Declaration of Conformity

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

Maker (Name, Address)	**Getein Biotech, Inc.** No. 9 Bofu Road, Luhe District, Nanjing, 211505, China
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 β2-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 *H. pylori* (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) *H. pylori* 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 13612:2002 EN 1041:2008 IEC 61010-1:2010 IEC 61326-1:2013	EN ISO 23640:2015 EN ISO15223-1:2012 EN ISO 18113-1:2011 IEC 61010-2-081:2015 IEC 61326-2-2:2013	EN ISO 13485:2016 EN ISO 18113-2:2011 EN ISO 18113-3:2011 IEC 61010-2-101:2015

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

Nanjing, 20th, Jul, 2019

(place and date of issue)

(name and signature or equivalent marking of authorized person)

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Getein Biotech, Inc.
No.9 Bofu Road
Luhe District
Nanjing
Jiangsu
211505
China

基蛋生物科技股份有限公司
中国
江苏省
南京市
六合区
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

...making excellence a habit.™

Getein Biotech, Inc.
Add: No.9 Bofu Road, Luhe District, Nanjing, 211505, China
Tel: 86-25-68568508 Email: overseas@geteincom.cn Web: www.bio-GP.com.cn

Document No.: GP-GMSQ-2022-110

Letter of Authorization

To whom it may concern,

We, Getein Biotech, Inc. (No.9 BoFu Road, Luhe District, Nanjing, 211505, China), hereby authorize Sanmedico SRL. as our official distributor for registering, promoting, selling, distributing, taking part in tenders, maintaining & after sale technical services of under-mentioned product in the territory of Moldova:

Sanmedico SRL will comply with the laws and regulations of the countries and regions where they are located in and where they are selling mentioned product to, otherwise, the risks and losses arising therefrom shall be undertaken by Sanmedico SRL

This authorization starts from Jan 1, 2022 and will be valid to December 31 2023

Getein Biotech, Inc. has the right to terminate the authorization before validity and will inform Sanmedico SRL with 10 days in advance.

Getein Biotech, Inc.

Name: Steven Zhou
Position: Overseas Sales Director

基蛋生物科技股份有限公司
GETEIN BIOTECH, INC.

Steven Zhou

基蛋生物 GeteinBiotech Getein Biotech,Inc.
No.9 Bofu Road, Luhe District, Nanjing, 211505, China
Tel: +86-25-68569084 Fax: +86-25-68568500 E-mail: overseas@ getein.com.cn

Exclusive Distributor Agreement

This agreement is made and entered into by and between the parties concerned on 1th Jan, 2022 in Nanjing, China on the basis of equality and mutual benefit to develop business on terms and conditions mutually agreed upon as follows:

1. The Parties Concerned

Party A: Getein Biotech,Inc.
Add: No.9 Bofu Road, Luhe District, Nanjing (211505) China.
Tel: 86-25-68568519
Fax: 86-25-68568500

Party B: Sanmedico SRL
Add: Republic of Moldova, Chisinau, MD-2059, Petricani street, 88/1, office 10
Tel: 373 22 62 30 32

2. Appointment

Party A hereby appoints Party B as its exclusive distributor in the Republic of Moldova for the promotion, sales, and after-sale services etc. of products (Refer to Item3) from Party A and Party B accepts and assumes such appointment.

3. Products List A

One Step Test for CK-MB/cTnI/Myo (Colloidal Gold)(Quantitative)
Cardiac Troponin I Fast Test Kit(Colloidal Gold)(Quantitative)
One Step Test for CK-MB (Colloidal Gold)(Quantitative)
One Step Test for CK-MB/cTnI (Colloidal Gold)(Quantitative)
One Step Test for H-FABP(Colloidal Gold)(Quantitative)
One Step Test for NT-proBNP/cTnI(Colloidal Gold)(Quantitative)
One Step Test for hs-CRP(Colloidal Gold)(Quantitative)
One Step Test for D-Dimer(Colloidal Gold)(Quantitative)
One Step Test for NT-proBNP(Colloidal Gold)(Quantitative)
One Step Test for HbA1c(Colloidal Gold)(Quantitative)
One Step Test for PCT(Colloidal Gold)(Quantitative)
One Step Test for HCG(Colloidal Gold)(Quantitative)
One Step Test for mAlb(Colloidal Gold)(Quantitative)
One Step Test for β2-MG(Colloidal Gold)(Quantitative)
One Step Test for CysC(Colloidal Gold)(Quantitative)
One Step Test for NAGL(Colloidal Gold)(Quantitative)
One Step Test for TSH(Colloidal Gold)(Quantitative)

No.9 Bofu Road, Luhe District, Nanjing, 211505, China
Tel: +86-25-68569084 Fax: +86-25-68568500 E-mail: overseas@ getein.com.cn

CK-MB/cTnI/Myo Fast Test Kit(Immunofluorescence Assay)
Cardiac Troponin I Fast Test Kit(Immunofluorescence Assay)
NT-proBNP/cTnI Fast Test Kit(Immunofluorescence Assay)
hs-CRP Fast Test Kit(Immunofluorescence Assay)
D-Dimer Fast Test Kit(Immunofluorescence Assay)
NT-proBNP Fast Test Kit(Immunofluorescence Assay)
PCT Fast Test Kit(Immunofluorescence Assay)
mAlb Fast Test Kit(Immunofluorescence Assay)
B2-MG Fast Test Kit(Immunofluorescence Assay)
CysC Fast Test Kit(Immunofluorescence Assay)
NAGL Fast Test Kit(Immunofluorescence Assay)
HbA1c Fast Test Kit(Immunofluorescence Assay)
TSH Fast Test Kit(Immunofluorescence Assay)
T3 Fast Test Kit(Immunofluorescence Assay)
T4 Fast Test Kit(Immunofluorescence Assay)
PRL Fast Test Kit(Immunofluorescence Assay)
LH Fast Test Kit(Immunofluorescence Assay)
FSH Fast Test Kit(Immunofluorescence Assay)
AMH Fast Test Kit(Immunofluorescence Assay)
tPSA Fast Test Kit(Immunofluorescence Assay)
25-OH-VD Fast Test Kit(Immunofluorescence Assay)
Getein 1100 Immunofluorescence Quantitative Analyzer
Getein 1600 Immunofluorescence Quantitative Analyzer

4. Territory:

In Republic of Moldova only.

Meanwhile Party B will not distribute for competitive firms identical or similar products, nor will associate directly or indirectly with the competitive firms in the field of products covered by this agreement; otherwise, party A has the right to decide whether to terminate the contract immediately or not.

5. Prices

Prices are stable for 12 months from the start of this agreement. Party A will not increase the prices subjectively, unless the raw material suppliers increase their prices. In case price increases have to be announced, Party B has to be informed at least one month (30 days) in advance.

This agreement shall come into force from Jan 1st,2022to Jan 1st,2024,is valid for 24 months.

6.Delivery

No.9 Bofu Road, Luhe District, Nanjing, 211505, China
Tel: +86-25-68569084 Fax: +86-25-68568500 E-mail: overseas@ getein.com.cn

Party A shall establish a delivery term for each Party B's order, which shall not exceed 4 weeks after the payment is received. Party A will advise Party B about the day of dispatching, with all requested information concerning the dispatched products.

7. FORCE MAJEURE

If the performance of any part of this agreement interfered with new laws or governmental restrictions, war, civil commotions, riots, strike lockout, acts of God such as flood, fire or any other similar causes which are beyond the control of the parties, no party shall be responsible for delay or failure of performance of this agreement for such length of time and to the extent performance is made impossible. In this case, the parties shall immediately negotiate to what extent deliveries that could not be executed can be carried out executed.

8.Payment Term

Every order Party B shall pay 50% by TT in advance, the rest of 50% will be paid within 30-60 days after the goods arrives. Due to financial audition, all the credit payment should be cleared by December 31th, 2022.

If Party B is unable to pay, Party B will agree to use fixed assets or real estate to offset the loan. Party A has the right to bring a lawsuit against Party B in China according to relevant Chinese laws.

9. Sales target

Yearly sales volume is 200,000 USD, which include both analyzers and strips. Party B agrees and accepts the sales volume...

10. Governing Law

The agreement is subject to the International Trade Law. Any dispute concerning this agreement shall be settled in accordance with the International Trade Law either through negotiation or through legal proceedings if negotiation has failed.

11.Declaration of Conformity.

Getein Biotech,Inc. declares herein the above mentioned device (Refer to Item3) 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.

12. Intellectual Property Agreement

Party A reserves the right of goods design, drawing, plane graph specification, technology, data and information, technological process, the marketing plan of intellectual property rights which included the

No.9 Bofu Road, Luhe District, Nanjing, 211505, China
Tel: +86-25-68569084 Fax: +86-25-68568500 E-mail: overseas@ getein.com.cn

Party A provide technical services to the Party B in the process of producing intellectual achievements . Without the Party A 's written consent, the Party B shall not disassemble the goods and the accompanying software, decoding, encoding, or any other reverse engineering by themselves or other third party.

13. Final Provisions

Attachments are an integral part of this contract, have the same legal effect with this contract; This contract was made in English with two originals, each party holds one, it is effective at the same time, and have the same legal effect.

Any change, modification, cancellation of this contract, to be replaced shall be made after agreed by both parties in writing.

Party A: Getein Biotech,Inc.	Party B: Sanmedico SRL
Date:	Date:
Represented by: Steven Zhou	Represented by: Vitalie Goreacii
Regional Sales Manager	Director

基蛋生物科技股份有限公司
GETEIN BIOTECH, INC.

Reference Code：GP-DT-018-07-19 Issued by 07/26/2019

CERTIFICATE

Getein Biotech

hereby certifies

Mr. Vitalie Goreacii

from Sanmedico SRL.

Completion of Getein Products Technical and Operational Training
& Qualification of After-sales Service

基蛋生物科技股份有限公司
GETEIN BIOTECH, INC.

Getein
Biotech, Inc.

CE IVD

25-OH-VD
Fast Test Kit
(Immunofluorescence Assay)

User Manual

REF IF1031 for Getein1100
IF2031 for Getein1600

INTENDED USE

25-OH-VD Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of 25-OH-VD in serum, plasma or whole blood. This test may help understand the metabolic changes of bone.

SUMMARY

Vitamin D3 is a fat-soluble precursor for steroid-like hormone. It is transformed into the biologically active molecule 1,25 dihydroxy vitamin D. After being synthesized in the skin or absorbed (in chylomicrons) from the gastrointestinal (GI) tract, most vitamin D is bound to specific carrier proteins in the blood (vitamin D–binding protein [DBP] and albumin) and transported to the liver. In the liver, vitamin D is hydroxylated by the enzyme 25-hydroxylase (CYP2R1) to become 25(OH)D. 25(OH)D is the major circulating form of vitamin D, testing of 25(OH)D help assessing the total-body vitamin D status.
Vitamin D is a major contributor for maintaining bone health, and vitamin D deficiency is also related with immunomodulation, diabetes, kinds of cancer, cardiovascular disease, autoimmune disease, congenital immune disease.

PRINCIPLE

The test is based on the principle of competitive immunoassay, it uses a high sensitive anti-human 25-OH-VD monoclonal antibody and 25-OH-VD antigen, the antibody is conjugated with fluorescence latex and coated on the junction of NC membrane and sample pad, the 25-OH-VD antigen is coated on the test line. The sample applied to the test strip moves by the suction of absorbent paper, the fluorescence latex-labelled anti-human 25-OH-VD monoclonal antibody binds with the 25-OH-VD in sample and forms a marked antigen-antibody complex. This complex moves to the test card detection zone. Then marked antigen-antibody complex is captured on the test line by the anti-human 25-OH-VD antigen. Meanwhile, 25-OH-VD antigen would compete with the 25-OH-VD in the sample for fluorescence latex-labelled anti-human 25-OH-VD monoclonal antibody.
Then insert test card into Getein1100 Immunofluorescence Quantitative Analyzer / Automatically inserted by Getein1600 Immunofluorescence Quantitative Analyzer (hereafter referred to as Getein1100 and Getein1600), the concentration of 25-OH-VD in sample will be measured and displayed on the screen. The value will be stored in Getein1100/Getein1600 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

CONTENTS

1. A kit for Getein1100 contains:
Package specifications: 25 tests/box, 10 tests/box
1) Getein 25-OH-VD test card in a sealed pouch with desiccant
2) Disposable pipet
3) Sample diluent
4) User manual: 1 piece/box
5) SD card/RFID card: 1 piece/box

2. A kit for Getein1600 contains:
Package specifications: 2×24 tests/box, 2×48 tests/box
1) Sealed cartridge with 24/48 Getein 25-OH-VD test cards
2) User manual: 1 piece/box
Materials required for Getein1600:
1) Sample diluent: 1 bottle/box
2) Box with pipette tips: 96 tips/box
3) Mixing plate: 1 piece/box

3. Sample diluent composition:
Phosphate buffered saline, proteins, detergent, preservative, stabilizer.

4. A test card consists of:
A plastic shell and a reagent strip which is composed of a sample pad, nitrocellulose membrane (one end of the membrane is coated with a fluorescence latex-labeled anti-human 25-OH-VD monoclonal antibody, the test line is coated with 25-OH-VD antigen, and the control line is coated with rabbit anti-mouse IgG antibody), absorbent paper and liner.

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

APPLICABLE DEVICES

Getein1100 Immunofluorescence Quantitative Analyzer
Getein1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Store the test card at 4~30℃ with a valid period of 24 months.
Use the test card for Getein1100 within 1 hour once the foil pouch is opened.
For test card of Getein1600: If the cartridge is opened, it could be stable within 24 hours once exposure to air. Please put the cartridge back to the foil pouch and reseal along the entire edge of zip-seal. The remaining test cards should be used up within 7 days.
Store the sample diluent at 0~30℃ with a valid period of 24 months.
Store the sample diluent at 2~8℃ for better results.

PRECAUTIONS

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

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for ***serum and plasma. Heparin, sodium citrate and EDTA*** can be used as the anticoagulant for plasma. Samples should be free of hemolysis.
2. If testing will be delayed, serum and plasma samples may be stored up to 7 days at 2~8℃ or stored at -20℃ for 6 months before testing.
3. Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
4. Do not use heat-inactivated or hemolysis samples.
6. SAMPLE VOLUME ***(for Getein1100): 40 µl***.

TEST PROCEDURE

1. Collect specimens according to user manual.

2. Test card, sample and reagent should reach to room temperature before test.

For Getein1100:

3. Confirm SD card or RFID card lot No. in accordance with test kit lot No.. Perform “SD card or RFID card Calib” calibration when necessary.
4. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
5. Put the test card on a clean table, horizontally placed.
6. Using sample transfer pipette, deliver ***40 μl*** of sample into one tube of sample diluent, mix gently and thoroughly for 1~5 mins. Then drop ***100 μl*** of the sample mixture into the sample port on the test card.
7. ***Reaction time: 15 minutes***. Insert the test card into Getein1100 and press "ENT" button or click on “Start” icon (for Android Getein1100) after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein1600:

9. Each cartridge for Getein1600 contains a specific RFID card which can calibrate automatically.
10. Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein1600 will do the testing and print the result automatically.

Notes:

1. It is required to perform “SD card or RFID card Calib” calibration when using a new batch of kits.
2. It is suggested to calibrate once for one batch of kits for Getein1100.
3. Make sure the test card and the sample insertion is correct and complete.

TEST RESULTS

Getein1100/Getein1600 can scan the test card automatically and display the result on the screen. For additional information, please refer to the user manual of Getein1100/Getein1600.

EXPECTED VALUE

The expected normal value for 25-OH-VD was determined by testing samples from 453 apparently healthy individuals. The reference range of 25-OH-VD is 30.0 ng/mL~50.0 ng/mL calculated by using normal distribution methods giving a level of confidence of approximately 95%. The concentration of 25-OH-VD varies with gender, age, season, geographical latitude and race.

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

PERFORMANCE CHARACTERISTICS

Measuring Range	8.0~70.0 ng/mL
Lower Detection Limit	≤8.0 ng/mL
Within-Run Precision	≤10%
Between-Run Precision	≤15%

LIMITATIONS

1. 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.
2. Samples containing interferent may influence the results. The table below listed the maximum allowance of these potential interferent.

Interferent	Hemoglobin	Triglyceride	Bilirubin
Concentration (Max)	2 g/L	4 g/L	0.6 g/L

REFERENCES

1. Houghton LA, Vieth R. The case against ergocalciferol (vitamin D2) as a vitamin supplement. Am J Clin Nutr 2006; 84: 694-697.
2. Armas LAG, Hollis BW. Heaney RP. Vitamin D2 is much less effective than Vitamin D3 in humans. J Clin Endocrinol Metab 2004; 89 (11): 5387-5391
3. Souberbielle JC, Body JJ, Lappe JM, et al. Vitamin D and musculoskeletal health, cardiocascular disease, autoimmunity and cancer. Recommendations for clinical practice. Autoimmun Rev 2010; 9: 709-715.
4. Lip P. Vitamin D deficiency and secondary hyperparathyroidism in the elderly: consequences for bone loss and fractures and therapeutic implications. Endocr Rev 2001 Aug; 88 (8): 3501-3504.
5. Willet AM. Vitamin D status and its relationship with parathyroid hormone and bone mineral status in older adolescents. Proceeding of the Nutrition Society 2005; 64: 193-203.
6. EN ISO 18113-1:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
7. 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 25-OH-VD Fast Test Kit (Immunofluorescence Assay) 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 15223-1:2016.

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

Thank you for purchasing 25-OH-VD Fast Test Kit (Immunofluorescence Assay).

Please read this user manual carefully before operating to ensure proper use.

Version: WIF47-S-02

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Tel: +86-25-68568508 Fax: +86-25-68568500
E-mail: tech@getein.com.cn overseas@getein.com.cn
Website: www.bio-GP.com.cn

CE IVD

CK-MB

Fast Test Kit

(Immunofluorescence Assay)
For in vitro Diagnostic Use

User Manual

Getein1100: Cat.# IF1018
Getein1600: Cat.# IF2018

INTENDED USE

CK-MB Fast Test Kit (Immunofluorescence Assay) is intended for in vitro quantitative determination of CK-MB in serum, plasma or whole blood. This test is used as an aid in the clinical diagnosis, prognosis and evaluation of myocardial injury such as Acute Myocardial Infarction (AMI), Unstable Angina, Acute Myocarditis and Acute Coronary Syndrome (ACS).

SUMMARY

Creatine kinases are dimer isozymes composed of two monomer subunits, CK-M (for skeletal muscle derived) and CK-B (for brain derived), which can form all three combinations of monomers: CK-BB, CK-MM, and CK-MB. BB is found primarily in the brain. Skeletal muscles primarily contain the MM isoform, with trace amount of MB (around 1-4% of total CK activity). Cardiac muscles also contain the MM isoform, but higher amount of MB, typically around 20% of total CK activity. CK-MB is a more sensitive marker of myocardial injury than total CK activity, because it has a lower basal level and a much narrower normal range. Medical literatures commonly state that CK-MB levels are elevated in 4 to 6 hours, peak at 10 to 24 hours, and return to normal within 3 to 4 days after an acute myocardial infarction. Classically, an increase of the myocardial-specific enzyme CK-MB is considered as the hallmark of acute myocardial infarction, and increased levels are frequently interpreted by the clinician as objective evidence of myocardial cell damage.

PRINCIPLE

Monoclonal antibody against human CK-MB were conjugated with fluorescence latex and another set of anti-human CK-MB monoclonal antibodies were coated on test line. After the sample has been applied to the test strip, the latex-labeled anti-human CK-MB monoclonal antibody will bind with the CK-MB in sample and form marked antigen-antibody complex. This complex move to the test card detection zone by capillary action. Then marked antigen-antibody complex will be captured on test line by another set of monoclonal antibody against human CK-MB resulting in purplish red streaks appear on the test line. The color intensity of test line increases in proportion to the amount of CK-MB in sample.

Insert test card into Getein1100 Immunofluorescence Quantitative Analyzer/Getein1600 Immunofluorescence Quantitative Analyzer (hereafter referred to as Getein1100 and Getein1600), the concentrations of CK-MB in sample will be determined and displayed on the screen. The value will be stored in Getein1100/Getein1600 and available for downloading. The result can be easily transmitted to LIS and HIS.

CONTENTS

1.A kit for Getein1100 contains:

Getein CK-MB test card in a sealed pouch with desiccant.....25
Disposable pipet.....25
User manual 1
SD card/ RFID card 1
Whole blood buffer.....1

2.A kit for Getein1600 contains:

Sealed cartridge with 24/48 Getein CK-MB test cards 2
User manual 1
Package specifications:
2×24 tests/kit, 2×48 tests/kit
Materials required for Getein1600:
Sample diluent.....1
Box with pipette tips 1
Mixing plate.....1

3.Sample diluent/Whole blood buffer composition:

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

4.A test card consists of:

A plastic shell and a reagent strip which is composed of a sample pad, a colloidal gold pad (coated with fluorescence latex-labeled anti-human CK-MB monoclonal antibodies), nitrocellulose membrane with test line (the test line is coated with another anti-human CK-MB monoclonal antibody, and the control line is coated with rabbit anti-mouse IgG antibody), absorbent paper and liner.

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

APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer
Getein1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Store the test card at 4~30℃ with a valid period of 24 months.
Use the test card for Getein1100 within 1 hour once the foil pouch is opened.
Use the test card for Getein1600 within 24 hours once opened.
Store the sample diluent/whole blood buffer at 0~30℃ with a valid period of 24 months.
Store the sample diluent/whole blood buffer at 2~8℃ 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 or the cartridge is damaged.
5.Do not open pouches or the cartridge 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 and whole blood*** samples.***Heparin and sodium citrate*** can 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, one drop of 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℃ or stored at -20℃ for 6 months before testing (whole blood sample may be stored up to 3 days at 2~8℃).
5.Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
6.Do not use heat-inactivated samples.
7.***SAMPLE VOLUME (for Getein1100): 100 µl.***

TEST PROCEDURE

1.Collect specimens according to user manual.
2.Test card, sample and reagent should be brought to room temperature before testing.

For Getein1100:

3.Confirm SD card or RFID card lot No. in accordance with test kit lot No.. Perform "SD card or RFID card Calib" calibration when necessary.
4.Enter testing interface of Getein1100.
5.Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
6.Put the test card on a clean table, horizontally placed.
7.Using sample transfer pipette, deliver 100 µl of sample (or 3~4 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 100 µl sample on the test card).
8.***Reaction time: 10 minutes.*** Insert the test card into Getein1100 and start test after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein1600:

9.Each cartridge for Getein1600 contains a specific RFID card which can calibrate automatically.
10.Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein1600 will do the testing and print the result automatically.

Notes:

1.It is required to perform "SD Card or RFID card Calib" calibration when using a new batch of kits.
2.It is suggested to calibrate once for one batch of kits for Getein1100.
3.Make sure the test card insertion is correct and complete.

TEST RESULTS

Getein1100/Getein1600 can scan the test card automatically and display the result on the screen. For additional information, please refer to the user manual of Getein1100/Getein1600.

EXPECTED VALUE

The expected normal value for CK-MB was determined by testing samples from 500 apparently healthy individuals. The 99th percentile of the concentration for CK-MB is 5.0 ng/ml. CK-MB concentration less than 5.0 ng/ml can be estimated as normal.
It is recommended that each laboratory establish its own expected values for the population it serves.

PERFORMANCE CHARACTERISTICS

Measuring Range	2.5~80.0 ng/ml
Lower Detection Limit	≤ 2.5ng/ml
Within-Run Precision (n=10)	≤10%
Between-Run Precision	≤15%

Method Comparison:

The assay was compared with ROCHE E170 and its matching CK-MB test kits with 200 serum samples. The correlation coefficient (r) for CK-MB is 0.982.

LIMITATIONS

1.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.
2.Samples containing interferents may influence the results. The table below listed the maximum allowance of these potential interferents.

Interferent	Hemoglobin	Triglyceride	Bilirubin
Concentration (Max)	5 g/L	10 g/L	0.2 g/L

REFERENCES

1.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.
2.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).
3.EN ISO 18113-1:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labeling) - Part 1: Terms, definitions and general requirements.
4.EN ISO 18113-2:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labeling) - 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 CK-MB Fast Test Kit (Immunofluorescence Assay) 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	LOT	Batch code
	Temperature limitation	IVD	*In vitro* diagnostic medical device
	Sufficient for	EC REP	Authorized representative in the European Community
CE	CE mark		Do not use if package is damaged

Thank you for purchasing CK-MB Fast Test Kit (Immunofluorescence Assay).
Please read this user manual carefully before operating to ensure proper use.

Version: WIF28-S-01

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Cardiac Troponin I
Fast Test Kit
(Immunofluorescence Assay)

User Manual

Getein1100: Cat.# IF1001
Getein1600: Cat.# IF2001

INTENDED USE

Cardiac Troponin I Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* 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 regulatory proteins: T, which connects the troponin complex and tropomyosin (another cardiac muscle regulatory protein); I, which prevents muscle contraction in the absence of calcium; 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 infarction (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 fluorescence latex and another anti-human cTnI monoclonal antibody coated on the test line. After the sample has been applied to the test strip, the fluorescence latex-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. The fluorescence intensity of the test line increases in proportion to the amount of cTnI in sample.

Then insert test card into Getein1100 Immunofluorescence Quantitative Analyzer/Getein1600 Immunofluorescence Quantitative Analyzer (hereinafter referred to as Getein1100 and Getein1600), the concentration of cTnI in sample will be measured and displayed on the screen. The value will be stored in Getein1100/Getein1600 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

CONTENTS

1. A kit for Getein1100 contains:
   Getein cTnI test card in a sealed pouch with desiccant 25
   Disposable pipet 25
   Whole blood buffer 1
   SD card 1
   User manual 1
2. A kit for Getein1600 contains:
   Sealed cartridge with 24/48 Getein cTnI test cards 2
   User manual 1
   Package specifications:
   2×24 tests/kit, 2×48 tests/kit
   Materials required for Getein1600:
   Sample diluent 1
   Box with pipette tips 1
   Mixing plate 1
3. Sample diluent/Whole blood buffer composition:
   Phosphate buffered saline, proteins, detergent, preservative, stabilizer.
4. A test card consists of:
   A plastic shell and a reagent strip which is composed of a sample pad, nitrocellulose membrane (one end of the membrane is coated with a fluorescence latex-labelled anti-human cTnI monoclonal antibody, the test line is coated with another anti-human cTnI monoclonal antibody, and the control line is coated with rabbit anti-mouse IgG antibody), absorbent paper and liner.

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

APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer
Getein1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Store the test card at 4~30℃ with a valid period of 24 months. Use the test card for Getein1100 within 1 hour once the foil pouch is opened.

For test card of Getein1600: if the cartridge is opened, it could be stable within 24 hours once exposed to air. If the test cards can't be used up at a time, please put the cartridge back to the foil pouch and reseal along the entire edge of zip-seal. The remaining test cards should be used up within 7 days.

Store the sample diluent/whole blood buffer at 0~30℃ with a valid period of 24 months.

Store the sample diluent/whole blood buffer at 2~8℃ 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 or the cartridge is damaged.
5. Do not open pouches or the cartridge 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 and whole blood samples. Heparin and 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, one drop of 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℃ or stored at -20℃ for 6 months before testing (whole blood sample may be stored up to 3 days at 2~8℃).
5. Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
6. Do not use heat-inactivated samples.
7. SAMPLE VOLUME *(for Getein1100): 100 µl*.

TEST PROCEDURE

1. Collect specimens according to user manual.
2. Test card, sample and reagent should be brought to room temperature before testing.

For Getein1100:

3. Confirm SD card lot No. in accordance with test kit lot No.. Perform “SD Card Calib” calibration when necessary (Details refer to 8.5.2 of Getein1100 User Manual).
4. On the main interface of Getein1100, press "ENT" button to enter testing interface.
5. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
6. Put the test card on a clean table, horizontally placed.
7. Using sample transfer pipette, deliver *100 µl* of sample (or 3~4 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 100 µl sample on the test card).
8. *Reaction time: 10 minutes.* Insert the test card into Getein1100 and press "ENT" button after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein1600:

9. Each cartridge for Getein1600 contains a specific RFID card which can calibrate automatically.
10. Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein1600 will do the testing and print the result automatically.

Notes:

1. It is required to perform “SD Card Calib” calibration when using a new batch of kits.
2. It is suggested to calibrate once for one batch of kits for Getein1100.
3. Make sure the test card and the sample insertion is correct and complete.

TEST RESULTS

Getein1100/Getein1600 can scan the test card automatically and display the result on the screen. For additional information, please refer to the user manual of Getein1100/Getein1600.

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 0.1 ng/ml. (The probability that value of a normal person below 0.1 ng/ml is 99%.)
It is recommended that each laboratory establish its own expected values for the population it serves.

PERFORMANCE CHARACTERISTICS

Measuring Range	0.1~50 ng/ml
Lower Detection Limit	≤ 0.1 ng/ml
Within-Run Precision	≤10%
Between-Run Precision	≤15%

Method Comparison:

The assay was compared with SIEMENS IMMULITE 2000 and its matching cTnI test kits with 200 serum samples (60 positive samples and 140 negative samples). The correlation coefficient (r) for cTnI is 0.952.

LIMITATIONS

1. 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.
2. Samples containing interferents may influence the results. The table below listed the maximum allowance of these potential interferents.

Interferent	Hemoglobin	Triglyceride	Bilirubin
Concentration (Max)	5 g/L	10 g/L	0.2 g/L

REFERENCES

1. 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.
2. 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).
3. EN ISO 18113-1:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
4. EN ISO 18113-2:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: *In vitro* diagnostic reagents for professional use (ISO 18113-2:2009).

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on Cardiac Troponin I Fast Test Kit (Immunofluorescence Assay) 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 15223-1:2007.

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

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

Version: WIF02-S-02

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CE IVD

CysC
Fast Test Kit
(Immunofluorescence Assay)

User Manual

Getein1100: Cat.# IF1008
Getein1600: Cat.# IF2008

INTENDED USE

CysC Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of Cystatin C (CysC) in serum, plasma or whole blood. The test result is used as an aid in the assessment and evaluation of index of glomerular filtration rate, and has important application value in renal function, kidney damage and renal transplantation.

SUMMARY

Cystatin C (CysC) is mainly used as a biomarker of kidney function. Cystatin C has a low molecular weight (approximately 13.3 kilodaltons), and it is removed from the bloodstream by glomerular filtration in the kidneys. If kidney function and glomerular filtration rate decline, the blood levels of cystatin C rise. Serum levels of cystatin C are a more precise test of kidney function (as represented by the glomerular filtration rate, GFR) than serum creatinine levels.
This finding is based mainly on cross-sectional studies (on a single point in time). Longitudinal studies (that follow cystatin C over time) are scarcer; some studies show promising results. Cystatin C levels are less dependent on age, sex, race and muscle mass compared to creatinine. Cystatin C measurement alone has not been shown to be superior to formula-adjusted estimations of kidney function. As opposed to previous claims, Cystatin C has been found to be influenced by body composition. It has been suggested that cystatin C might predict the risk of developing chronic kidney disease, thereby signaling a state of 'preclinical' kidney dysfunction.

PRINCIPLE

The test uses an anti-human CysC monoclonal antibody conjugated with fluorescence latex and another anti-human CysC monoclonal antibody coated on the test line. After the sample has been applied to the test strip, the fluorescence latex-labelled anti-human CysC monoclonal antibody binds with the CysC in sample and forms a marked antigen-antibody complex. This complex moves to the test card detection zone by capillary action, then be captured on the test line by another anti-human CysC monoclonal antibody. The fluorescence intensity of the test line increases in proportion to the amount of CysC in sample.
Then insert test card into Getein1100 Immunofluorescence Quantitative Analyzer/Getein1600 Immunofluorescence Quantitative Analyzer (hereinafter referred to as Getein1100 and Getein1600), the concentration of CysC in sample will be measured and displayed on the screen. The value will be stored in Getein1100/Getein1600 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

CONTENTS

1. A kit for Getein1100 contains:
   Getein CysC test card in a sealed pouch with desiccant 25
   Disposable pipet 25
   Sample diluent 25
   SD card 1
   User manual 1
2. A kit for Getein1600 contains:
   Sealed cartridge with 24/48 Getein CysC test cards 2
   User manual 1
   Package specifications:
   2×24 tests/kit, 2×48 tests/kit
   Materials required for Getein1600:
   Sample diluent 1
   Box with pipette tips 1
   Coated wells 1
3. Sample diluent composition:
   Phosphate buffered saline, proteins, detergent, preservative, stabilizer.
4. A test card consists of:
   A plastic shell and a reagent strip which is composed of a sample pad, nitrocellulose membrane (one end of the membrane is coated with a fluorescence-labelled anti-human CysC monoclonal antibody, the test line is coated with another anti-human CysC monoclonal antibody and the control line is coated with rabbit anti-mouse IgG antibody), absorbent paper and liner.

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

APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer
Getein1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Store the test card at 4~30℃ with a valid period of 24 months. Use the test card for Getein1100 within 1 hour once the foil pouch is opened.
For test card of Getein1600: if the cartridge is opened, it could be stable within 24 hours once exposed to air. If the test cards can't be used up at a time, please put the cartridge back to the foil pouch and reseal along the entire edge of zip-seal. The remaining test cards should be used up within 7 days.
Store the sample diluent/whole blood buffer at 0~30℃ with a valid period of 24 months.
Store the sample diluent/whole blood buffer at 2~8℃ 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 or the cartridge is damaged.
5. Do not open pouches or the cartridge 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 and whole blood samples. 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. If testing will be delayed, serum and plasma samples may be stored up to 7 days at 2~8℃ or stored at -20℃ for 6

months before testing (whole blood sample may be stored up to 3 days at 2~8℃).
4. Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
5. Do not use heat-inactivated samples.
6. SAMPLE VOLUME *(for Getein1100): 10 µl*.

TEST PROCEDURE

1. Collect specimens according to user manual.
2. Test card, sample and reagent should be brought to room temperature before testing.

For Getein1100:

3. Confirm SD card lot No. in accordance with test kit lot No.. Perform “SD Card Calib” calibration when necessary (Details refer to 8.5.2 of Getein1100 User Manual).
4. On the main interface of Getein1100, press "ENT" button to enter testing interface.
5. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
6. Put the test card on a clean table, horizontally placed.
7. Using sample transfer pipette, deliver *10 µl* of sample into one tube of sample diluent, mix gently and thoroughly. Then drop *100 µl* of sample mixture (or 3~4 drops of sample mixture when using disposable pipet) into the sample port on the test card.
8. *Reaction time: 3 minutes.* Insert the test card into Getein1100 and press "ENT" button after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein1600:

9. Each cartridge for Getein1600 contains a specific RFID card which can calibrate automatically.
10. Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein1600 will do the testing and print the result automatically.

Notes:

1. It is required to perform “SD Card Calib” calibration when using a new batch of kits for Getein1100.
2. It is suggested to calibrate once for one batch of kits for Getein1100.
3. Make sure the test card insertion is correct and complete.

TEST RESULTS

Getein1100/Getein1600 can scan the test card automatically and display the result on the screen. For additional information, please refer to the user manual of Getein1100/Getein1600.

EXPECTED VALUE

The expected normal value for CysC was determined by testing samples from 233 apparently healthy individuals. The reference range of CysC is 0.51 mg/L~1.09 mg/L calculated by using normal distribution methods.
It is recommended that each laboratory establish its own expected values for the population it serves.

PERFORMANCE CHARACTERISTICS

Measuring Range	0.5~10.0 mg/L
Lower Detection Limit	≤0.5 mg/L
Within-Run Precision	≤10%
Between-Run Precision	≤15%

Method Comparison:

The assay was compared with HITACHI 7170A analyzer and its matching MAKER CysC test kits with 204 serum samples (30 positive samples and 174 negative samples). The correlation coefficient (r) is 0.985.

LIMITATIONS

1. 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.
2. Samples containing interferents may influence the results. The table below listed the maximum allowance of these potential interferents.

Interferent	Hemoglobin	Triglyceride	Bilirubin
Concentration (Max)	10 g/L	10 g/L	0.2 g/L

REFERENCES

1. Bjurman C, Snygg-Martin U, Olaison L, et al. Cystatin C in a composite risk score for mortality in patients with infective endocarditis: a cohort study. BMJ Open. 2012, Jul 12, 2(4).
2. Chae HW, Shin JI, Kwon AR, et al. Spot urine albumin to creatinine ratio and serum cystatin C are effective for detection of diabetic nephropathy in childhood diabetic patients. J Korean Med Sci. 2012, 27(7):784-787.
3. Odutayo A, Cherney D. Cystatin C and acute changes in glomerular filtration rate. Clin Nephrol. 2012, 78(1):64-75.
4. EN ISO 18113-1:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
5. EN ISO 18113-2:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: *In vitro* diagnostic reagents for professional use (ISO 18113-2: 2009).

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on CysC Fast Test Kit (Immunofluorescence Assay) 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 15223-1:2007.

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

Thank you for purchasing CysC Fast Test Kit (Immunofluorescence Assay). Please read this user manual carefully before operating to ensure proper use.

Version: WIF13-S-02

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CE IVD

D-Dimer

Fast Test Kit

(Immunofluorescence Assay)

User Manual

Getein1100: Cat.# IF1006
Getein1600: Cat.# IF2006

INTENDED USE

D-Dimer Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of D-Dimer in plasma or whole blood. The test is used as an aid in the assessment and evaluation of patients suspected of deep-vein thrombosis or pulmonary embolism.

SUMMARY

Deep-vein thrombosis is a common condition, with a lifetime cumulative incidence of 2 to 5 percent. Untreated deep-vein thrombosis can result in pulmonary embolism, a potentially fatal outcome. Anticoagulant therapy reduces both morbidity and mortality from venous thromboembolism, and early diagnosis is therefore important. Accurate diagnosis of deep-vein thrombosis minimizes the risk of thromboembolic complications and averts the exposure of patients without thrombosis to the risks of anticoagulant therapy.

D-Dimer is a marker of endogenous fibrinolysis and should therefore be detectable in patients with deep-vein thrombosis. In recent years, an increasing number of studies have shown the D-Dimer assay has a high negative predictive value and D-Dimer is a sensitive but nonspecific marker of deep-vein thrombosis. Negative D-Dimer can exclude deep-vein thrombosis and pulmonary embolism.

PRINCIPLE

The test uses an anti-human D-Dimer monoclonal antibody conjugated with fluorescence latex and another anti-human D-Dimer monoclonal antibody coated on the test line. After the sample has been applied to the test strip, the fluorescence latex-labelled anti-human D-Dimer monoclonal antibody binds with the D-Dimer 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 another anti-human D-Dimer monoclonal antibody. The fluorescence intensity of the test line increases in proportion to the amount of D-Dimer in sample.

Then insert test card into Getein1100 Immunofluorescence Quantitative Analyzer/Getein1600 Immunofluorescence Quantitative Analyzer (hereinafter referred to as Getein1100 and Getein1600), the concentration of D-Dimer in sample will be measured and displayed on the screen. The value will be stored in Getein1100/Getein1600 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

CONTENTS

1. A kit for Getein1100 contains:
   Getein D-Dimer test card in a sealed pouch with desiccant 25
   Disposable pipet 25
   Sample diluent 25
   SD card 1
   User manual 1
2. A kit for Getein1600 contains:
   Sealed cartridge with 24/48 Getein D-Dimer test cards 2
   User manual 1
   Package specifications:
   2×24 tests/kit, 2×48 tests/kit
   Materials required for Getein1600:
   Sample diluent 1
   Box with pipette tips 1
   Mixing plate 1
3. Sample diluent composition:
   Phosphate buffered saline, proteins, detergent, preservative, stabilizer.
4. A test card consists of:
   A plastic shell and a reagent strip which is composed of a sample pad, nitrocellulose membrane (one end of the membrane is coated with a fluorescence latex-labelled anti-human D-Dimer monoclonal antibody, the test line is coated with another anti-human D-Dimer monoclonal antibody and the control line is coated with rabbit anti-mouse IgG antibody), absorbent paper and liner.

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

APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer
Getein1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Store the test card at 4~30℃ with a valid period of 24 months. Use the test card for Getein1100 within 1 hour once the foil pouch is opened.

For test card of Getein1600: if the cartridge is opened, it could be stable within 24 hours once exposed to air. If the test cards can't be used up at a time, please put the cartridge back to the foil pouch and reseal along the entire edge of zip-seal. The remaining test cards should be used up within 7 days.

Store the sample diluent/whole blood buffer at 0~30℃ with a valid period of 24 months.

Store the sample diluent/whole blood buffer at 2~8℃ 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 or the cartridge is damaged.
5. Do not open pouches or the cartridge 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 ***plasma and whole blood samples.*** ***Sodium citrate*** can be used as the anticoagulant for plasma and whole blood. Samples should be free of hemolysis.
2. Suggest using plasma for better results.
3. If testing will be delayed, plasma sample may be stored up to 3 days at 2~8℃ or stored at -20℃ for 1 month before testing (whole blood sample may be stored up to 3 days at 2~8℃).
4. Refrigerated or frozen sample should reach room temperature

and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
5. Do not use heat-inactivated samples.
6. SAMPLE VOLUME *(for Getein1100): 100 µl*.

TEST PROCEDURE

1. Collect specimens according to user manual.
2. Test card, sample and reagent should be brought to room temperature before testing.

For Getein1100:

3. Confirm SD card lot No. in accordance with test kit lot No.. Perform “SD Card Calib” calibration when necessary (Details refer to 8.5.2 of Getein1100 User Manual).
4. On the main interface of Getein1100, press "ENT" button to enter testing interface.
5. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
6. Put the test card on a clean table, horizontally placed.
7. Using sample transfer pipette, deliver *100 µl* of sample into one tube of sample diluent, mix gently and thoroughly. Then drop 100 µl of sample mixture (or 3~4 drops of sample when using disposable pipet) into the sample port on the test card.
8. *Reaction time: 10 minutes.* Insert the test card into Getein1100 and press "ENT" button after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein1600:

9. Each cartridge for Getein1600 contains a specific RFID card which can calibrate automatically.
10. Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein1600 will do the testing and print the result automatically.

Notes:

1. It is required to perform “SD Card Calib” calibration when using a new batch of kits.
2. It is suggested to calibrate once for one batch of kits for Getein1100.
3. Make sure the test card and the sample insertion is correct and complete.

TEST RESULTS

Getein1100/Getein1600 can scan the test card automatically and display the result on the screen. For additional information, please refer to the user manual of Getein1100/Getein1600.

EXPECTED VALUE

The expected normal value for D-Dimer was determined by testing samples from 500 apparently healthy individuals. The 95th percentile of the concentration for D-Dimer is 0.5 mg/L. (The probability that value of a normal person below 0.5 mg/L is 95%.)

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

PERFORMANCE CHARACTERISTICS

Measuring Range	0.1~10.0 mg/L
Lower Detection Limit	≤0.1 mg/L
Within-Run Precision	≤10%
Between-Run Precision	≤15%

Method Comparison:

The assay was compared with SIEMENS CA-7000 and its matching D-Dimer test kits with 200 plasma samples (60 positive samples and 140 negative samples). The correlation coefficient (r) for D-Dimer is 0.978.

LIMITATIONS

1. 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.
2. Samples containing interferents such as rheumatoid factor, human anti-mouse antibody and heterophile antibody may influence the results. In this case, results of this test should be used in conjunction with clinical findings and other tests. The table below listed the maximum allowance of these potential interferents.

Interferent	Hemoglobin	Triglyceride	Bilirubin
Concentration (Max)	5 g/L	25 g/L	0.1 g/L

REFERENCES

1. Sarig G, Klil-Drori AJ, Chap-Marshak D, Brenner B, Drugan A. Activation of coagulation in amniotic fluid during normal human pregnancy.Thromb Res. 2011 Apr 18.
2. Roldán V, Marín F, Muiña B, Torregrosa JM, Hernández-Romero D, Valdés M, Vicente V, Lip GY. Plasma von Willebrand Factor Levels Are an Independent Risk Factor for Adverse Events Including Mortality and Major Bleeding in Anticoagulated Atrial Fibrillation Patients. J Am Coll Cardiol. 2011 Apr 11.
3. Sakamoto K, Yamamoto Y, Okamatsu H, Okabe M. D-dimer is helpful for differentiating acute aortic dissection and acute pulmonary embolism from acute myocardial infarction. Hellenic J Cardiol. 2011 Mar-Apr; 52(2):123-127.
4. EN ISO 18113-1:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
5. EN ISO 18113-2:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: *In vitro* diagnostic reagents for professional use (ISO 18113-2:2009).

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on D-Dimer Fast Test Kit (Immunofluorescence Assay) 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 15223-1:2007.

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

Thank you for purchasing D-Dimer Fast Test Kit (Immunofluorescence Assay). Please read this user manual carefully before operating to ensure proper use.

Version: WIF05-S-02

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CE IVD

PCT

Fast Test Kit

(Immunofluorescence Assay)

User Manual

Getein1100: Cat.# IF1007
Getein1600: Cat.# IF2007

INTENDED USE

PCT Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of Procalcitonin (PCT) in serum, plasma or whole blood. The test is used as an aid in the assessment and evaluation of patients suspected of bacterial infection, trauma or shock.

SUMMARY

PCT is a peptide precursor of the hormone calcitonin, the latter being involved with calcium homeostasis. It is composed of 116 amino acids and is produced by parafollicular cells (C cells) of the thyroid and by the neuroendocrine cells of the lung and the intestine.
Measurement of PCT can be used as a marker of severe sepsis and generally grades well with the degree of sepsis, although levels of PCT in the blood are very low. PCT has the greatest sensitivity and specificity for differentiating patients with systemic inflammatory response syndrome (SIRS) from those with sepsis.
PCT levels may be useful to distinguish bacterial infections from nonbacterial infections. It has shown that PCT may help guide therapy and reduce antibiotic use, which can help save on cost of antibiotic prescriptions and drug resistance.

PRINCIPLE

The test uses an anti-human PCT monoclonal antibody conjugated with fluorescence latex. For PCT product, test line 1 was coated with anti-human PCT polyclonal antibody and test line 2 was coated with another anti-human PCT monoclonal antibody. After the sample has been applied to the test strip, the fluorescence latex-labelled anti-human PCT monoclonal antibody binds with the PCT 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 other anti-human PCT monoclonal antibody or the polyclonal antibody. The fluorescence intensity of the test line increases in proportion to the amount of PCT in sample.
Then insert test card into Getein1100 Immunofluorescence Quantitative Analyzer/Getein1600 Immunofluorescence Quantitative Analyzer (hereinafter referred to as Getein1100 and Getein1600), the concentration of PCT in sample will be measured and displayed on the screen. The value will be stored in Getein1100/Getein1600 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

CONTENTS

1. A kit for Getein1100 contains:
   Getein PCT test card in a sealed pouch with desiccant 25
   Disposable pipet 25
   Whole blood buffer 1
   SD card 1
   User manual 1
2. A kit for Getein1600 contains:
   Sealed cartridge with 24/48 Getein PCT test cards 2
   User manual 1
   Package specifications:
   2×24 tests/kit, 2×48 tests/kit
   Materials required for Getein1600:
   Sample diluent 1
   Box with pipette tips 1
   Mixing plate 1
3. Sample diluent/Whole blood buffer composition:
   Phosphate buffered saline, proteins, detergent, preservative, stabilizer.
4. A test card consists of:
   A plastic shell and a reagent strip which is composed of a sample pad, fluorescence latex pad, nitrocellulose membrane (one end of the membrane is coated with a fluorescence latex-labelled anti-human PCT monoclonal antibody, the test line are coated with another anti-human PCT monoclonal antibody and polyclonal antibody, and the control line is coated with rabbit anti-mouse IgG antibody), absorbent paper and liner.

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

APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer
Getein1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Store the test card at 4~30℃ with a valid period of 24 months. Use the test card for Getein1100 within 1 hour once the foil pouch is opened.
For test card of Getein1600: if the cartridge is opened, it could be stable within 24 hours once exposed to air. If the test cards can't be used up at a time, please put the cartridge back to the foil pouch and reseal along the entire edge of zip-seal. The remaining test cards should be used up within 7 days.
Store the sample diluent/whole blood buffer at 0~30℃ with a valid period of 24 months.
Store the sample diluent/whole blood buffer at 2~8℃ 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 or the cartridge is damaged.
5. Do not open pouches or the cartridge 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 the manual to ensure proper test performance.

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for ***serum, plasma and whole blood samples. Heparin and 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, one drop of 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℃ or stored at -20℃ for 6 months before testing (whole blood sample may be stored up to 3 days at 2~8℃).
5. Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
6. Do not use heat-inactivated samples.
7. SAMPLE VOLUME ***(for Getein1100): 100 µl***.

TEST PROCEDURE

1. Collect specimens according to user manual.
2. Test card, sample and reagent should be brought to room temperature before testing.

For Getein1100:

3. Confirm SD card lot No. in accordance with test kit lot No.. Perform “SD Card Calib” calibration when necessary (Details refer to 8.5.2 of Getein1100 User Manual).
4. On the main interface of Getein1100, press "ENT" button to enter testing interface.
5. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
6. Put the test card on a clean table, horizontally placed.
7. Using sample transfer pipette, deliver ***100 µl*** of sample (or 3~4 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 100 µl sample on the test card).
8. ***Reaction time: 15 minutes.*** Insert the test card into Getein1100 and press "ENT" button after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein1600:

9. Each cartridge for Getein1600 contains a specific RFID card which can calibrate automatically.
10. Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein1600 will do the testing and print the result automatically.

Notes:

1. It is required to perform “SD Card Calib” calibration when using a new batch of kits.
2. It is suggested to calibrate once for one batch of kits for Getein1100.
3. Make sure the test card and the sample insertion is correct and complete.

TEST RESULTS

Getein1100/Getein1600 can scan the test card automatically and display the result on the screen. For additional information, please refer to the user manual of Getein1100/Getein1600.

EXPECTED VALUE

The expected normal value for PCT was determined by testing samples from 500 apparently healthy individuals. The 99th percentile of the concentration for PCT is 0.1 ng/ml. (The probability that value of a normal person below 0.1 ng/ml is 99%.) The table below comes from the research of ACCP/SCCM (American College of Chest Physicians/Society of Critical Care Medicine), showing the PCT value and its clinical meaning [4]:

PCT concentration	Clinical significance
< 0.5 ng/ml	Local bacterial infection is possible, systemic infection (sepsis) is not likely.
≥ 0.5 and < 2.0 ng/ml	Systemic infection (sepsis) is possible, a moderate risk of severe sepsis and/or septic shock.
≥ 2.0 ng/ml	Systemic infection (sepsis) is likely, a high risk of severe sepsis and/or septic shock.

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

PERFORMANCE CHARACTERISTICS

Measuring Range	0.1~50.0 ng/ml
Lower Detection Limit	≤0.1 ng/ml
Within-Run Precision	≤10%
Between-Run Precision	≤15%

Method Comparison:

The assay was compared with Roche MODULAR ANALYTICS E170 automatic immunoassay system and its matching PCT test kits with 200 serum samples (68 positive samples and 132 negative samples). The correlation coefficient (r) for PCT is 0.983.

LIMITATIONS

1. 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.
2. Samples containing interferent may influences the results. The table below listed the maximum allowance of these potential interferents.

Interferent	Hemoglobin	Triglyceride	Bilirubin
Concentration (Max)	5 g/L	10 g/L	0.2 g/L

REFERENCES

1. Balcl C, Sungurtekin H, Gürses E, Sungurtekin U, Kaptanoglu B. Usefulness of procalcitonin for diagnosis of sepsis in the intensive care unit, Crit Care. 2003 February 7 (1):85~90.
2. Schuetz P, Christ-Crain M, Thomann R, et al. Effect of procalcitonin-based guidelines vs standard guidelines on antibiotic use in lower respiratory tract infections: the ProHOSP randomized controlled trial. JAMA. Sep 9 2009; 302(10):1059-66.
3. Briel M, Schuetz P, Mueller B, et al. Procalcitonin-guided antibiotic use vs a standard approach for acute respiratory tract infections in primary care. Arch Intern Med. Oct 13 2008; 168(18):2000-7; discussion 2007-8.
4. Meisner M. Procalcitonin (PCT) - A New innovative infection parameter. Biochemical and clinical aspects. Thieme Stuttgart, New York 2000, ISBN: 3-13-105503-0.
5. EN ISO 18113-1:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
6. EN ISO 18113-2:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: *In vitro* diagnostic reagents for professional use (ISO 18113-2:2009).

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on PCT Fast Test Kit (Immunofluorescence Assay) 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 15223-1:2007.

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

Thank you for purchasing PCT Fast Test Kit (Immunofluorescence Assay). Please read this user manual carefully before operating to ensure proper use.

Version: WIF06-S-02

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GP CE IVD

D-Dimer Control

Cat.# QC 006

User Manual

PRODUCT NAME

D-Dimer Control

PRODUCT SPECIFICATION

D-Dimer Control - Level 1/2/3
Level 1 ····· 1 x 1 ml
Level 2 ····· 1 x 1 ml
Level 3 ····· 1 x 1 ml

INTENDED USE

This product is intended for *in vitro* diagnostic use in the quality control of D-Dimer on the Getein Platforms.

PRINCIPLE

The lyophilized D-Dimer control is prepared from dissolving stable and high quality recombinant D-Dimer antigen into calf serum. With matching equipments and reagents, it can fulfill value transfer work. As different equipments and reagents have uncertainty to some extent, different control results may appear.

CONTENTS

The kit contains:
1. D-Dimer Control –Level 1 ····· 1 x 1 ml
2. D-Dimer Control –Level 2 ····· 1 x 1 ml
3. D-Dimer Control –Level 3 ····· 1 x 1 ml
4. User manual ····· 1
5. Target value sheet ····· 1

MATCHING EQUIPMENTS

FIA8000 Quantitative Immunoassay Analyzer
Getein1100/1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

UNOPENED: The product is stable for 18 months when stored at -20℃ and is stable for 7 days at 2-8℃ avoid light. **OPENED:** The product is stable for 7 days at 2-8℃ if kept capped in original container and free from contamination. Only the required amount of product should be removed. After use, any residual product should NOT BE RETURNED to the original vial. The residual product is recommended to be dispensed into smaller vials and they are stable for 18 months when stored at -20 to -70℃.

MATERIALS REQUIRED BUT NOT PROVIDED

1. 1 ml pipette
2. Distilled water
3. Getein test kit
4. Getein instrument

TEST PROCEDURE

1. The product should be brought to room temperature (15-30℃) prior to use.
2. Open the vial carefully in case of loss of content.
3. Reconstitute each vial with 1 ml of distilled water.

4. Gently mix until all material has dissolved. Avoid violent shaking.
5. Keep it at room temperature for 5-10 minutes before use.
6. Treat the control in the same manner as patient specimen in the assay procedure. Follow the directions of test kit and the instrument application instruction.

ASSIGNED VALUES

Refer to values listed on the target value sheet.
If the result is beyond the range, it indicates the existence of some unreliable factors in the testing system. Referring to the control graph helps judge the accuracy and stability of the testing system.
The expected range of the mean is provided to aid laboratory until it has established its own mean and SD for its methods.

PERFORMANCE CHARACTERISTICS

1. Homogeneity: ≤ 15%
2. Accuracy range: Target value ± 40%

LIMITATIONS

1. This product can only be used on the Getein Platforms.
2. Variation exists between different equipments developed by different methods even using the same control product.
3. This product is not intended to be used as standard material.

NOTES

1. For *in vitro* diagnostic use only.
2. Do not use the product beyond the expiration date.
3. Avoid multiple freeze-thaw cycles.
4. Do not use the product if it is contaminated with bacteria.
5. Proper handling and disposal methods should be followed in accordance with local regulations.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on D-Dimer control 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 15223-1:2007.

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

Thank you for purchasing D-Dimer Control.
Please read this user manual carefully before operating to ensure proper use.

Version: WZK04-S-01

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Please contact Getein Biotech Company if you have any questions.

GP CE IVD

CysC Control

Cat.# QC 008

User Manual

PRODUCT NAME

CysC Control

PRODUCT SPECIFICATION

CysC Control - Level 1/2/3

Level 1 ····· 1 x 1 ml
Level 2 ····· 1 x 1 ml
Level 3 ····· 1 x 1 ml

INTENDED USE

This product is intended for *in vitro* diagnostic use in the quality control of CysC on the Getein Platforms.

PRINCIPLE

The lyophilized CysC control is prepared from dissolving stable and high quality recombinant CysC antigen into calf serum. With matching equipments and reagents, it can fulfill value transfer work. As different equipments and reagents have uncertainty to some extent, different control results may appear.

CONTENTS

The kit contains:

1. CysC Control –Level 1 ····· 1 x 1 ml
2. CysC Control –Level 2 ····· 1 x 1 ml
3. CysC Control –Level 3 ····· 1 x 1 ml
4. User manual ····· 1
5. Target value sheet ····· 1

MATCHING EQUIPMENTS

FIA8000 Quantitative Immunoassay Analyzer
Getein1100/1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

UNOPENED: The product is stable for 18 months when stored at -20˚C and is stable for 7 days at 2-8˚C avoid light. **OPENED:** The product is stable for 7 days at 2-8˚C if kept capped in original container and free from contamination. Only the required amount of product should be removed. After use, any residual product should NOT BE RETURNED to the original vial. The residual product is recommended to be dispensed into smaller vials and they are stable for 18 months when stored at -20 to -70˚C.

MATERIALS REQUIRED BUT NOT PROVIDED

1. 1 ml pipette
2. Distilled water
3. Getein test kit
4. Getein instrument

TEST PROCEDURE

1. The product should be brought to room temperature (15-30˚C) prior to use.
2. Open the vial carefully in case of loss of content.
3. Reconstitute each vial with 1 ml of distilled water.

4. Gently mix until all material has dissolved. Avoid violent shaking.
5. Keep it at room temperature for 5-10 minutes before use.
6. Treat the control in the same manner as patient specimen in the assay procedure. Follow the directions of test kit and the instrument application instruction.

ASSIGNED VALUES

Refer to values listed on the target value sheet.
If the result is beyond the range, it indicates the existence of some unreliable factors in the testing system. Referring to the control graph helps judge the accuracy and stability of the testing system.
The expected range of the mean is provided to aid laboratory until it has established its own mean and SD for its methods.

PERFORMANCE CHARACTERISTICS

1. Homogeneity: ≤ 15%
2. Accuracy range: Target value ± 40%

LIMITATIONS

1. This product can only be used on the Getein Platforms.
2. Variation exists between different equipments developed by different methods even using the same control product.
3. This product is not intended to be used as standard material.

NOTES

1. For *in vitro* diagnostic use only.
2. Do not use the product beyond the expiration date.
3. Avoid multiple freeze-thaw cycles.
4. Do not use the product if it is contaminated with bacteria.
5. Proper handling and disposal methods should be followed in accordance with local regulations.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on CysC control 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 15223-1:2007.

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

Thank you for purchasing CysC Control.
Please read this user manual carefully before operating to ensure proper use.

Version: WZK10-S-01

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Getein Biotech, Inc.

Stock Code: 603387

OPTIMIZED POINT-OF-CARE SOLUTION

MAKING TEST EASY

Getein1100

Immunofluorescence Quantitative Analyzer

Cardiac Markers

Coagulation Markers

Diabetes Mellitus

Inflammation

Thyroid Function

Metabolic Marker

Renal Function

Tumor Markers

Reproduction /Fertility

Infectious Disease

Getein1100

Immunofluorescence Quantitative Analyzer

HIGHLY EFFICIENT & ACCURATE

Advanced fluorescence immunoassay

Multiple quality control

REAL-TIME AND RAPID TEST

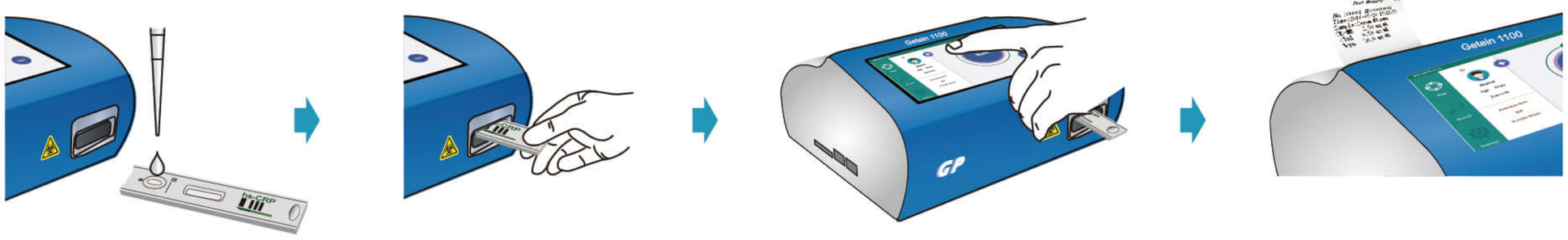
One-step test

3-15 min/test

5 sec/test for multiple tests

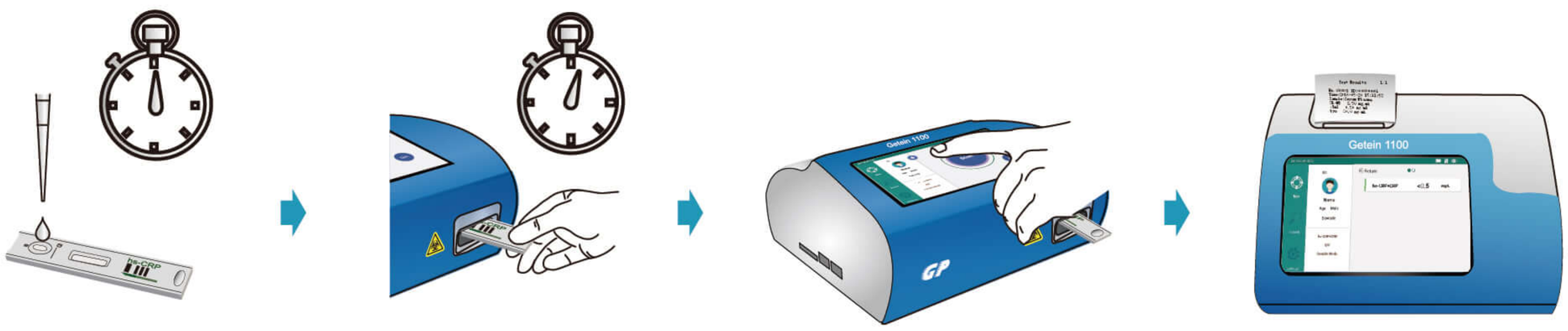
OPERATION MODES

Inside Mode (single sample rapid test mode)



Sample Dispense → Test Card Insert → Click “Start” Icon → Result Show and Print

Quick mode (mass samples rapid test mode)



Sample Dispense → Timing the Reaction Manually → Click “Start” Icon → Result Show and Print

CONVENIENT OPERATION

RFID card calibration

Keyboard and mouse connectivity through USB port

Handwriting input available

Continuous test for 3 hours with lithium battery

USER-FRIENDLY INTERFACE

Android system

7 inch touch screen

FRONT VIEW

PORTABLE DESIGN

Small in size: 261 ×241 ×115 mm

Light in weight: 2.0 kg

LARGE MEMORY

Up to 10,000 results storage capacity

TECHNICAL PARAMETERS

Methodology	Immunofluorescence
Result	Quantitative
Sample Type	WB, plasma, serum, urine, Stool, Nasal swab, Saliva, Capillary blood
Storage Capacity	10000 data
Language	English/Chinese/Spanish/Portuguese
Screen	7 inch touch screen
Power Supply	100-240 V~50 Hz/60 Hz, 60 VA
Working Environment	Tempreture: 10-35℃ Relative humidity ≤70% Air pressure 70.0~106.0 kpa
Dimension	261 mm×241 mm×115 mm (D×W×H)
Weight	2.0 kg

TEST ITEMS

Cat. #	TEST ITEMS	DISEASES	CUT-OFF VALUE	SAMPLE TYPES	MEASURING RANGE	SAMPLE VOLUME	REACTION TIME	QUALIFICATION
Cardiac Markers								
IF1001	cTnI	Myocardial infarction	0.1 ng/mL	S/P/WB	0.1-50.0 ng/mL	100 µL	10 min	NMPA CE
IF1089	BNP	Heart failure	100.0 pg/mL	P/WB	5.0-5000.0 pg/mL	100 µL	10 min	NMPA CE
IF1002	NT-proBNP	Heart failure	300 pg/mL	S/P/WB	100-35000 pg/mL	100 µL	10 min	NMPA CE
IF1005	CK-MB/cTnI/Myo	Myocardial damage /infarction	CK-MB: 5.0 ng/mL cTnI: 0.1 ng/mL Myo: 70 ng/mL	S/P/WB	2.5-80.0 ng/mL 0.1-50.0 ng/mL 30.0-600.0 ng/mL	100 µL	10 min	NMPA CE
IF1012	CK-MB/cTnI	Myocardial damage /infarction	CK-MB: 5.0 ng/mL cTnI: 0.1 ng/mL	S/P/WB	2.5-80.0 ng/mL 0.1-50.0 ng/mL	100 µL	10 min	CE
IF1014	H-FABP	Myocardial damage	6.36 ng/mL	S/P/WB	1.0-120.0 ng/mL	100 µL	3 min	NMPA CE
IF1016	CK-MB/cTnI/H-FABP	Myocardial damage /infarction	CK-MB: 5.0 ng/mL cTnI: 0.1 ng/mL H-FABP: 6.36 ng/mL	S/P/WB	2.5-80.0 ng/mL 0.1-50.0 ng/mL 2.0-100.0 ng/mL	100 µL	10 min	NMPA CE
IF1018	CK-MB	Myocardial injury	5.0 ng/mL	S/P/WB	2.5-80.0 ng/mL	100 µL	10 min	CE
NEW IF1078	ST2	Heart failure	35.0 ng/mL	S/P/WB	3.1-200.0 ng/mL	100 µL	10 min	CE
Coagulation Markers								
IF1006	D-Dimer	Venous thromboembolism	0.5 mg/L	P/WB	0.1-10.0 mg/L	100 µL	10 min	NMPA CE
Inflammation								
IF1003	hs-CRP+CRP	Cardiovascular inflammation /normal inflammation	3 mg/L 10 mg/L	S/P/WB/ Fingertip blood	0.5-200 mg/L	10 µL	3 min	NMPA CE
IF1007	PCT	Sepsis, bacterial infection	0.1 ng/mL	S/P/WB	0.1-50.0 ng/mL	100 µL	15 min	NMPA CE
IF1015	PCT/CRP	Sepsis, bacterial infection	PCT: 0.1 ng/mL CRP: 3.0 mg/L	S/P/WB	0.1-50.0 ng/mL 0.5-200.0 mg/L	100 µL	15 min	NMPA CE
IF1044	SAA	Bacterial/Virus infection	10.0 mg/L	S/P/WB/ Fingertip blood	5.0-200.0 mg/L	10 µL	5 min	NMPA CE
IF1090	SAA/CRP	Neonatal sepsis, Bacterial/virus infection	SAA: 10.0 mg/L CRP: 10.0 mg/L	S/P/WB/ Capillary blood	5.0-200.0 mg/L 0.5-200.0 mg/L	10 µL	5 min	NMPA CE
IF1088	IL-6	Acute inflammation	7.0 pg/mL	S/P/WB/ Peripheral blood	1.5-4000.0 pg/mL	100 µL	15 min	CE
Renal Function								
IF1008	CysC	Acute and chronic renal diseases	0.51-1.09 mg/L	S/P/WB	0.5-10.0 mg/L	10 µL	3 min	NMPA CE
IF1009	mAlb	Diabetic nephropathy, hypertensive nephropathy	20.0 mg/L	Urine	10.0-200.0 mg/L	100 µL	3 min	NMPA CE
IF1010	NGAL	Acute kidney injury	Serum: 200 ng/mL Urine: 100 ng/mL	S/Urine	50-5000 ng/mL	10 µL	10 min	NMPA CE
IF1011	β_2-MG	Acute and chronic kidney diseases/tumours	0.8-3.0 mg/L	S/P/WB	0.5-20.0 mg/L	10 µL	3 min	NMPA CE
Diabetes Mellitus								
IF1017	HbA1c	Diabetes mellitus	3.8%-5.8%	WB	2%-14%	10 µL	5 min	NGSP NMPA IFCC CE
Metabolic Marker								
IF1031	25-OH-VD	Osteomalacia, osteoporosis	30.0-50.0 ng/mL	S/P	8.0-70.0 ng/mL	40 µL	15 min	NMPA CE
Thyroid Function								
IF1024	TSH	Thyroid malfunction	0.27-4.20 µIU/mL	S/P	0.10-50.00 µIU/mL	100 µL	15 min	NMPA CE
IF1022	T3	Hyperthyroidism, hypothyroidism	1.30-3.10 nmol/L	S/P	0.30-10.00 nmol/L	40 µL	15 min	CE
IF1023	T4	Hyperthyroidism, hypothyroidism	59.0-154.0 nmol/L	S/P	5.4-320.0 nmol/L	40 µL	15 min	CE
IF1067	fT3	Hyperthyroidism, hypothyroidism	3.1-6.8 pmol/L	S/P	0.4-50.0 pmol/L	100 µL	15 min	CE
IF1068	fT4	Hyperthyroidism, hypothyroidism	12.0-22.0 pmol/L	S/P	0.3-100.0 pmol/L	100 µL	15 min	CE

Cat. #	TEST ITEMS	DISEASES	CUT-OFF VALUE	SAMPLE TYPES	MEASURING RANGE	SAMPLE VOLUME	REACTION TIME	QUALIFICATION
Reproduction/Fertility								
IF1013	HCG+β	Fertility	5.1 mIU/mL	S/P	5-100000 mIU/mL	100 μL	10 min	NMPA CE
IF1055	LH	Homeostasis fertility regualtion	Refer to User Manual	S/P	0.2-150.0 mIU/mL	100 μL	15 min	CE
IF1056	FSH	PCOS, infertility evaluation and pituitary disorders	Refer to User Manual	S/P	0.2-150.0 mIU/mL	100 μL	15 min	CE
IF1066	AMH	Fertility, PCOS, gonadal function, precocious/late puberty	Refer to User Manual	S/P	0.10-20.00 ng/mL	200 μL	15 min	CE
IF1048	PRL	Infertility, gonadal disorders	Refer to User Manual	S/P	0.50-200.0 ng/mL	100 μL	15 min	CE
IF1071	Prog	Infertility, evaluation of ovulation	Refer to User Manual	S/P	0.10-40.00 ng/mL	100 μL	15 min	CE
Tumor Markers								
IF1053	tPSA	Prostate cancer	4.0 ng/mL	S/P	0.50-100.00 ng/mL	100 μL	15 min	
IF1072	fPSA	Prostate cancer	1.0 ng/mL	S/P	0.10-30.00 ng/ml	100 μL	10 min	
IF1050	AFP	Liver cancer, cancer of ovaries or testicles, etc.	7.0 ng/mL	S/P	2.0-500.0 ng/mL	100 μL	15 min	CE
IF1051	CEA	Cancer marker: colon cancer etc.	4.7 ng/mL	S/P/WB	2.0-500.0 ng/mL	100 μL	15 min	CE
Infectious Disease								
IF1057	Anti-HCV	Hepatitis C	1 S/CO	S/P	1.00-20.00 S/CO	100 μL	15 min	
IF1058	Anti-TP	Syphilis	1 S/CO	S/P	1.00-50.00 S/CO	100 μL	15 min	CE
IF1059	Anti-HIV	AIDS	1 S/CO	S/P	1.00-1000.00 S/CO	100 μL	15 min	
IF1064	HBsAg	Hepatitis B	1 IU/mL	S/P	1.00-100.00 IU/mL	100 μL	15 min	
NEW IF1063	Anti-HBs	Hepatitis B	10.00 mIU/mL	S/P/WB	10.00-1000.00 mIU/mL	100 μL	15 min	
IF1084	2019-nCoV IgM/IgG	COVID-19	1 COI	S/P/WB		100 μL	10 min	CE
NEW IF1091	SARS-CoV-2 Antigen	COVID-19	1 COI	Nasal swab/Saliva		100 μL	15 min	CE
NEW IF1092	SARS-CoV-2 Total Antibody/ Neutralizing Antibody	COVID-19	Refer to User Manual	S/P/WB		100 μL	10 min	CE
NEW IF1095	SARS-CoV-2 Neutralizing Antibody	COVID-19	Refer to User Manual	S/P/WB		100 μL	10 min	
IF1047	*H. pylori*	*H. pylori* infection	5 ng/mL	Stool	1-200 ng/mL	150 mg	10 min	CE
Others								
NEW IF1077	Ferritin	Anemia/tumors	Male: 30-400 ng/mL Female: 13-150 ng/mL	S/P	0.50-2000.00 ng/mL	100 μL	15 min	CE
NEW IF1069	Total IgE	Allergic disorders	Refer to User Manual	S/P/WB	1.00-2000.00 IU/mL	100 μL	15 min	CE

Coming Soon: FOB, ASO, RF, anti-CCP, Folate…

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ISO13485 FSC CE NMPA NGSP IFCC IVD