure proper use.

Version: WCG01A-DX-S-02



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