



Getein
Biotech, Inc.

Stock Code: 603387

OPTIMIZED POINT-OF-CARE SOLUTION
MAKING TEST EASY

Getein 1100

Immunofluorescence Quantitative Analyzer



Cardiac
Markers



Coagulation
Markers



Diabetes
Mellitus



Inflammation



Thyroid
Function



Metabolic
Marker



Renal
Function



Tumor
Markers



Reproduction
/Fertility



Infectious
Disease

Getein 1100

Immunofluorescence Quantitative Analyzer



HIGHLY EFFICIENT & ACCURATE

Advanced fluorescence immunoassay

Multiple quality control



REAL-TIME AND RAPID TEST

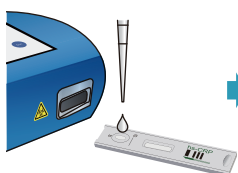
One-step test

3-15 min/test

5 sec/test for multiple tests

OPERATION MODES

Inside Mode (Single sample rapid test mode)



Sample Transfer



Test Card Insert



Click "Start" Icon

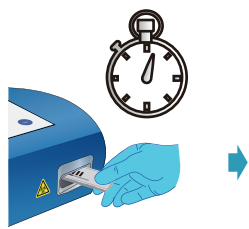


Results Output

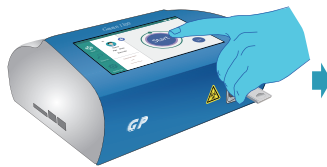
Outside Mode (Mass samples rapid test mode)



Sample Transfer



Timing the Reaction Manually



Click "Start" Icon



Results Output



CONVENIENT OPERATION

RFID card calibration

Keyboard and mouse connectivity through USB ports

Handwriting input available

Continuous test for 3 hours with optional lithium battery



USER-FRIENDLY INTERFACE

Android system

7-inch touch screen



1 7-inch Touch Screen

2 RFID Recognition Zone

3 Test Card Slot

4 SD Card Slot

5 USB Slot

6 Built-in Thermal Printer



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

10,000 data

Language

English/Chinese/Spanish/Portuguese

Screen

7-inch touch screen

Power Supply

100-240 V ~ 50 Hz/60 Hz, 60 VA

Working Environment

Temperature: 10-35°C
Relative humidity ≤ 70%
Air pressure 70.0 ~ 106.0 kpa

Dimensions

261 mm(L) × 241 mm(W) × 115 mm(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 | cTnl | Myocardial infarction | 0.10 ng/mL | S/P/WB | 0.10-50.00 ng/mL | 100 µL | 10 min | NMPA CE |
| IF1098 | TnT | Myocardial infarction | 14.0 pg/mL | S/P/WB | 10.0-10000.0 pg/mL | 100 µL | 15 min | NMPA CE |
| NEW IF1078 | ST2 | Chronic heart failure | 35.0 ng/mL | S/P/WB | 3.0-200.0 ng/mL | 100 µL | 15 min | 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 |
| IF1014 | H-FABP | Myocardial damage | 6.36 ng/mL | S/P/WB | 1.00-120.00 ng/mL | 100 µL | 3 min | NMPA CE |
| IF1018 | CK-MB | Myocardial injury | 5.00 ng/mL | S/P/WB | 2.50-80.00 ng/mL | 100 µL | 10 min | NMPA CE |
| IF1004 | NT-proBNP/cTnl | Heart failure/AMI | NT-proBNP: 185 pg/mL cTnl: 0.10 ng/mL | S/P/WB | 100-15000 pg/mL 0.10-50.00 ng/mL | 100 µL | 10 min | NMPA CE |
| IF1012 | CK-MB/cTnl | Myocardial damage/infarction | CK-MB: 5.00 ng/mL cTnl: 0.10 ng/mL | S/P/WB | 2.50-80.00 ng/mL 0.10-50.00 ng/mL | 100 µL | 10 min | NMPA CE |
| IF1005 | CK-MB/cTnl/Myo | Myocardial damage/infarction | CK-MB: 5.00 ng/mL cTnl: 0.10 ng/mL Myo: 70.0 ng/mL | S/P/WB | 2.50-80.00 ng/mL 0.10-50.00 ng/mL 30.0-600.0 ng/mL | 100 µL | 10 min | NMPA CE |
| IF1016 | CK-MB/cTnl/H-FABP | Myocardial damage/infarction | CK-MB: 5.00 ng/mL cTnl: 0.10 ng/mL H-FABP: 6.36 ng/mL | S/P/WB | 2.50-80.00 ng/mL 0.10-50.00 ng/mL 2.00-100.00 ng/mL | 100 µL | 10 min | NMPA CE |
| Coagulation Marker | | | | | | | | |
| IF1006 | D-Dimer | Venous thromboembolism | 0.50 mg/L | P/WB | 0.10-10.00 mg/L | 100 µL | 10 min | NMPA CE |
| Inflammation | | | | | | | | |
| IF1007 | PCT | Sepsis, bacterial infection | 0.10 ng/mL | S/P/WB | 0.05-50.00 ng/mL | 100 µL | 15 min | NMPA CE |
| NEW IF1139 | Calprotectin | Inflammatory bowel disease | <50.0 µg/g | Fecal specimen | 10.0-600.0 µg/g | 100 µL | 15 min | CE |
| IF1003 | hs-CRP+CRP | Cardiovascular inflammation | 3.0 mg/L 10.0 mg/L | S/P/WB Fingertip blood | 0.5-200.0 mg/L | 10 µL | 3 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 |
| IF1088 | IL-6 | Acute inflammation | Refer to user manual | S/P/WB Fingertip blood | 1.5-4000.0 pg/mL | 20 µL | 15 min | NMPA CE |
| IF1090 | SAA/CRP | Sepsis, bacterial/virus infection | SAA: 10.0 mg/L CRP: 10.0 mg/L | S/P/WB Fingertip blood | 5.0-200.0 mg/L 0.5-200.0 mg/L | 10 µL | 5 min | NMPA CE |
| IF1015 | PCT/CRP | Sepsis, bacterial infection | PCT: 0.10 ng/mL CRP: 3.0 mg/L | S/P/WB | 0.10-50.00 ng/mL 0.5-200.0 mg/L | 20 µL | 15 min | NMPA CE |
| Renal Function | | | | | | | | |
| IF1008 | CysC | Renal diseases | 0.51-1.09 mg/L | S/P/WB | 0.50-10.00 mg/L | 10 µL | 3 min | NMPA CE |
| IF1009 | mAlb | Diabetic nephropathy | 20.0 mg/L | Urine | 10.0-200.0 mg/L | 100 µL | 3 min | NMPA CE |
| IF1011 | β₂-MG | Kidney diseases/tumours | 0.80-3.00 mg/L | S/P/WB | 0.50-20.00 mg/L | 10 µL | 3 min | NMPA CE |
| IF1010 | NGAL | Acute kidney injury | Serum: 200.0 ng/mL Urine: 100.0 ng/mL | S/Urine | 50.0-5000.0 ng/mL | 10 µL | 10 min | NMPA CE |
| Diabetes Mellitus | | | | | | | | |
| IF1017 | HbA1c | Diabetes mellitus | 3.80%-5.80% | WB | 2.00%-14.00% | 10 µL | 5 min | NMPA CE NGSP/IFCC |
| Metabolic Marker | | | | | | | | |
| IF1112 | Osteocalcin | Osteoporosis | Male: 14-70 ng/mL Female: 11-48 ng/mL | S/P | 1.5-300.0 ng/mL | 100 µL | 15 min | 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 | Thyroid Function | 1.30-3.10 nmol/L | S/P | 0.30-10.00 nmol/L | 100 µL | 15 min | NMPA CE |
| IF1023 | T4 | Thyroid Function | 59.00-154.00 nmol/L | S/P | 5.40-320.00 nmol/L | 100 µL | 15 min | NMPA CE |
| IF1067 | ft3 | Thyroid Function | 3.10-6.80 pmol/L | S/P/WB | 0.60-50.00 pmol/L | 100 µL | 15 min | NMPA CE |
| IF1068 | ft4 | Thyroid Function | 12.00-22.00 pmol/L | S/P/WB | 0.30-100.00 pmol/L | 100 µL | 15 min | NMPA CE |

| Cat. # | TEST ITEMS | DISEASES | CUT-OFF VALUE | SAMPLE TYPES | MEASURING RANGE | SAMPLE VOLUME | REACTION TIME | QUALIFICATION |
|--|--------------------------------|------------------------------|--|----------------------------|---|---------------|---------------|----------------|
| Vitamin | | | | | | | | |
| IF1031 | 25-OH-VD | Osteoporosis | 20.00-50.00 ng/mL | S/P/WB/ Fingertip blood | 8.00-100.00 ng/ml | 20 µL | 8 min | NMPA CE |
| NEW IF1094 | Folate | Megaloblastic anemia | 3.89 ng/mL~26.80 ng/mL (8.83 nmol/L-60.80 nmol/L) | S | 1.2-40.0 ng/mL (2.72-90.8 nmol/L) | 20 µL | 15 min | CE |
| NEW IF1070 | Vitamin B12 | Megaloblastic anemias | 197.00-771.00 pg/mL (145.40-569.00 pmol/L) | S | 100.0-2000.0 pg/mL or 73.8 -1476.0 pmol/L | 100 µL | 15 min | CE |
| Fertility | | | | | | | | |
| IF1013 | HCG+β | Fertility | 5.1 mIU/mL | S/P | 5.0-100000.0 mIU/mL | 100 µL | 10 min | NMPA CE |
| IF1055 | LH | PCOS, infertility evaluation | Refer to User Manual | S/P | 0.20-150.00 mIU/mL | 100 µL | 15 min | NMPA CE |
| IF1056 | FSH | PCOS, infertility evaluation | Refer to User Manual | S/P | 0.20-150.00 mIU/mL | 100 µL | 15 min | NMPA CE |
| IF1066 | AMH | Fertility, PCOS | Refer to User Manual | S/P | 0.10-20.00 ng/mL | 100 µL | 15 min | NMPA CE |
| IF1048 | PRL | Infertility | Refer to User Manual | S/P | 0.50-200.00 ng/mL | 100 µL | 15 min | NMPA CE |
| IF1071 | Prog | Infertility | Refer to User Manual | S/P | 0.10-40.00 ng/mL | 100 µL | 15 min | NMPA CE |
| IF1138 | Estradiol | Ovarian function | Refer to User Manual | S/P | 40.0-4800.0 pg/mL | 100 µL | 15 min | CE |
| IF1073 | Testosterone | Female PCOS | Male: 1.75-7.81 ng/mL Female: 0.10-0.75 ng/mL | S/P | 0.10-16.00 ng/mL | 100 µL | 15 min | CE |
| Tumor Markers | | | | | | | | |
| IF1053 | tPSA | Prostate cancer | 4.00 ng/mL | S/P | 0.40-100.00 ng/mL | 100 µL | 15 min | NMPA |
| IF1072 | fPSA | Prostate cancer | 1.00 ng/mL | S/P | 0.03-30.00 ng/mL | 100 µL | 10 min | NMPA |
| IF1050 | AFP | Liver cancer, etc. | 7.0 ng/mL | S/P | 2.0-500.0 ng/mL | 100 µL | 15 min | NMPA CE |
| IF1051 | CEA | Malignant tumour screening | 4.7 ng/mL | S/P | 2.0-500.0 ng/mL | 100 µL | 15 min | NMPA CE |
| IF1079 | CA125 | Ovarian cancer | 35.0 U/mL | S/P/WB | 2-500.0 U/mL | 100 µL | 15 min | CE |
| IF1080 | CA19-9 | Pancreatic cancer | 27.0 U/mL | S/P/WB | 2-1000.0 U/mL | 100 µL | 15 min | CE |
| IF1081 | CA15-3 | Breast cancer | 26.2 U/mL | S/P/WB | 1.5-300.0 U/mL | 100 µL | 10 min | CE |
| IF1052 | PG I/PG II | Atrophic gastritis | PG I < 70.0 ng/mL PG I/PG II < 3.0 ng/mL | S/P | PG I: 1.0-200.0 ng/mL PG II: 1.0-100.0 ng/mL | 100 µL | 15 min | NMPA CE |
| Infectious Disease | | | | | | | | |
| IF1057 | Anti-HCV | Hepatitis C | 1.00 S/CO | S/P | / | 100 µL | 15 min | |
| IF1058 | Anti-TP | Syphilis | 1.00 S/CO | S/P | / | 100 µL | 15 min | CE |
| IF1059 | Anti-HIV | AIDS | 1.00 S/CO | S/P | 1.00-1000.00 S/CO | 100 µL | 15 min | |
| IF1064 | HBsAg | Hepatitis B | 1.00 IU/mL | S/P | 1.00-100.00IU/mL | 100 µL | 15 min | |
| IF1063 | Anti-HBs | Hepatitis B | 10.00 mIU/mL | S/P/WB | 10.00-1000.00 mIU/mL | 100 µL | 15 min | |
| IF1091 | SARS-CoV-2 Antigen | COVID-19 | 1.00 COI | Nasal swab | / | 100 µL | 15 min | CE |
| IF1047 | H. pylori Antigen | H. pylori infection | 5.0 ng/mL | Stool | 1.0-200.0 ng/mL | 10-50 mg | 10 min | CE |
| IF1086 | Influenza A/B | Respiratory viral infection | 1.00 COI | Nasal swab | / | 100 µL | 15 min | CE |
| IF1136 | Dengue NS1 Ag | Dengue virus infection | 1.00 S/CO | S/P/WB | 1.00-50.00 S/CO | 100 µL | 15 min | CE |
| NEW IF1137 | Dengue IgG/IgM Antibody | Dengue fever | COI<1.00 | S/P/WB | 0.50-100.00 COI | 100 µL | 15 min | CE |
| NEW IF1140 | H. Pylori Antibody | Functional dyspepsia | COI<1.0, S/CO | S/P/WB | 0.50-100.00 S/CO | 100 µL | 15 min | CE |
| NEW IF1085 | RSV/Influenza A/B | Flu, LRTI | COI<1.00 | Human nasal swab sample | | 100 µL | 15 min | CE |
| Specific Protein and Rheumatism | | | | | | | | |
| IF1075 | RF | Rheumatoid arthritis | 15.9 IU/mL | S/P/WB | 10.0-640.0 IU/mL | 10 µL | 10 min | NMPA CE |
| IF1076 | ASO | Rheumatoid arthritis | 408.0 IU/mL | S/P/WB | 60.0-1370.0 IU/mL | 10 µL | 10 min | NMPA CE |
| IF1029 | Anti-CCP | Rheumatoid arthritis | 25.0 U/mL | S/P/WB | 10.0-400.0 U/mL | 10 µL | 15 min | CE |
| Others | | | | | | | | |
| IF1110 | Cortisol | Adrenal cortex function | Refer to User Manual | S/P | 11-1655 nmol/L | 100 µL | 15 min | CE |
| IF1069 | Total IgE | Allergic disorders | Refer to User Manual | S/P/WB | 1.00-2000.00 IU/mL | 100 µL | 15 min | CE |
| NEW IF1042 | FOB | PUD | 50 ng/mL | Fecal | 25-1000 ng/mL | 10-50 mg | 10 min | CE |
| IF1077 | Ferritin | Anemia/tumors | Male: 30.00-400.00 ng/mL Female: 13.00-150.00 ng/mL | S/P | 0.50-1000.00 ng/mL | 10 µL | 15 min | NMPA CE |



EC Declaration of Conformity

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

Ref. No.:20220513-A05

Manufacturer
(Name, Address)

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

Authorized Representative
(Name, Address)

CMC Medical Devices & Drugs S.L.
Add: C/ Horacio Lengo N° 18, CP 29006, Málaga, Spain

Medical device

| No. | Product Name |
|-----|---|
| 1 | Getein 1100 Immunofluorescence Quantitative Analyzer |
| 2 | Cardiac Troponin I Fast Test Kit (Immunofluorescence Assay) |
| 3 | NT-proBNP Fast Test Kit (Immunofluorescence Assay) |
| 4 | hs-CRP+CRP Fast Test Kit (Immunofluorescence Assay) |
| 5 | NT-proBNP/cTnI Fast Test Kit (Immunofluorescence Assay) |
| 6 | CK-MB/cTnI/Myo Fast Test Kit (Immunofluorescence Assay) |
| 7 | D-Dimer Fast Test Kit (Immunofluorescence Assay) |
| 8 | PCT Fast Test Kit (Immunofluorescence Assay) |
| 9 | CysC Fast Test Kit (Immunofluorescence Assay) |
| 10 | mAlb Fast Test Kit (Immunofluorescence Assay) |
| 11 | NGAL Fast Test Kit (Immunofluorescence Assay) |
| 12 | β 2-MG Fast Test Kit (Immunofluorescence Assay) |
| 13 | CK-MB/cTnI Fast Test Kit (Immunofluorescence Assay) |
| 14 | HCG+ β Fast Test Kit (Immunofluorescence Assay) |
| 15 | H-FABP Fast Test Kit (Immunofluorescence Assay) |
| 16 | PCT/CRP Fast Test Kit (Immunofluorescence Assay) |
| 17 | CK-MB/cTnI/H-FABP Fast Test Kit (Immunofluorescence Assay) |
| 18 | HbA1c Fast Test Kit (Immunofluorescence Assay) |
| 19 | NT-proBNP/NGAL Fast Test Kit (Immunofluorescence Assay) |
| 20 | CK-MB Fast Test Kit (Immunofluorescence Assay) |
| 21 | hs-cTnI Fast Test Kit (Immunofluorescence Assay) |
| 22 | T3 Fast Test Kit (Immunofluorescence Assay) |
| 23 | T4 Fast Test Kit (Immunofluorescence Assay) |
| 24 | TSH Fast Test Kit (Immunofluorescence Assay) |
| 25 | Scr Fast Test Kit (Immunofluorescence Assay) |
| 26 | PLGF Fast Test Kit (Immunofluorescence Assay) |



- 27 HCY Fast Test Kit (Immunofluorescence Assay)
- 28 Anti-CCP Fast Test Kit (Immunofluorescence Assay)
- 29 25-OH-VD Fast Test Kit (Immunofluorescence Assay)
- 30 Lp-PLA2 Fast Test Kit (Immunofluorescence Assay)
- 31 FOB Fast Test Kit (Immunofluorescence Assay)
- 32 SAA Fast Test Kit (Immunofluorescence Assay)
- 33 H. pylori Fast Test Kit (Immunofluorescence Assay)
- 34 PRL Fast Test Kit (Immunofluorescence Assay)
- 35 Transferrin Fast Test Kit (Immunofluorescence Assay)
- 36 Insulin Fast Test Kit (Immunofluorescence Assay)
- 37 PG I /PG II Fast Test Kit (Immunofluorescence Assay)
- 38 LH Fast Test Kit (Immunofluorescence Assay)
- 39 FSH Fast Test Kit (Immunofluorescence Assay)
- 40 Anti-TP Fast Test Kit (Immunofluorescence Assay)
- 41 AFP/CEA Fast Test Kit (Immunofluorescence Assay)
- 42 AMH Fast Test Kit (Immunofluorescence Assay)
- 43 fT3 Fast Test Kit (Immunofluorescence Assay)
- 44 fT4 Fast Test Kit (Immunofluorescence Assay)
- 45 Total IgE Fast Test Kit (Immunofluorescence Assay)
- 46 Vit-B12 Fast Test Kit (Immunofluorescence Assay)
- 47 Prog Fast Test Kit (Immunofluorescence Assay)
- 48 Testosterone Fast Test Kit (Immunofluorescence Assay)
- 49 E2 Fast Test Kit (Immunofluorescence Assay)
- 50 RF Fast Test Kit (Immunofluorescence Assay)
- 51 ASO Fast Test Kit (Immunofluorescence Assay)
- 52 Ferritin Fast Test Kit (Immunofluorescence Assay)
- 53 ST2 Fast Test Kit (Immunofluorescence Assay)
- 54 CA125 Fast Test Kit (Immunofluorescence Assay)
- 55 CA19-9 Fast Test Kit (Immunofluorescence Assay)
- 56 CA15-3 Fast Test Kit (Immunofluorescence Assay)
- 57 RSV/Influenza A/B Fast Test Kit (Immunofluorescence Assay)
- 58 Influenza A/B Fast Test Kit (Immunofluorescence Assay)
- 59 RSV Fast Test Kit (Immunofluorescence Assay)
- 60 IL-6 Fast Test Kit (Immunofluorescence Assay)
- 61 BNP Fast Test Kit (Immunofluorescence Assay)
- 62 SAA/CRP Fast Test Kit (Immunofluorescence Assay)
- 63 Folate acid Fast Test Kit (Immunofluorescence Assay)
- 64 hs-CRP Fast Test Kit (Immunofluorescence Assay)
- 65 TnT Fast Test Kit (Immunofluorescence Assay)
- 66 PCT/IL-6 Fast Test Kit (Immunofluorescence Assay)



- 67 HBP Fast Test Kit (Immunofluorescence Assay)
- 68 S100-β Fast Test Kit (Immunofluorescence Assay)
- 69 CK-MB/hs-cTnl/Myo Fast Test Kit (Immunofluorescence Assay)
- 70 Cortisol Fast Test Kit (Immunofluorescence Assay)
- 71 CEA Fast Test Kit (Immunofluorescence Assay)
- 72 AFP/CEA Fast Test Kit (Immunofluorescence Assay)

Classification Other device (according to Annex II of the directive 98/79/EC)

Conformity assessment route Annex III of the 98/79/EC

| | | | |
|--|---------------------|---------------------|---------------------|
| Applicable coordination standards | EN 13612:2002 | EN ISO 14971:2019 | EN ISO15223-1:2016 |
| | EN ISO 18113-1:2011 | EN ISO 18113-2:2011 | EN ISO 18113-3:2011 |
| | EN ISO 23640:2015 | EN ISO 13485:2016 | ISO 780:2015 |
| | EN 61326-2-6:2006 | IEC 61326-1:2013 | |
| | EN 61010-2-101:2002 | IEC 61010-1:2010 | |

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 I.

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 BSI Group The Netherlands B. V. The manufacturer is exclusively responsible for the declaration of conformity.

General Manager Enben Su

Nanjing
13th, May, 2022
 (place and date of issue)

 (name and signature or equivalent marking of authorized person)



CE

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:

Please see scope page.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2020-05-29

Latest Revision Date: 2023-04-26

Effective Date: 2023-07-26

Expiry Date: 2026-07-25

Page: 1 of 3



...making excellence a habit.™

Certificate No: **MD 728432**

Registered Scope:

Design & Development, Manufacture and Distribution of Chemiluminescence Immunoassay, Biochemistry Assay, Point of Care Assay (including Colloidal Gold Assay, Immunofluorescence Assay, Dry Chemistry Assay), PCR Assay and Colloidal Gold self-testing Assay to detect infectious disease. 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), PCR Assay to detect infectious disease, Immunofluorescence self-testing Assay to detect dyslipidemia disease, Blood Coagulation Assay to detect thrombotic disease.

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，传染病相关PCR分子诊断试剂和胶体金自测试剂。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，传染病相关PCR分子诊断试剂，血脂异常疾病相关免疫荧光自测试剂，血栓疾病相关血凝试剂配套使用的分析仪。



Original Registration Date: 2020-05-29

Latest Revision Date: 2023-04-26

Effective Date: 2023-07-26

Expiry Date: 2026-07-25

Page: 2 of 3

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.

An electronic certificate can be authenticated [online](#).

Printed copies can be validated at www.bsi-global.com/ClientDirectory or telephone +86 10 8507 3000.

Information and Contact: BSI, John M. Keynesplein 9, 1066 EP Amsterdam The Netherlands. Tel: +31 (0) 20 3460 780

BSI Group The Netherlands B.V., registered in the Netherlands under number 33264284, at John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands

A Member of the BSI Group of Companies.

Certificate No: **MD 728432**

| Location | Registered Activities |
|--|---|
| <p>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</p> | <p>Design & Development, Manufacture and Distribution of Chemiluminescence Immunoassay, Biochemistry Assay, Point of Care Assay (including Colloidal Gold Assay, Immunofluorescence Assay, Dry Chemistry Assay), PCR Assay and Colloidal Gold self-testing Assay to detect infectious disease. 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), PCR Assay to detect infectious disease, Immunofluorescence self-testing Assay to detect dyslipidemia disease, Blood Coagulation Assay to detect thrombotic disease.</p> <p>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, 传染病相关PCR分子诊断试剂和胶体金自测试剂。 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, 传染病相关PCR分子诊断试剂, 血脂异常疾病相关免疫荧光自测试剂, 血栓疾病相关血凝试剂配套使用的分析仪。</p> |
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Original Registration Date: 2020-05-29

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Latest Revision Date: 2023-04-26

Expiry Date: 2026-07-25

Page: 3 of 3

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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.





CA19-9 Fast Test Kit (Immunofluorescence Assay)

IF1080 for Getein 1100
IF5080 for Getein 1160
IF3080 for Getein 1180
IF2080 for Getein 1600
IF4080 for Getein 1200



Instructions for Use

INTENDED USE

CA19-9 Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of Cancer Antigen 19-9 (CA19-9) in serum, plasma or whole blood. The test is utilized for the adjunctive diagnosis of pancreatic cancer. For professional and laboratory use only.

SUMMARY

CA19-9 is a glycoprotein with a molecular weight ranging from approximately 200 to 1000 kDa. It is the most widely used biomarker for pancreatic cancer. CA19-9 holds significant clinical value in various aspects such as assisting in the diagnosis of pancreatic cancer, evaluating the efficacy of radiotherapy and chemotherapy, predicting prognosis, and determining overall survival. Furthermore, CA19-9 also possesses diagnostic significance for digestive system tumors like bile duct cancer and colorectal cancer. However, it should be noted that elevated levels of CA19-9 can also be attributed to other factors, such as benign lesions or inflammation in the gastrointestinal tract and liver. In clinical practice, CA19-9 is primarily utilized for dynamic monitoring in malignant tumor patients to assist in assessing disease progression and treatment efficacy. It is not recommended as a basis for early diagnosis or definitive diagnosis of malignant tumors, and it is not suitable for tumor screening in the general population.

PRINCIPLE

CA19-9 Fast Test Kit (Immunofluorescence Assay) is a lateral flow immunoassay in a sandwich design. After the sample has been applied to the test strip, the fluorescence labelled CA19-9 monoclonal antibody binds with the CA19-9 in sample and forms a marked antigen-antibody complex. The complex moves

to the test card detection zone by capillary action. Then marked antigen-antibody complex is captured on the test line by another CA19-9 monoclonal antibody. The fluorescence intensity of the test line increases in proportion to the amount of CA19-9 in sample. Fluorescent signals intensity can be analyzed by applicable device thus the CA19-9 in sample be detected quantitatively.

APPLICABLE DEVICE

Getein 1100 Immunofluorescence Quantitative Analyzer
Getein 1160 Immunofluorescence Quantitative Analyzer
Getein 1180 Immunofluorescence Quantitative Analyzer
Getein 1200 Immunofluorescence Quantitative Analyzer
Getein 1600 Immunofluorescence Quantitative Analyzer

CONTENTS

| Materials provided | Getein 1100/ Getein 1160/ Getein 1180 | | Getein 1200/Getein 1600 | |
|----------------------|---|----------|---|---|
| | 10 T/kit | 25 T/kit | 2*24 T/kit | 2*48 T/kit |
| CA19-9 test card* | 10 pcs | 25 pcs | 24 test cards in 1 cartridge, and 2 cartridges in 1 box | 48 test cards in 1 cartridge, and 2 cartridges in 1 box |
| Disposable pipet | 10 pcs | 25 pcs | / | / |
| Sample diluent** | 10 tube | 25 tube | 1 box | 1 box |
| Instructions for use | 1 pc | 1 pc | 1 pc | 1 pc |
| SD card | 1 pc | 1 pc | 1 pc in each cartridge | 1 pc in each cartridge |

*CA19-9 test card

A test card mainly consists of: Fluorescence labelled CA19-9 monoclonal antibody, CA19-9 monoclonal antibody and polyclonal IgG antibody.

** Sample diluent

(1) Sample diluent for Getein 1100/Getein 1160/Getein 1180 is 0.4 ml contained in each tube mainly consists of:

-Phosphate buffer (20 mmol/L), NaN₃ (<0.1%).

(2) Sample diluent for Getein 1200/Getein 1600 is an independent packing box mainly consists of:

-Phosphate buffer (20 mmol/L), NaN₃ (<0.1%) (25 mL/bottle for Getein 1200, 40 mL/bottle for Getein 1600),

-Box with pipette tips (96 tips/box),

-Mixing plate (1 piece/box).

Note:

- The standard curve data can be written to RFID card in the kit. According to the function of RFID card, we define it as "Standard Curve Data Card", short for "SD Card".
- Do not mix or interchange different batches of kits.

STORAGE AND STABILITY

Realtime stability:

Store the kit at 4~30°C with a valid period of 24 months. The test kits are stable until the expiry date printed on the labels.

In-use stability:

For the test card of Getein 1100/Getein 1160/Getein 1180: Use the test card within 1 hour once the foil pouch is opened.

For the test card of Getein 1200/Getein 1600: 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.

PRECAUTIONS

- For *in vitro* diagnostic use only.
- For professional and laboratory use only, not for near-patient test and self-testing.
- Do not use the test card if the foil pouch or the cartridge is damaged.
- Do not open pouches until performing the test.
- Handle all specimens as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.
- Carefully read and follow instructions for use to ensure proper test performance.

SPECIMEN COLLECTION AND PREPARATION

- Serum, plasma and whole blood can be used as samples in the assay.
- Heparin, sodium citrate and EDTA can be used as the anticoagulants for plasma and whole blood. Do not use hemolysis specimens.
- This assay is designed and validated for use with human blood, other specimens or body fluids may not get accurate

results.

- It is recommended to test the sample within 4 hours after collection. Stable in serum and plasma for 7 days when stored at 2~8°C and 6 months when stored at -20°C. Stable in whole blood for 3 days when stored at 2~8°C.
- Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.

TEST PROCEDURE

- User must carefully read and operate in strict accordance with the instructions for use before testing, otherwise reliable results cannot be guaranteed.
- Test kit and sample should be brought to room temperature before testing.

For Getein 1100:

- Confirm SD card lot No. in accordance with test kit lot No.. Perform "SD card" calibration when necessary.
- Select the corresponding "Sample" on the analyzer according to the sample type (see the user manual of analyzer for details).
- Remove the test card from the sealed pouch immediately before use and put the test card on a clean table, horizontally placed.
- Use disposable pipet or pipette, deliver 100 µL of sample into one tube of sample diluent, mix thoroughly. Then drop 100 µL of sample mixture into the sample well on the test card.
- Reaction time: **15 minutes**. After reaction time is elapsed, insert the test card into Getein 1100 and press "ENT" button or click on "Start" icon. The result will be shown on the screen and printed automatically.

For Getein 1160/Getein 1180:

- Confirm SD card lot No. in accordance with test kit lot No.. Perform "SD card" calibration when necessary.
- Select the corresponding "Sample" on the analyzer according to the sample type (see the user manual of analyzer for details).
- Remove the test card from the sealed pouch immediately before use and put the test card on a clean table, horizontally placed.
- Use disposable pipet or pipette, deliver 100 µL of sample into one tube of sample diluent, mix thoroughly. Then drop 100 µL

of sample mixture into the sample well on the test card.

5) Insert the test card into Getein 1160/Getein 1180 immediately after sample loading. The analyzer will count down the reaction time (**15 minutes**) and automatically test the card after reaction time is elapsed. The result will be shown on the screen and displayed automatically.

For Getein 1200/Getein 1600:

- Each cartridge for Getein 1200/Getein 1600 contains a specific RFID card which can calibrate automatically.
- Place the sample diluent at the correct position in Getein 1200/Getein 1600.
- Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein 1200/Getein 1600 will do the testing and print the result automatically.

LIMITATIONS

- As with all diagnostic tests, a definitive clinical diagnosis should not be made based on the result of a single test. The test results should be interpreted considering all other test results and clinical information such as clinical signs and symptoms.
- Some substances in blood as listed below may interfere with the test and cause erroneous results. The maximum allowance concentration of each is as follows:

| Interferent | Concentration (Max) |
|--------------|---------------------|
| Triglyceride | 400 mg/dL |
| Bilirubin | 60 mg/dL |
| Hemoglobin | 500 mg/dL |

EXPECTED VALUE

Statistical analysis of the results from measurements of 300 serum samples from apparently healthy individuals reveals that the entire dataset exhibits a non-normal distribution. Therefore, the 95th percentile for CA19-9 is estimated to be 27.0 U/mL, and the 99th percentile is estimated to be 39.0 U/mL using the percentile method.

It is recommended that each laboratory determine the applicability of the reference ranges through experimentation and establish their own laboratory-specific reference ranges if necessary.

PERFORMANCE CHARACTERISTICS















| | |
|-----------------------|-----------------|
| Measuring Range | 2.0~1000.0 U/mL |
| Lower Detection Limit | ≤2.0 U/mL |
| Within-Run Precision | ≤10% |
| Between-Lot Precision | ≤15% |

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DESCRIPTION OF SYMBOLS USED


The following graphical symbols used in or found on CA19-9 Fast Test Kit (Immunofluorescence Assay) are the most common ones appearing on medical devices and their packaging. They are explained in more detail in the European Standard EN ISO 15223-1:2021.

| Key to symbols used | | | |
|--|---|---|--|
|  | Manufacturer |  | Use-by date |
|  | Do not re-use |  | Date of manufacture |
|  | Consult instructions for use or consult electronic instructions for use |  | Batch code |
|  | Temperature limit |  | <i>In vitro</i> diagnostic medical device |
|  | Contains sufficient for <n> tests |  | Authorized representative in the European Community/European Union |
|  | CE mark |  | Do not use if package is damaged and consult instructions for use |
|  | Catalogue number |  | Caution |

Thank you for using CA19-9 Fast Test Kit (Immunofluorescence Assay). Please read the instructions for use carefully before operating to ensure proper use.

Version: WIF87-S-03

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CA125 Fast Test Kit (Immunofluorescence Assay)

IF1079 for Getein 1100
IF5075 for Getein 1160
IF3075 for Getein 1180
IF2079 for Getein 1600
IF4079 for Getein 1200



Instructions for Use

INTENDED USE

CA125 Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of Cancer Antigen 125 (CA125) in serum, plasma or whole blood samples. The test is indicated for use as an aid in the detection of ovarian carcinoma. For professional and laboratory use.

SUMMARY

CA125 is an antigen recognized by monoclonal antibodies generated by immunizing mice with ovarian serous cystadenocarcinoma cells, and it is also hybridized with myeloma cells. Due to the presence of certain mucin-like molecular characteristics in its amino acid sequence, it is named CA125. CA125 has a high detection rate in the serum of patients with non-mucinous epithelial ovarian tumors. It is not expressed in normal ovarian epithelial cells (in adults and fetuses). Ovarian cancer accounts for about 20% of gynecologic tumors, with an incidence rate of 15/100,000. CA125 can be detected in amniotic fluid and the body cavity epithelial cells of fetuses. It can also be present in the epithelial cells of the fallopian tubes, endometrium, and cervix in adults. Certain benign gynecologic diseases can cause elevated CA125 levels, such as ovarian cysts, ovarian endometriosis, endometriosis, uterine fibroids, and cervical inflammation. Although CA125 is a non-specific marker, it remains the most important biomarker for the diagnosis and prognosis of ovarian tumor patients.

PRINCIPLE

CA125 Fast Test Kit (Immunofluorescence Assay) is a lateral flow immunoassay in a sandwich design. After the sample has been applied to the test strip, the fluorescence latex-labelled CA125 monoclonal antibody binds with the CA125 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 CA125 monoclonal antibody. The fluorescence intensity of the test line increases in proportion to the amount of CA125 in sample. Fluorescent signals intensity can be analyzed by applicable device thus the CA125 in sample be detected quantitatively.

APPLICABLE DEVICE

Getein 1100 Immunofluorescence Quantitative Analyzer
Getein 1160 Immunofluorescence Quantitative Analyzer
Getein 1180 Immunofluorescence Quantitative Analyzer
Getein 1600 Immunofluorescence Quantitative Analyzer
Getein 1200 Immunofluorescence Quantitative Analyzer

CONTENTS

| Materials provided | Getein 1100/ Getein 1160/ Getein 1180 | | Getein 1200/ Getein 1600 | |
|----------------------|---|----------------|---|---|
| | 10 T/kit | 25 T/kit | 2*24 T/kit | 2*48 T/kit |
| CA125 test card* | 10 pcs | 25 pcs | 24 test cards in 1 cartridge, and 2 cartridges in 1 box | 48 test cards in 1 cartridge, and 2 cartridges in 1 box |
| Disposable pipet | 10 pcs | 25 pcs | / | / |
| Sample diluent** | 10*0.4 mL/tube | 25*0.4 mL/tube | 1 box | 1 box |
| Instructions for use | 1 pc | 1 pc | 1 pc | 1 pc |
| SD card | 1 pc | 1 pc | 1 pc in each cartridge | 1 pc in each cartridge |

*CA125 test card

A test card consists of: Fluorescence latex-labelled CA125 monoclonal antibody, CA125 monoclonal antibody and goat anti-mouse IgG antibody.

** Sample diluent

(1)Sample diluent for Getein 1100/ Getein 1160/ Getein 1180 is 0.4 mL contained in each tube consists of:

-Sample diluent contains phosphate buffer (20 mmol/L), Na₃ (<0.1%).

(2)Sample diluent for Getein 1200/ Getein 1600 is an independent packing box consists of:

-Sample diluent contains phosphate buffer (20 mmol/L), Na₃ (<

<0.1%) (25 mL/bottle for Getein 1200, 40 mL/bottle for Getein 1600)

***Other Materials required for Getein 1200/Getein 1600:

- (1) Box with pipette tips (96 tips/box),
- (2) Mixing plate (1 piece/box).

Note:

1. The standard curve data can be written to RFID card in the kit. According to the function of RFID card, we define it as "Standard Curve Data Card", short for "SD Card".
2. Do not mix or interchange different batches of kits.

STORAGE AND STABILITY

Realtime stability:

Store the kit at 4~30°C with a valid period of 24 months. The test kits are stable until the expiry date printed on the labels.

In-use stability:

For the test card of Getein 1100/ Getein 1160/Getein 1180: Use the test card within 1 hour once the foil pouch is opened.

For the test card of Getein 1200/Getein 1600: 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.

PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. For professional and laboratory use only, not for near-patient test and self-testing.
3. Do not use the test card if the foil pouch or the cartridge is damaged.
4. Do not open pouches until performing the test.
5. Handle all specimens as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.
6. Carefully read and follow instructions for use to ensure proper test performance.

SPECIMEN COLLECTION AND PREPARATION

1. Serum, plasma and whole blood can be used as samples in the assay.
2. Heparin, sodium citrate can be used as the anticoagulants for

- plasma and whole blood. Do not use hemolysis specimens.
3. This assay is designed and validated for use with human blood, other specimens or body fluids may not get accurate results.
 4. It is recommended to test the sample within 4 hours after collection. Stable in serum and plasma for 7 days when stored at 2~8°C and 6 months when stored at -20°C. Stable in whole blood for 3 days when stored at 2~8°C.
 5. Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.

TEST PROCEDURE

1. User must carefully read and operate in strict accordance with the instructions for use before testing, otherwise reliable results cannot be guaranteed.
2. Test kit and sample should be brought to room temperature before testing.

For Getein 1100:

- 1) Confirm SD card lot No. in accordance with test kit lot No. Perform "SD card" calibration when necessary.
- 2) Select the corresponding "Sample" on the analyzer according to the sample type (see the instructions of analyzer for details).
- 3) Remove the test card from the sealed pouch immediately before use and put the test card on a clean table, horizontally placed.
- 4) Use disposable pipet or pipette, deliver 100 µL of sample into one tube of sample diluent, mix thoroughly. Then drop 100 µL of sample mixture into the sample well on the test card.
- 5) Reaction time: **15 minutes**. After reaction time is elapsed, insert the test card into Getein 1100 and press "ENT" button or click on "Start" icon. The result will be shown on the screen and printed automatically.

For Getein 1160/Getein 1180:

- 1) Confirm SD card lot No. in accordance with test kit lot No. Perform "SD card" calibration when necessary.
- 2) Select the corresponding "Sample" on the analyzer according to the sample type (see the instructions of analyzer for details).
- 3) Remove the test card from the sealed pouch immediately before use and put the test card on a clean table, horizontally

- placed.
- Use disposable pipet or pipette, deliver 100 μ L of sample into one tube of sample diluent, mix thoroughly. Then drop 100 μ L of sample mixture into the sample well on the test card.
 - Insert the test card into Getein 1160/Getein 1180 immediately after sample loading. The analyzer will count down the reaction time (15 minutes) and automatically test the card after reaction time is elapsed. The result will be shown on the screen and displayed automatically.

For Getein 1200/Getein 1600:

- Each cartridge for Getein 1200/Getein 1600 contains a specific RFID card which can calibrate automatically.
- Place the sample diluent at the correct position in Getein 1200/Getein 1600.
- Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein 1200/Getein 1600 will do the testing and print the result automatically.

LIMITATIONS

- The test results of this reagent are for clinical reference only, and cannot be used as the basis for diagnosis or exclusion of cases alone additional tests should be performed accordingly.
- Some substances in blood as listed below may interfere with the test and cause erroneous results. The maximum allowance concentration of each is as follows:

| Interferent | Concentration (Max) |
|--------------|---------------------|
| Triglyceride | 400 mg/dL |
| Bilirubin | 60 mg/dL |
| Hemoglobin | 500 mg/dL |

EXPECTED VALUE

Statistical analysis of the results from measurements of 500 serum samples from apparently healthy individuals reveals that the entire dataset exhibits a non-normal distribution. Therefore, the 95th percentile for the CA 125 is estimated to be 35.0 U/mL. The reference ranges for plasma and whole blood samples are the same as those for serum samples. It is recommended that each laboratory determine the applicability of the reference ranges through experimentation and establish their own laboratory-specific reference ranges if necessary.

PERFORMANCE CHARACTERISTICS














| | |
|-----------------------|-----------------|
| Measuring Range | 2.0~500.0 U/mL |
| Lower Detection Limit | \leq 2.0 U/mL |
| Within-Run Precision | \leq 10% |
| Between-Run Precision | \leq 15% |

REFERENCES

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DESCRIPTION OF SYMBOLS USED


The following graphical symbols used in or found on CA125 Fast Test Kit (Immunofluorescence Assay) are the most common ones appearing on medical devices and their packaging. They are explained in more detail in the European Standard EN ISO 15223-1:2021.

| Key to symbols used | | | |
|--|---|---|--|
|  | Manufacturer |  | Use-by date |
|  | Do not re-use |  | Date of manufacture |
|  | Consult instructions for use or consult electronic instructions for use |  | Batch code |
|  | Temperature limit |  | In vitro diagnostic medical device |
|  | Contains sufficient for <n> tests |  | Authorized representative in the European Community/European Union |
|  | CE mark |  | Do not use if package is damaged and consult instructions for use |
|  | Catalogue number | | |

Thank you for using CA125 Fast Test Kit (Immunofluorescence Assay). Please read this instructions for use carefully before operating to ensure proper use.

Version: WIF86-S-01

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CEA

Fast Test Kit

(Immunofluorescence Assay)

Instructions for Use

INTENDED USE

CEA Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of carcinoembryonic antigen (CEA) in serum or plasma samples. The test is used as an aid in the diagnosis and management of cancer patients. For professional and laboratory use only.

This test can NOT be used to guide the diagnosis of pair trisomy 21.

SUMMARY

CEA is a glycosylated molecule with a molecular weight of approximately 180,000 Daltons. CEA (Carcinoembryonic Antigen) is synthesized by epithelial tissues of the fetal gastrointestinal tract, pancreas, and liver cells. Typically, the levels of CEA increase during the first six months of pregnancy and become very low in the serum after birth. CEA is a non-organ-specific tumor-associated antigen, and tumors that secrete CEA are mostly located in hollow organs such as the gastrointestinal tract, respiratory tract, and urinary tract. Normally, CEA is metabolized by the gastrointestinal tract, but in the presence of tumors, CEA enters the blood and lymphatic circulation, causing abnormally high serum CEA levels. This results in elevated serum CEA in patients with various types of tumors mentioned above.

Clinically, when CEA exceeds 60 µg/L, it can be seen in colon cancer, rectal cancer, gastric cancer, and lung cancer. Elevated CEA levels indicate the presence of residual or progressive lesions. For patients with lung cancer, breast cancer, bladder cancer, and ovarian cancer, serum CEA levels significantly increase, mostly indicating tumor infiltration, with about 70% being metastatic cancers. Generally, CEA levels return to normal 6 weeks after surgical resection; otherwise, it suggests

the presence of residual tumor. If the CEA concentration continuously increases or its value exceeds the normal range by 5-6 times, it indicates a poor prognosis.

PRINCIPLE

CEA Fast Test Kit (Immunofluorescence Assay) is a lateral flow immunoassay in a sandwich design. After sample has been applied to the test strip, the fluorescence labelled CEA monoclonal antibody binds with the CEA in sample and forms marked antibody-antigen complex. The complex moves to the detection zone by capillary action. Then marked antigen-antibody complex is captured on the test line by another CEA monoclonal antibody. The fluorescence intensity of the test line increases in proportion to the amount of CEA antigen in the sample. Fluorescent signals intensity can be analyzed by applicable device thus the CEA in sample be detected quantitatively.

CONTENTS

| Materials provided | Getein 1100/Getein 1160/Getein 1180 | | Getein 1150 | | Getein 1200/Getein 1600 | | |
|----------------------|-------------------------------------|----------|-------------|----------|------------------------------|------------------------------|------------------------------|
| | 10 T/kit | 25 T/kit | 10 T/kit | 25 T/kit | 2×12 T/kit | 2×24 T/kit | 2×48 T/kit |
| CEA test card | 10 pcs | 25 pcs | 10 pcs | 25 pcs | 2 cartridges, 12 pcs in each | 2 cartridges, 24 pcs in each | 2 cartridges, 48 pcs in each |
| Disposable pipet | 10 pcs | 25 pcs | 10 pcs | 25 pcs | / | / | / |
| Sample diluent | 10 tubes | 25 tubes | 10 tubes | 25 tubes | 1 box | 1 box | 1 box |
| Instructions for use | 1 pc | 1 pc | 1 pc | 1 pc | 1 pc | 1 pc | 1 pc |
| SD card | 1 pc | 1 pc | / | / | 1 pc in each cartridge | 1 pc in each cartridge | 1 pc in each cartridge |

1) Main key components in the kit

- Fluorescence labelled CEA monoclonal antibody and CEA monoclonal antibody.

2) Main key components in Sample diluent for Getein 1100/Getein 1150/Getein 1160/Getein 1180

- Phosphate buffer (20 mmol/L), NaN₃ (< 0.1%).

3) Main key components in Sample diluent for Getein 1600/Getein 1200

- Phosphate buffer (20 mmol/L), NaN₃ (< 0.1%) (25 mL/bottle for Getein 1200, 40 mL/bottle for Getein 1600);

- Box with pipette tips (96 tips/box);

- Mixing plate (1 piece/box).

Note:

- The SD card, also known as the standard curve data card, stores standard curve data for the specific test items and uses RFID technology to transfer the data to analyzers via touch.
- The standard curve data for Getein 1150 is written to the QR code on the outer packaging box.
- Do not mix or interchange different batches of kits.

APPLICABLE DEVICES

Getein 1100 Immunofluorescence Quantitative Analyzer
 Getein 1150 Immunofluorescence Quantitative Analyzer
 Getein 1160 Immunofluorescence Quantitative Analyzer
 Getein 1180 Immunofluorescence Quantitative Analyzer
 Getein 1200 Immunofluorescence Quantitative Analyzer
 Getein 1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Realtime stability:

Store the kit at 4–30°C with a valid period of 24 months. The test kits are stable until the expiry date printed on the labels.

In-use stability:

For the test card of Getein 1100/Getein 1150/Getein 1160/Getein 1180: Use the test card within 1 hour once the foil pouch is opened.

For test card of Getein 1200/Getein 1600: 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.

PRECAUTIONS

- For *in vitro* diagnostic use only.
- For professional and laboratory use only, not for near-patient test and self-testing.
- Do not use the test card if the foil pouch or the cartridge is damaged.
- Do not open pouches until performing the test.
- Do not reuse the test card and disposable pipet.
- Handle all specimens as potentially infectious. The foil bag is

non-degradable. Proper handling and disposal methods should be followed in accordance with local regulations.

- It is recommended that operators take necessary self-protection measures (work clothes and disposable gloves, etc) when touching kits or samples.

SPECIMEN COLLECTION AND PREPARATION

- This test can be used for serum and plasma samples. Heparin, sodium citrate and EDTA can be used as the anticoagulant for plasma. Samples should be free of hemolysis.
- The test should be performed within 4 hours after blood collection.
- If testing is delayed, serum and plasma samples may be stored up to 7 days at 2–8°C or stored at -20°C for 6 months before testing.
- Refrigerated or frozen sample should be reached to room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
- SAMPLE VOLUME (for Getein 1100/Getein 1150/Getein 1160/Getein 1180):** 100 µL.

TEST PROCEDURE

- User must carefully read and operate in strict accordance with the instructions for use before testing, otherwise reliable results cannot be guaranteed.
- Test kit and sample should be brought to room temperature before testing.

For Getein 1100:

- Confirm SD card lot No. in accordance with test kit lot No. It is required to perform "SD card" calibration when using a new batch of kits.
- Select the corresponding "Sample" on the analyzer according to the sample type (see the user manual of analyzer for details).
- Remove the test card from the sealed pouch before use. Horizontally place the test card.
- Deliver **100 µL** of sample into one tube of sample diluent using disposable pipet or pipette, mix gently and thoroughly. Then drop **100 µL** of sample mixture into the sample well on the test card.
- Reaction time: 15 minutes.** After reaction time is elapsed, insert the test card into Getein 1100 and press "ENT" button

(click on "Start" icon for Android Getein 1100). The result will be shown on the screen and printed automatically.

For Getein 1160/Getein 1180:

- 1) Confirm SD card lot No. in accordance with test kit lot No. It is required to perform "SD card" calibration when using a new batch of kits.
- 2) Select the corresponding "Sample" on the analyzer according to the sample type (see the user manual of analyzer for details).
- 3) Remove the test card from the sealed pouch before use. Horizontally place the test card.
- 4) Deliver **100 µL** of sample into one tube of sample diluent using disposable pipet or pipette, mix gently and thoroughly. Then drop **100 µL** of sample mixture into the sample well on the test card.
- 5) Insert the test card into Getein 1160/Getein 1180 **immediately** after sample loading. The analyzer will count down the reaction time (15 minutes) and automatically test the card after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein 1150:

- 1) Turn on the instrument and enter the sample test interface. Insert the test card and scan the QR code (**On the outer packaging box**) to complete calibration as prompted by the instrument.
- 2) Select the corresponding "Sample" mode on the analyzer (refer to the analyzer user manual for details).
- 3) Deliver **100 µL** of sample into one tube of sample diluent using disposable pipet or pipette, mix gently and thoroughly. Then drop **100 µL** of sample mixture into the sample well on the test card.
- 4) Press the "Start" button immediately after sample loading. The analyzer will initiate a 15-minute reaction countdown, and the test results will be automatically displayed on the screen upon completion.

For Getein 1200/Getein 1600:

- 1) Place the reagent cartridge in the cartridge zone. Each cartridge for Getein 1200/Getein 1600 contains a specific RFID card (SD card) which can calibrate automatically.
- 2) Place the sample diluent at the correct position in Getein 1200/Getein 1600.
- 3) Place samples in the designed area of the sample holder, insert the holder, set parameters (more operational details

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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. Dilute the sample which concentration is higher than the upper limit with sample diluent, and the recommended dilution ratio is less than 5 times.
3. Interferents in samples may influence the results. The table below listed the maximum allowance of these potential interferents.

| Interferent | Triglyceride | Bilirubin |
|---------------------|--------------|-----------|
| Concentration (Max) | 1000 mg/dL | 20 mg/dL |

EXPECTED VALUE

The expected normal value for CEA was determined by testing samples from 1000 apparently healthy individuals. The 95th percentile of CEA is 4.7 ng/mL.

Each laboratory should verify the transferability of the expected values to its own population, and if necessary, determine its own expected values according to good laboratory practice.

PERFORMANCE CHARACTERISTICS

| | |
|-----------------------|-----------------|
| Measuring Range | 2.0–500.0 ng/mL |
| Limit of Detection | ≤ 2.0 ng/mL |
| Within-Run Precision | ≤ 10% |
| Between-Lot Precision | ≤ 15% |


















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5. Das S, Kaushik S. Cancer antigen 125 (CA 125) and carcinoembryonic antigen (CEA) ratio can identify different stages of ovarian cancer preoperatively [J]. Clinica Chimica Acta, 2019, 493 (Supl.1): S116-S116.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on CEA 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 ISO 15223-1:2021.

| Key to symbols used | | | |
|--|---|---|---|
|  | Manufacturer |  | Use-by date |
|  | Do not re-use |  | Date of manufacture |
|  | Consult instructions for use or consult electronic instructions for use |  | Batch code |
|  | Temperature limit |  | <i>In vitro</i> diagnostic medical device |
|  | Contains sufficient for <n> tests |  | Authorized representative |
|  | CE mark |  | Do not use if package is damaged and consult instructions for use |
|  | Catalogue number |  | Keep dry |
|  | Keep away from sunlight |  | Caution |
|  | Unique device identifier | | |

Thank you for using CEA Fast Test Kit (Immunofluorescence Assay). Please read the instructions for use carefully before operating to ensure proper use.



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CMC Medical Devices & Drugs S.L.

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Tel: +34951214054

| Catalogue number | Applicable analyzer | Package specification |
|------------------|---------------------|-----------------------|
| IF1051-10T | Getein 1100 | 10 T/kit |
| IF1051 | Getein 1100 | 25 T/kit |
| IF8051-10T | Getein 1150 | 10 T/kit |
| IF8051 | Getein 1150 | 25 T/kit |
| IF5051-10T | Getein 1160 | 10 T/kit |
| IF5051 | Getein 1160 | 25 T/kit |
| IF3051-10T | Getein 1180 | 10 T/kit |
| IF3051 | Getein 1180 | 25 T/kit |
| IF2051-24T | Getein 1200 | 2×12 T/kit |
| IF2051 | Getein 1200 | 2×24 T/kit |
| IF2051-96T | Getein 1200 | 2×48 T/kit |
| IF4051-24T | Getein 1600 | 2×12 T/kit |
| IF4051 | Getein 1600 | 2×24 T/kit |
| IF4051-96T | Getein 1600 | 2×48 T/kit |



D-Dimer Fast Test Kit (Immunofluorescence Assay)

User Manual

INTENDED USE

D-Dimer Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of D-Dimer in human plasma or whole blood samples. The test is used as an aid in the exclusion of deep vein thrombosis (DVT) and pulmonary embolism (PE) disease in patient suspected of DVT or PE, and an aid in the diagnosis of disseminated intravascular coagulation (DIC).

For professional and laboratory use only.

SUMMARY

Thrombin converts fibrinogen to soluble fibrin by cleaving the fibrinopeptides A and B. The fibrin monomers polymerize spontaneously. Active factor XIII links two D domains and generates a solid fibrin clot. A new plasmin resistant antigenic determinant (D-dimer) is produced. Fragments containing D-dimer are accordingly formed during the degradation of a fibrin clot by plasmin. D-dimer antigens are specific markers of fibrin clot formation and fibrinolysis and may be clinically useful markers for excluding venous thromboembolism.

The primary diagnostic application of D-dimer testing is to rule out thromboembolic events, such as deep vein thrombosis or pulmonary embolism. If the D-dimer test result is below the decision threshold, a thromboembolic event can be ruled out by the negative predictive value (NPV) of the test. The D-dimer test, in combination with a well-validated preclinical trial probability score, is an effective and safe screening tool to rule out thromboembolic events. However, the presence of symptoms over a certain period of time, such as more than one week, may yield normal D-dimer values. Fibrin degradation products are a sensitive marker in disseminated intravascular coagulation (DIC).

In addition to DVT, PE and DIC, D-dimers may reflect other causes associated with fibrin formation, such as age, pregnancy complications, malignant disease or vascular

abnormalities. Therefore, elevated D-Dimer levels should be interpreted in the context of possible underlying disease and clinical symptoms.

PRINCIPLE

D-Dimer Fast Test Kit (Immunofluorescence Assay) is a lateral flow immunoassay in a sandwich design. After the sample has been applied to the test strip, the fluorescence labelled 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 D-Dimer monoclonal antibody. The fluorescence intensity of the test line increases in proportion to the amount of D-Dimer in sample. Fluorescent signals intensity can be analyzed by applicable device thus the D-Dimer in sample be detected quantitatively.

CONTENTS

| Materials provided | Getein 1100/ Getein 1150/ Getein 208 | | Getein 1150 | | Getein 1200/Getein 1600 | | |
|----------------------|--|----------|-------------|----------|---------------------------------|---------------------------------|---------------------------------|
| | 10 T/kit | 25 T/kit | 10 T/kit | 25 T/kit | 2×12 T/kit | 2×24 T/kit | 2×48 T/kit |
| D-Dimer test card* | 10 pcs | 25 pcs | 10 pcs | 25 pcs | 2 cartridges, 12 pcs in each | 2 cartridges, 24 pcs in each | 2 cartridges, 48 pcs in each |
| Disposable pipet | 10 pcs | 25 pcs | 10 pcs | 25 pcs | / | / | / |
| Sample diluent** | 10 tubes | 25 tubes | 10 tubes | 25 tubes | 1 box | 1 box | 1 box |
| Instructions for use | 1 pc | 1 pc | 1 pc | 1 pc | 1 pc | 1 pc | 1 pc |
| SD card | 1 pc | 1 pc | / | / | 1 pc in each cartridge | 1 pc in each cartridge | 1 pc in each cartridge |

* D-Dimer test card

A test card mainly consists of: Fluorescence labelled D-Dimer monoclonal antibody and D-Dimer monoclonal antibody.

** Sample diluent

(1) Sample diluent for Getein 1100/Getein 1150/Getein 1160/Getein 1180/Getein 208 in each tube mainly consists of: phosphate buffer, NaN₃ (< 0.1%).

(2) Sample diluent for Getein 1200/Getein 1600 is an independent packing box mainly consists of:

- phosphate buffer, NaN₃ (< 0.1%) (25 mL/bottle for Getein 1200, 40 mL/bottle for Getein 1600),

- Box with pipette tips (96 tips/box),

- Mixing plate (1 piece/box).

Note:

- The SD card, also known as the standard curve data card, stores standard curve data for the specific test items and uses RFID technology to transfer the data to analyzers via touch.
- The standard curve data for Getein 1150 is written to the QR code on the outer packaging box.
- Do not mix or interchange different batches of kits.

APPLICABLE DEVICE

Getein 1100 Immunofluorescence Quantitative Analyzer
Getein 1150 Immunofluorescence Quantitative Analyzer
Getein 1160 Immunofluorescence Quantitative Analyzer
Getein 1180 Immunofluorescence Quantitative Analyzer
Getein 1200 Immunofluorescence Quantitative Analyzer
Getein 1600 Immunofluorescence Quantitative Analyzer
Getein 208 Hand-held Integrated System

STORAGE AND STABILITY

Realtime stability:

Store the kit at 4–30°C with a valid period of 24 months. The test kits are stable until the expiry date printed on the labels.

In-use stability:

For the test card of Getein 1100/Getein 1150/Getein 1160/Getein 1180/Getein 208: Use the test card within 1 hour once the foil pouch is opened.

For test card of Getein 1200/Getein 1600: 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.

PRECAUTIONS

- For *in vitro* diagnostic use only.
- For professional and laboratory use only, not for near-patient test and self-testing.
- Do not use the test card if the foil pouch or the cartridge is damaged.
- Do not open pouches until performing the test.
- Do not reuse the test card and disposable pipet.
- Handle all specimens as potentially infectious. The foil bag is non-degradable. Proper handling and disposal methods should be followed in accordance with local regulations.
- It is recommended that operators take necessary self-protection measures (work clothes and disposable gloves, etc) when touching kits or samples.

SPECIMEN COLLECTION AND PREPARATION

- 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.
- Suggest using plasma for better results.
- Plasma are stable for 4 hours at room temperature (15–30°C), 3 days at 2–8°C, and 1 month at -20°C.
- Whole blood and fingertip blood are stable for 4 hours at room temperature (15–30°C), 3 days at 2–8°C and avoid cryopreservation.
- Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.

TEST PROCEDURE

- User must carefully read and operate in strict accordance with the instructions for use before testing, otherwise reliable results cannot be guaranteed.
- Test kit and sample should be brought to room temperature before testing.

For Getein 1100:

- Confirm SD card lot No. in accordance with test kit lot No. It is required to perform "SD card" calibration when using a new batch of kits.
- Select the corresponding "Sample" on the analyzer according to the sample type (see the user manual of analyzer for details).
- Remove the test card from the sealed pouch before use. Horizontally place the test card.
- Deliver 100 µL of sample into one tube of sample diluent using disposable pipet or pipette, mix gently and thoroughly. Then drop 100 µL of sample mixture into the sample well on the test card.
- Reaction time: 10 minutes.** After reaction time is elapsed, insert the test card into Getein 1100 and press "ENT" button (click on "Start" icon for Android Getein 1100). The result will be shown on the screen and printed automatically.

For Getein 1160/Getein 1180:

- Confirm SD card lot No. in accordance with test kit lot No. It is required to perform "SD card" calibration when using a new batch of kits.
- Select the corresponding "Sample" on the analyzer according to the sample type (see the user manual of analyzer for details).
- Remove the test card from the sealed pouch before use. Horizontally place the test card.

4) Deliver 100 µL of sample into one tube of sample diluent using disposable pipet or pipette, mix gently and thoroughly. Then drop 100 µL of sample mixture into the sample well on the test card.

5) Insert the test card into Getein 1160/Getein 1180 **immediately** after sample loading. The analyzer will count down the reaction time (10 minutes) and automatically test the card after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein 1150:

1) Turn on the instrument and enter the sample test interface. Insert the test card and scan the QR code (**On the outer packaging box**) to complete calibration as prompted by the instrument.

2) Select the corresponding “Sample” mode on the analyzer (refer to the analyzer user manual for details).

3) Deliver 100 µL of sample into one tube of sample diluent using disposable pipet or pipette, mix gently and thoroughly. Then drop 100 µL of sample mixture into the sample well on the test card.

4) Press the “Start” button immediately after sample loading. The analyzer will initiate a 10-minute reaction countdown, and the test results will be automatically displayed on the screen upon completion.

For Getein 208:

1) Enter testing interface of Getein 208. Confirm SD card lot No. in accordance with test kit lot No. Read the relevant information in the SD card for calibration.

2) Select the corresponding “Sample” mode on the analyzer (refer to the analyzer user manual for details). Insert test card according to the analyzer prompts.

3) Deliver 60 µL of sample into one tube of sample diluent using disposable pipet or pipette, mix gently and thoroughly. Then drop 60 µL of sample mixture into the sample well on the test card according to the analyzer prompts.

4) After sample adding, the analyzer will initiate a 10-minute reaction countdown, and the test results will be automatically displayed on the screen upon completion.

For Getein 1200/Getein 1600:

1) Each cartridge for Getein 1200/Getein 1600 contains a specific RFID card (SD card) which can calibrate automatically.

2) Place the sample diluent at the correct position in Getein 1200/Getein 1600.

3) Place samples in the designated area of the sample holder, insert the holder, set parameters (more operational details refer to the user manual of analyzer) and run the instrument,

Getein 1200/Getein 1600 will do the testing and print the result automatically.

LIMITATIONS

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

- Patient samples may contain heterophilic antibodies (e.g. human anti-mouse antibodies (HAMA) and rheumatoid factors) that could react in immunoassays to give a falsely elevated or depressed result. This assay has been designed to minimize interference from heterophilic antibodies. Nevertheless, complete elimination of this interference from all patient specimens cannot be guaranteed.

EXPECTED VALUE

The expected value for D-Dimer was determined by testing samples from 500 apparently healthy individuals. The 95th percentile of the concentration for D-Dimer is 0.50 mg/L. Each laboratory should verify the transferability of the expected values to its own population, and if necessary, determine its own expected values according to good laboratory practice.

PERFORMANCE CHARACTERISTICS

| | |
|-----------------------|----------------|
| Measuring Range | 0.10–10.0 mg/L |
| Limit of Detection | ≤ 0.10 mg/L |
| Within-Run Precision | ≤ 10% |
| Between-Lot Precision | ≤ 15% |

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5. EN ISO 18113-1:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.

6. 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.

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 ISO 15223-1:2021.

| Key to symbols used | | | |
|---------------------|---|--|---|
| | Manufacturer | | Use-by date |
| | Do not re-use | | Date of manufacture |
| | Consult instructions for use or consult electronic instructions for use | | Batch code |
| | Temperature limit | | In vitro diagnostic medical device |
| | Contains sufficient for <n> tests | | Authorized representative |
| | CE mark | | Do not use if package is damaged and consult instructions for use |
| | Catalogue number | | Keep dry |
| | Keep away from sunlight | | Caution |
| | Unique device identifier | | |

Thank you for using D-Dimer Fast Test Kit (Immunofluorescence Assay). Please read the instructions for use carefully before operating to ensure proper use.

Willbrandt 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.
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 Tel: +34951214054

| Catalogue number | Applicable analyzer | Package specification |
|------------------|---------------------|-----------------------|
| IF1006-10T | Getein 1100 | 10 T/kit |
| IF1006 | Getein 1100 | 25 T/kit |
| IF8006-10T | Getein 1150 | 10 T/kit |
| IF8006 | Getein 1150 | 25 T/kit |
| IF5006-10T | Getein 1160 | 10 T/kit |
| IF5006 | Getein 1160 | 25 T/kit |
| IF3006-10T | Getein 1180 | 10 T/kit |
| IF3006 | Getein 1180 | 25 T/kit |
| IF6006-10T | Getein 1200 | 10 T/kit |
| IF6006 | Getein 208 | 25 T/kit |
| IF4006-24T | Getein 1200 | 2×12 T/kit |
| IF4006 | Getein 1200 | 2×24 T/kit |
| IF4006-96T | Getein 1200 | 2×48 T/kit |
| IF2006-24T | Getein 1600 | 2×12 T/kit |
| IF2006 | Getein 1600 | 2×24 T/kit |
| IF2006-96T | Getein 1600 | 2×48 T/kit |



IVD

fPSA Fast Test Kit

(Immunofluorescence Assay)

IF1072 for Getein 1100
 IF5072 for Getein 1160
 IF3072 for Getein 1180
 IF2072 for Getein 1600
 IF4072 for Getein 1200

REF

Instructions for Use

INTENDED USE

fPSA Fast Test Kit (Immunofluorescence Assay) is intended for in vitro quantitative determination of free PSA in human serum and plasma samples. It is mainly used for dynamic monitoring of patients with malignant tumors to assist in judging the disease process or treatment effect. It cannot be used as a basis for early diagnosis of malignant tumors, and is not suitable for tumor screening in the general population.

This assay is intended to be used in conjunction with the Getein total PSA test as an aid in distinguishing prostate cancer from benign prostatic conditions in men age 50 years or older who have a digital rectal examination (DRE) that is not suspicious for prostate cancer and the Getein total PSA value between 4 ng/mL and 10 ng/mL.

SUMMARY

Prostate-specific antigen (PSA) is a single-chain glycoprotein with molecular weight of 34 kilodaltons. As a serine protease with chymotrypsin-like activity, PSA belongs to the kallikrein family. PSA exists as a free or complex form with protease inhibitors such as α -1-antichymotrypsin (ACT) in blood. PSA is produced mainly by the glandular epithelium of the prostate and is secreted into the seminal fluid in high concentrations. Low levels of PSA are found in the blood as a result of leakage of PSA from the prostate gland. The function of PSA is the proteolytic cleavage of gel forming proteins in the seminal fluid resulting in liquification of the seminal gel and increased sperm mobility.

PSA tests lack sufficient sensitivity and specificity to be considered ideal or absolutely diagnostic for screening or early detection because PSA is not specific for prostate cancer. PSA is organ specific, but has long been known to

be elevated in non-malignant conditions such as benign prostatic hyperplasia (BPH). A number of studies have found that the percent of free PSA was significantly lower in patients having prostate cancer than those with benign disease or normal controls. The ratio fPSA/tPSA has subsequently been demonstrated to improve the sensitivity and specificity in patients with tPSA values in the "gray zone" of 4-10 ng/mL.

An equimolar tPSA determination is the prerequisite for reliable ratios. In patients receiving therapy, particularly hormone withdrawal therapy, the fPSA/tPSA ratio cannot be utilized to differentiate prostate hyperplasia from cancer of the prostate. Combining tests from different manufacturers to determine tPSA and fPSA can produce erroneous values, since total PSA tests may be standardized by differing methods or detect free PSA to differing degrees.

PRINCIPLE

The test uses an anti-human fPSA monoclonal antibody I conjugated with fluorescence latex coated on the junction of nitrocellulose membrane and sample pad, and another fPSA monoclonal antibody II coated on the test line. After the sample has been applied to the test strip, the fluorescence latex-labelled anti-human fPSA antibody I binds with fPSA in sample and forms a marked antigen-antibody complex. This complex moves to the test detection zone by capillary action. Then marked antigen-antibody complex is captured on the test line by anti-human fPSA antibody II. The fluorescence intensity of test line increases in proportion to the amount of fPSA in sample.

Then insert test card into Getein 1100/Getein 1160/Getein 1180 Immunofluorescence Quantitative Analyzer/Automatically inserted by Getein 1200/Getein 1600 Immunofluorescence Quantitative Analyzer (hereafter referred to as Getein 1100, Getein 1160, Getein 1180, Getein 1200 and Getein 1600), the concentration of fPSA in sample will be measured and displayed on the screen. The value will be stored in Getein 1100/Getein 1160/Getein 1180/Getein 1200/Getein 1600 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

CONTENTS

1. A kit for Getein 1100/Getein 1160/Getein 1180 contains:
 Package specifications: 25 tests/kit, 10 tests/kit

- 1) Getein fPSA test card in a sealed pouch with desiccant
- 2) Disposable pipet
- 3) Sample diluent
- 4) Instructions for use: 1 piece/kit
- 5) SD card: 1 piece/kit

2. A kit for Getein 1200/Getein 1600 contains:

Package specifications: 2x24 tests/kit, 2x48 tests/kit
 Sealed cartridge with 24/48 Getein fPSA test cards
 Instructions for use: 1 piece/kit

Materials required for Getein 1200/Getein 1600:

- 1) Sample diluent: 1 bottle/kit
- 2) Box with pipette tips: 96 tips/kit
- 3) Mixing plate: 1 piece/kit

3. Sample diluent composition:

Phosphate buffered saline, protein stabilizer and surfactant.

4. A test card consists of:

A plastic shell and a reagent strip which is composed of a sample pad (the junction of sample pad and nitrocellulose membrane is coated with fluorescence latex-labeled anti-human fPSA monoclonal antibody I), nitrocellulose membrane (the test line is coated with another anti-human fPSA monoclonal antibody II and the control line is coated with goat anti-mouse IgG antibody), absorbent paper and liner.

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

APPLICABLE DEVICE

Getein 1100 Immunofluorescence Quantitative Analyzer
 Getein 1160 Immunofluorescence Quantitative Analyzer
 Getein 1200 Immunofluorescence Quantitative Analyzer
 Getein 1180 Immunofluorescence Quantitative Analyzer
 Getein 1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Store the test kit at 4~30°C with a valid period of 24 months.

Use the test card for Getein 1100/Getein 1160/Getein 1180 within 1 hour once the foil pouch is opened.

For test card of Getein 1200/Getein 1600: 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.

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 instructions for use to ensure proper test performance.

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for **serum and plasma samples**, other bodily fluids may cause incorrect or inaccurate results.
2. **Heparin, sodium citrate and EDTA** can be used as the anticoagulant for plasma. Samples should be free of hemolysis.
3. The test should be performed within 4 hours after blood collection. If testing is delayed, serum and plasma samples may be stored up to 5 days at 2~8°C or stored at -20°C for 6 months before testing.
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 or hemolysis samples.
6. **SAMPLE VOLUME (for Getein 1100/Getein 1160/Getein 1180): 100 μ L**

TEST PROCEDURE

1. Collect specimens according to instructions for use.
2. Test card, sample and reagent should reach to room temperature before test.

For Getein 1100:

1. Confirm SD card lot No. in accordance with test kit lot No. Perform "SD card" calibration when necessary.
2. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
3. Put the test card on a clean table, horizontally placed.
4. Using sample transfer pipette, deliver **100 μ L** of sample

into one tube of sample diluent, mix gently and thoroughly. Then drop **100 µL** of sample mixture into the sample well on the test card.

- 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 Getein 1160/Getein 1180:

- Confirm SD card lot No. in accordance with test kit lot No..Perform “SD card” calibration when necessary.
- Enter testing interface of Getein 1160/Getein 1180.
- Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
- Put the test card on a clean table,horizontally placed.
- Using sample transfer pipette, deliver **100 µL** of sample into one tube of sample diluent, mix gently and thoroughly. Then drop **100 µL** of sample mixture into the sample well on the test card.
- Insert the test card into Getein 1160/Getein 1180 immediately after sample loading. The analyzer will count down the reaction time (10 minutes) and automatically test the card after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein 1200/Getein 1600:

- Each cartridge for Getein 1200/Getein 1600 contains a specific RFID card which can calibrate automatically.
- Place the sample diluent at the correct position of Getein 1200/Getein 1600.
- Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein 1200/Getein 1600 will do the testing and print the result automatically.

Notes:

- It is required to perform “SD card” calibration when using a new batch of kits.
- It is suggested to calibrate once for one batch of kits for Getein 1100/Getein 1160/Getein 1180.
- Make sure the test card and the sample insertion is correct and complete.

TEST RESULTS

Getein 1100/Getein 1160/Getein 1180/Getein 1200/Getein 1600 can scan the test card automatically and display the result on the screen. For additional information, please refer to the instructions for use of Getein 1100/Getein

1160/Getein 1180/Getein 1200/Getein 1600.

Others: Measuring range of the fPSA test kit is 0.03-30.00 ng/mL. Dilute the sample which concentration is higher than the upper limit with negative samples, and the dilution ration should be less than 4 times.

EXPECTED VALUE

The expected normal value for free PSA was determined by testing samples from 250 apparently healthy individuals. The reference range of free PSA is 1.00 ng/mL calculated by using normal distribution methods (95th percentile).

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

PERFORMANCE CHARACTERISTICS

| | |
|-----------------------|------------------|
| Measuring Range | 0.03-30.00 ng/mL |
| Lower Detection Limit | ≤ 0.03 ng/mL |
| Within-Run Precision | ≤ 10% |
| Between-Run Precision | ≤ 15% |

LIMITATIONS

- As with all diagnostic tests, a definitive clinical diagnosis should not be made based on the result of a single test. The test results should be interpreted considering all other test results and clinical information such as clinical signs and symptoms.
- Interferents in samples may influence the results. The table below listed the maximum allowance of these potential interferent.

| Interferent | Triglyceride | Bilirubin |
|---------------------|--------------|-----------|
| Concentration (Max) | 25 g/L | 0.6 g/L |

REFERENCES

- Chen R, Huang Y, Cai X, et al. Age-Specific Cutoff Value for the Application of Percent Free Prostate-Specific Antigen (PSA) in Chinese Men with Serum PSA Levels of 4.0-10.0 ng/ml. PLoS One. 2015, 10 (6): e0130308.
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DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on fPSA 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 ISO 15223-1:2021.

| Key to symbols used | | | |
|---------------------|---|--|---|
| | Manufacturer | | Use-by date |
| | Do not re-use | | Date of manufacture |
| | Consult instructions for use or consult electronic instructions for use | | Batch code |
| | Temperature limit | | In vitro diagnostic medical device |
| | Contains sufficient for <n> tests | | Do not use if package is damaged and consult instructions for use |
| | Catalogue number | | |

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

Version: WIF74-S-07

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ft3

Fast Test Kit

(Immunofluorescence Assay)

Instruction for Use

INTENDED USE

ft3 Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of free triiodothyronine (ft3) in human serum, plasma and whole blood. It is used as an aid in diagnosis of thyroid diseases.

For professional and laboratory use only.

SUMMARY

Triiodothyronine (T3) is a thyroid hormone. It plays an important role in the body's control of metabolism. T3 circulates in the bloodstream as an equilibrium mixture of free and serum bound hormone. Free T3 (ft3) is the unbound and biologically active form, which represents only 0.2-0.4% of the total T3. The remaining T3 is inactive and bound to serum proteins, while the distribution of T3 between these binding proteins (thyroxine binding globulin, pre-albumin, albumin) is controversially discussed.

The detection of ft3 has the advantage of being independent of changes in the concentrations and binding properties of the binding proteins. Therefore, ft3 is a useful tool in clinical routine diagnostics for the assessment of the thyroid status. Free T3 measurements support the differential diagnosis of thyroid disorders, are needed to distinguish different forms of hyperthyroidism, and to identify patients with T3 thyrotoxicosis.

PRINCIPLE

ft3 Fast Test Kit (Immunofluorescence Assay) is based on immunofluorescence competitive method to quantitatively detect the content of ft3 in human serum, plasma or whole blood.

The test uses an T3 monoclonal antibody conjugated with fluorescence and T3-BSA coated on the test line. After the sample has been applied to the test strip, the analyte competes

with T3-BSA coated on the test line to bind to fluorescently labeled T3 monoclonal antibody and forms different antigen-antibody complexes respectively. The fluorescence intensity of the test line decreases proportionally to the amount of free T3 in the sample. Fluorescent signals intensity can be analyzed by applicable device thus the free T3 in sample be detected quantitatively.

CONTENTS

| Materials provided | Getein 1100/ Getein 1160/ Getein 1180 | | Getein 1150 | | Getein 1200/Getein 1600 | | |
|----------------------|---|----------|-------------|----------|---------------------------------|---------------------------------|---------------------------------|
| | 10 T/kit | 25 T/kit | 10 T/kit | 25 T/kit | 2×12 T/kit | 2×24 T/kit | 2×48 T/kit |
| ft3 test card | 10 pcs | 25 pcs | 10 pcs | 25 pcs | 2 cartridges, 12 pcs in each | 2 cartridges, 24 pcs in each | 2 cartridges, 48 pcs in each |
| Disposable pipet | 10 pcs | 25 pcs | 10 pcs | 25 pcs | / | / | / |
| Reaction tube | 10 tubes | 25 tubes | 10 tubes | 25 tubes | / | / | / |
| Sample diluent | 10 tubes | 25 tubes | 10 tubes | 25 tubes | 1 box | 1 box | 1 box |
| Instructions for use | 1 pc | 1 pc | 1 pc | 1 pc | 1 pc | 1 pc | 1 pc |
| SD card | 1 pc | 1 pc | / | / | 1 pc in each cartridge | 1 pc in each cartridge | 1 pc in each cartridge |

Note:

- The SD card, also known as the standard curve data card, stores standard curve data for the specific test items and uses RFID technology to transfer the data to analyzers via touch.
- The standard curve data for Getein 1150 is written to the QR code on the outer packaging box.
- Do not mix or interchange different batches of kits.

APPLICABLE DEVICE

Getein 1100 Immunofluorescence Quantitative Analyzer
 Getein 1150 Immunofluorescence Quantitative Analyzer
 Getein 1160 Immunofluorescence Quantitative Analyzer
 Getein 1180 Immunofluorescence Quantitative Analyzer
 Getein 1200 Immunofluorescence Quantitative Analyzer
 Getein 1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Realtime stability:

Store the kit at 4–30°C with a valid period of 24 months. The

test kits are stable until the expiry date printed on the labels.

In-use stability:

For the test card of Getein 1100/Getein 1150/Getein 1160/Getein 1180: Use the test card within 1 hour once the foil pouch is opened.

For test card of Getein 1200/Getein 1600: 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.

PRECAUTIONS

- For *in vitro* diagnostic use only.
- For professional and laboratory use only, not for near-patient test and self-testing.
- Do not use the test card if the foil pouch or the cartridge is damaged.
- Do not open pouches until performing the test.
- Do not reuse the test card and disposable pipet.
- Handle all specimens as potentially infectious. The foil bag is non-degradable. Proper handling and disposal methods should be followed in accordance with local regulations.
- It is recommended that operators take necessary self-protection measures (work clothes and disposable gloves, etc) when touching kits or samples.

SPECIMEN COLLECTION AND PREPARATION

- This test can be used for **serum, plasma and whole blood samples**. Heparin, EDTA and sodium citrate can be used as the anticoagulant for plasma and whole blood. Samples should be free of hemolysis.
- Suggest using serum and plasma samples for better results.
- Serum and plasma are stable for 4 hours at room temperature (15–30°C), 7 days at 2–8°C, and 6 months at -20°C.
- Whole blood is stable for 4 hours at room temperature (15–30°C), 3 days at 2–8°C and avoid cryopreservation.
- Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
- SAMPLE VOLUME (for Getein 1100/Getein 1150/ Getein 1160/Getein 1180): **100 µL**.

TEST PROCEDURE

1. User must carefully read and operate in strict accordance with the instructions for use before testing, otherwise reliable results cannot be guaranteed.
2. Test kit and sample should be brought to room temperature before testing.

For Getein 1100:

- 1) Confirm SD card lot No. in accordance with test kit lot No. It is required to perform "SD card" calibration when using a new batch of kits.
- 2) Select the corresponding "Sample" on the analyzer according to the sample type (see the user manual of analyzer for details).
- 3) Remove the test card from the sealed pouch before use. Horizontally place the test card.
- 4) Use a disposable pipet or pipette to draw **100 µL** of sample into a reaction tube, then add **100 µL** sample diluent to the same reaction tube, mix gently and thoroughly and wait for **5-10 minutes**.
- 5) Use the same disposable pipet or pipette to draw **100 µL** of the above mixture and dispense it into the sample well on the test card.
- 6) **Reaction time: 15 minutes.** After reaction time is elapsed, insert the test card into Getein1100 and press "ENT" button (click on "Start" icon for Android Getein 1100). The result will be shown on the screen and printed automatically.

For Getein 1160/Getein 1180:

- 1) Confirm SD card lot No. in accordance with test kit lot No. It is required to perform "SD card" calibration when using a new batch of kits.
- 2) Select the corresponding "Sample" on the analyzer according to the sample type (see the user manual of analyzer for details).
- 3) Remove the test card from the sealed pouch before use. Horizontally place the test card.
- 4) Use a disposable pipet or pipette to draw **100 µL** of sample into a reaction tube, then add **100 µL** sample diluent to the same reaction tube, mix gently and thoroughly and wait for 5-10 minutes.
- 5) Use the same disposable pipet or pipette to draw **100 µL** of the above mixture and dispense it into the sample well on the test card.
- 6) Insert the test card into Getein 1160/Getein 1180 **immediately** after sample loading. The analyzer will count down the reaction time (15 minutes) and automatically test the card after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein 1150:

- Turn on the instrument and enter the sample test interface. Insert the test card and scan the QR code (**On the outer packaging box**) to complete calibration as prompted by the instrument.
- Select the corresponding "Sample" mode on the analyzer (refer to the analyzer user manual for details).
- Use a disposable pipet or pipette to draw **100 µL** of sample into a reaction tube, then add **100 µL** sample diluent to the same reaction tube, mix gently and thoroughly and wait for **5-10 minutes**.
- Use the same disposable pipet or pipette to draw **100 µL** of the above mixture and dispense it into the sample well on the test card.
- Press the "Start" button immediately after sample loading. The analyzer will initiate a 15-minute reaction countdown, and the test results will be automatically displayed on the screen upon completion.

For Getein 1200/Getein 1600:

- Each cartridge for Getein 1200/Getein 1600 contains a specific RFID card (SD card) which can calibrate automatically.
- Place the sample diluent at the correct position in Getein 1200/Getein 1600.
- Place samples in the designed area of the sample holder, insert the holder, set parameters (more operational details refer to the user manual of analyzer) and run the instrument, Getein 1200/Getein 1600 will do the testing and print the result automatically.

Notes:

When using a disposable pipet to aspirate liquid, it is necessary to squeeze the head of the disposable pipet to ensure that the liquid level is flush with the black scale line, otherwise the sample volume will be inaccurate.

LIMITATIONS

- As with all diagnostic tests, a definitive clinical diagnosis should not be made based on the result of a single test. The test results should be interpreted considering all other test results and clinical information such as clinical signs and symptoms.
- Interferents in samples may influence the results. The table below listed the maximum allowance of these potential interferent.

| Interferent | Concentration (Max) |
|--------------|---------------------|
| Triglyceride | 20 g/L |
| Bilirubin | 0.1 g/L |

EXPECTED VALUE

The expected normal value for fT3 was determined by testing samples from 254 apparently healthy individuals. The reference range of fT3 is 3.10–6.80 pmol/L calculated by using normal distribution methods (95% confidence interval).

Each laboratory should verify the transferability of the expected values to its own population, and if necessary, determine its own expected values according to good laboratory practice.

PERFORMANCE CHARACTERISTICS

| | |
|-----------------------|-------------------|
| Measuring range | 0.60–50.00 pmol/L |
| Limit of Detection | ≤ 0.60 pmol/L |
| Within-run Precision | ≤ 15% |
| Between-lot Precision | ≤ 15% |


















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- Zhu, Lijie et al. Relationship of serum free T3 with the coronary artery calcification and major adverse cardiac events in patients with suspected coronary artery disease. *Zhonghua xin xue guan bing za zhi*. 2014, 42 (12): 1017-1021.
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- Klee GG. Clinical usage recommendations and analytic performance goals for total and free triiodothyronine measurements. *Clin Chem*. 1996, 42(1):155-159.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on fT3 Fast Test Kit (Immunofluorescence Assay) are the most common ones appearing on medical devices and their packaging. They are explained in more detail in the European Standard EN ISO


15223-1:2021.

| Key to symbols used | | | |
|--|---|---|---|
|  | Manufacturer |  | Use-by date |
|  | Do not re-use |  | Date of manufacture |
|  | Consult instructions for use or consult electronic instructions for use |  | Batch code |
|  | Temperature limit |  | <i>In vitro</i> diagnostic medical device |
|  | Contains sufficient for <n> tests |  | Authorized representative |
|  | CE mark |  | Do not use if package is damaged and consult instructions for use |
|  | Catalogue number |  | Keep dry |
|  | Keep away from sunlight |  | Caution |
|  | Unique device identifier | | |

Thank you for using fT3 Fast Test Kit (Immunofluorescence Assay). Please read the instructions for use carefully before operating to ensure proper use.

Version: WIF71-S-12

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| Catalogue number | Applicable analyzer | Package specification |
|------------------|---------------------|-----------------------|
| IF1067-10T | Getein 1100 | 10 T/kit |
| IF1067 | Getein 1100 | 25 T/kit |
| IF8067-10T | Getein 1150 | 10 T/kit |
| IF8067 | Getein 1150 | 25 T/kit |
| IF5067-10T | Getein 1160 | 10 T/kit |
| IF5067 | Getein 1160 | 25 T/kit |
| IF3067-10T | Getein 1180 | 10 T/kit |
| IF3067 | Getein 1180 | 25 T/kit |
| IF4067-24T | Getein 1200 | 2×12 T/kit |
| IF4067 | Getein 1200 | 2×24 T/kit |
| IF4067-96T | Getein 1200 | 2×48 T/kit |
| IF2067-24T | Getein 1600 | 2×12 T/kit |
| IF2067 | Getein 1600 | 2×24 T/kit |
| IF2067-96T | Getein 1600 | 2×48 T/kit |



FT4

Fast Test Kit

(Immunofluorescence Assay)

Instructions for Use

INTENDED USE

FT4 Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of free T4 in human serum, plasma and whole blood samples. This test can be used as an aid in the assessment of thyroid status. For professional and laboratory use only.

SUMMARY

Thyroxine (T4) is the main thyroid hormone secreted into the bloodstream by the thyroid gland. Together with triiodothyronine (T3), it plays a vital role in regulating the body's metabolic rate, influences the cardiovascular system, growth and bone metabolism, and is important for normal development of gonadal functions and nervous system.

T4 circulates in the bloodstream as an equilibrium mixture of free and serum bound hormone. Free T4 (fT4) is the unbound and biologically active form, which represents only 0.03 % of the total T4. The remaining T4 is inactive and bound to serum proteins such as thyroxine binding globulin (TBG, 75%), pre-albumin (15%), and albumin (10%). The determination of free T4 has the advantage of being independent of changes in the concentrations and binding properties of these binding proteins; additional determination of a binding parameter (T uptake, TBG) is therefore unnecessary. Therefore, free T4 is a useful tool in clinical routine diagnostics for the assessment of the thyroid status.

PRINCIPLE

FT4 Fast Test Kit (Immunofluorescence Assay) is based on immunofluorescence competitive method to quantitatively detect the content of FT4 in human serum, plasma or whole blood.

Store the test as an T4 monoclonal antibody conjugated with fluorescence and T4-BSA coated on the test line. After the sample has been applied to the test strip, the analyte competes with T4-BSA coated on the test line to bind to fluorescent labeled T4 monoclonal antibody and forms different antigen-antibody complexes respectively. The fluorescence intensity of test line has relationship with the amount of free T4 in sample.

CONTENTS

| Materials provided | Getein 1100/ Getein 1150/ Getein 1180 | | Getein 1150 | | Getein 1200/Getein 1600 | | |
|----------------------|---|----------|-------------|----------|---------------------------------|---------------------------------|---------------------------------|
| | 10 T/kit | 25 T/kit | 10 T/kit | 25 T/kit | 2×12 T/kit | 2×24 T/kit | 2×48 T/kit |
| FT4 test card | 10 pcs | 25 pcs | 10 pcs | 25 pcs | 2 cartridges, 12 pcs in each | 2 cartridges, 24 pcs in each | 2 cartridges, 48 pcs in each |
| Disposable pipet | 10 pcs | 25 pcs | 10 pcs | 25 pcs | / | / | / |
| Reaction tube | 10 tubes | 25 tubes | 10 tubes | 25 tubes | / | / | / |
| Sample diluent | 10 tubes | 25 tubes | 10 tubes | 25 tubes | 1 box | 1 box | 1 box |
| Instructions for use | 1 pc | 1 pc | 1 pc | 1 pc | 1 pc | 1 pc | 1 pc |
| SD card | 1 pc | 1 pc | / | / | 1 pc in each cartridge | 1 pc in each cartridge | 1 pc in each cartridge |

Note:

- The SD card, also known as the standard curve data card, stores standard curve data for the specific test items and uses RFID technology to transfer the data to analyzers via touch.
- The standard curve data for Getein 1150 is written to the QR code on the outer packaging box.
- Do not mix or interchange different batches of kits.

APPLICABLE DEVICE

Getein 1100 Immunofluorescence Quantitative Analyzer
 Getein 1150 Immunofluorescence Quantitative Analyzer
 Getein 1160 Immunofluorescence Quantitative Analyzer
 Getein 1180 Immunofluorescence Quantitative Analyzer
 Getein 1200 Immunofluorescence Quantitative Analyzer
 Getein 1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Realtime stability:

Store the test at 4–30°C with a valid period of 24 months. The test kits are stable until the expiry date printed on the labels.

In-use stability:

For the test card of Getein 1100/Getein 1150/Getein 1160/Getein 1180: Use the test card within 1 hour once the foil pouch is opened.

For test card of Getein 1200/Getein 1600: 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.

PRECAUTIONS

- For *in vitro* diagnostic use only.
- For professional and laboratory use only, not for near-patient test and self-testing.
- Do not use the test card if the foil pouch or the cartridge is damaged.
- Do not open pouches until performing the test.
- Do not reuse the test card and disposable pipet.
- Handle all specimens as potentially infectious. The foil bag is non-degradable. Proper handling and disposal methods should be followed in accordance with local regulations.
- It is recommended that operators take necessary self-protection measures (work clothes and disposable gloves, etc) when touching kits or samples.

SPECIMEN COLLECTION AND PREPARATION

- This test can be used for **serum, plasma and whole blood samples**. Heparin, EDTA and sodium citrate can be used as the anticoagulant for plasma and whole blood. Samples should be free of hemolysis.
- Suggest using serum and plasma samples for better results.
- Serum and plasma are stable for 4 hours at room temperature (15–30°C), 7 days at 2–8°C, and 6 months at -20°C.
- Whole blood is stable for 4 hours at room temperature (15–30°C), 3 days at 2–8°C and avoid cryopreservation.
- Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
- SAMPLE VOLUME (for Getein 1100/Getein 1150/Getein 1160/Getein 1180): **100 µL**.

TEST PROCEDURE

1. User must carefully read and operate in strict accordance with the instructions for use before testing, otherwise reliable results cannot be guaranteed.

2. Test kit and sample should be brought to room temperature before testing.

For Getein 1100:

- Confirm SD card lot No. in accordance with test kit lot No. It is required to perform "SD card" calibration when using a new batch of kits.
- Select the corresponding "Sample" on the analyzer according to the sample type (see the user manual of analyzer for details).
- Remove the test card from the sealed pouch before use. Horizontally place the test card.
- Use a disposable pipet or pipette to draw **100 µL** of sample into a reaction tube, then add **100 µL** sample diluent to the same reaction tube, mix gently and thoroughly and wait for **2-5 minutes**.
- Use the same disposable pipet or pipette to draw **100 µL** of the above mixture and dispense it into the sample well on the test card.
- Reaction time: 15 minutes.** After reaction time is elapsed, insert the test card into Getein1100 and press "ENT" button (click on "Start" icon for Android Getein 1100). The result will be shown on the screen and printed automatically.

For Getein 1160/Getein 1180:

- Confirm SD card lot No. in accordance with test kit lot No. It is required to perform "SD card" calibration when using a new batch of kits.
- Select the corresponding "Sample" on the analyzer according to the sample type (see the user manual of analyzer for details).
- Remove the test card from the sealed pouch before use. Horizontally place the test card.
- Use a disposable pipet or pipette to draw **100 µL** of sample into a reaction tube, then add **100 µL** sample diluent to the same reaction tube, mix gently and thoroughly and wait for **2-5 minutes**.
- Use the same disposable pipet or pipette to draw **100 µL** of the above mixture and dispense it into the sample well on the test card.
- Insert the test card into Getein 1160/Getein 1180 **immediately** after sample loading. The analyzer will count

down the reaction time (15 minutes) and automatically test the card after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein 1150:

- 1) Turn on the instrument and enter the sample test interface. Insert the test card and scan the QR code (**On the outer packaging box**) to complete calibration as prompted by the instrument.
- 2) Select the corresponding "Sample" mode on the analyzer (refer to the analyzer user manual for details).
- 3) Use a disposable pipet or pipette to draw **100 µL** of sample into a reaction tube, then add **100 µL** sample diluent to the same reaction tube, mix gently and thoroughly and wait for **2-5 minutes**.
- 4) Use the same disposable pipet or pipette to draw 100 µL of the above mixture and dispense it into the sample well on the test card.
- 5) Press the "Start" button immediately after sample loading. The analyzer will initiate a 15-minute reaction countdown, and the test results will be automatically displayed on the screen upon completion.

For Getein 1200/Getein 1600:

- 1) Each cartridge for Getein 1200/Getein 1600 contains a specific RFID card (SD card) which can calibrate automatically.
- 2) Place the sample diluent at the correct position in Getein 1200/Getein 1600.
- 3) Place samples in the designed area of the sample holder, insert the holder, set parameters (more operational details refer to the user manual of analyzer) and run the instrument, Getein 1200/Getein 1600 will do the testing and print the result automatically.

Notes:

When using a disposable pipet to aspirate liquid, it is necessary to squeeze the head of the disposable pipet to ensure that the liquid level is flush with the black scale line, otherwise the sample volume will be inaccurate.

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. Interferents in samples may influence the results. The table below listed the maximum allowance of these potential interferent.

| Interferent | Concentration (Max) |
|--------------|---------------------|
| Triglyceride | 20 g/L |
| Bilirubin | 0.1 g/L |

EXPECTED VALUE

The expected normal value for fT4 was determined by testing samples from 261 apparently healthy individuals. The reference range of fT4 is 12.00–22.00 pmol/L calculated by using normal distribution methods (95% confidence interval).

Each laboratory should verify the transferability of the expected values to its own population, and if necessary, determine its own expected values according to good laboratory practice.

PERFORMANCE CHARACTERISTICS

| | |
|-----------------------|--------------------|
| Measuring range | 0.30–100.00 pmol/L |
| Limit of Detection | ≤ 0.30 pmol/L |
| Within-run Precision | ≤ 15% |
| Between-lot Precision | ≤ 15% |

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DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on fT4 Fast Test Kit (Immunofluorescence Assay) are the most common ones appearing on medical devices and their packaging. They are explained in more detail in the European Standard EN ISO 15223-1:2021.

| Key to symbols used | | | |
|---------------------|---|--|---|
| | Manufacturer | | Use-by date |
| | Do not re-use | | Date of manufacture |
| | Consult instructions for use or consult electronic instructions for use | | Batch code |
| | Temperature limit | | In vitro diagnostic medical device |
| | Contains sufficient for <n> tests | | Authorized representative |
| | CE mark | | Do not use if package is damaged and consult instructions for use |
| | Catalogue number | | Keep dry |
| | Keep away from sunlight | | Caution |
| | Unique device identifier | | |

Thank you for purchasing fT4 Fast Test Kit (Immunofluorescence Assay). Please read the instructions for use carefully before operating to ensure proper use.

Version: WIF72-S-12



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CMC Medical Devices & Drugs S.L.
 Add: C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain
 Tel: +34951214054

| Catalogue number | Applicable analyzer | Package specification |
|------------------|---------------------|-----------------------|
| IF1068-10T | Getein 1100 | 10 T/kit |
| IF1068 | Getein 1100 | 25 T/kit |
| IF8068-10T | Getein 1150 | 10 T/kit |
| IF8068 | Getein 1150 | 25 T/kit |
| IF5068-10T | Getein 1160 | 10 T/kit |
| IF5068 | Getein 1160 | 25 T/kit |
| IF3068-10T | Getein 1180 | 10 T/kit |
| IF3068 | Getein 1180 | 25 T/kit |
| IF4068-24T | Getein 1200 | 2×12 T/kit |
| IF4068 | Getein 1200 | 2×24 T/kit |
| IF4068-96T | Getein 1200 | 2×48 T/kit |
| IF2068-24T | Getein 1600 | 2×12 T/kit |
| IF2068 | Getein 1600 | 2×24 T/kit |
| IF2068-96T | Getein 1600 | 2×48 T/kit |



tPSA

Fast Test Kit

(Immunofluorescence Assay)

Instructions for Use

INTENDED USE

tPSA Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of tPSA in human serum and plasma samples. It can be used as an aid in the diagnosis and management of patients with prostate cancer. For professional and laboratory use only.

SUMMARY

Prostate-specific antigen (PSA) is a single-chain glycoprotein with molecular weight of 34 kilodaltons. As a serine prostatic with chymotrypsin-like activity, PSA belongs to the kallikrein family. PSA exists as a free or complex form with protease inhibitors such as α -1-antichymotrypsin (ACT) in blood. Total PSA represents the sum of both free and complex forms. Elevated PSA in serum or plasma is found in patients with prostate cancer, benign prostatic hypertrophy, or inflammatory tissues. PSA is uniquely associated with prostate tissues from normal, inflamed or cancerous stages.

PSA has been found in normal, benign hyperplastic, malignant prostatic tissue, metastatic prostatic carcinoma and also in prostatic fluid as well as in seminal fluid. PSA is not found in any other tissues in men, and it is not produced by cancers originating in the lung, colon, rectum, stomach, pancreas or thyroid. PSA measurement is an essential tool in assessing the status of disease in patients with prostate cancer when serial samples are measured over time. The clinical value realized by monitoring tPSA concentration in patients with prostate cancer regardless of the treatment regimen is well known.

PRINCIPLE

tPSA Fast Test Kit (Immunofluorescence Assay) is a lateral flow

immunoassay with a sandwich design. After the sample is applied to the test strip, the fluorescence labelled PSA monoclonal antibody binds to the PSA in the sample, forming a marked antigen-antibody complex. This complex then moves to the test zone on the test card by capillary action. In the test zone, the marked antigen-antibody complex is captured by another PSA monoclonal antibody. The fluorescence intensity of the test zone increases in proportion to the amount of tPSA in sample. Fluorescent signals intensity can be analyzed by applicable device thus the tPSA in sample be detected quantitatively.

CONTENTS

| Materials provided | Getein 1100/ Getein 1150/ Getein 1180 | | Getein 1150 | | Getein 1200/Getein 1600 | | |
|----------------------|---|----------|-------------|----------|---------------------------------|---------------------------------|---------------------------------|
| | 10 T/kit | 25 T/kit | 10 T/kit | 25 T/kit | 2×12 T/kit | 2×24 T/kit | 2×48 T/kit |
| tPSA test card* | 10 pcs | 25 pcs | 10 pcs | 25 pcs | 2 cartridges, 12 pcs in each | 2 cartridges, 24 pcs in each | 2 cartridges, 48 pcs in each |
| Disposable pipet | 10 pcs | 25 pcs | 10 pcs | 25 pcs | / | / | / |
| Sample diluent** | / | / | / | / | 1 box | 1 box | 1 box |
| Instructions for use | 1 pc | 1 pc | 1 pc | 1 pc | 1 pc | 1 pc | 1 pc |
| SD card | 1 pc | 1 pc | / | / | 1 pc in each cartridge | 1 pc in each cartridge | 1 pc in each cartridge |

* tPSA test card

A test card mainly consists of: Fluorescence labelled PSA monoclonal antibody, PSA monoclonal antibody.

** Sample diluent

Sample diluent for Getein 1200/Getein 1600 is an independent packing box mainly consists of:

- Phosphate buffer (20 mmol/L), NaNO_3 (< 0.1%) (25 mL/bottle for Getein 1200, 40 mL/bottle for Getein 1600),

- Box with pipette tips (96 tips/box),

- Mixing plate (1 piece/box).

Note:

- The SD card, also known as the standard curve data card, stores standard curve data for the specific test items and uses RFID technology to transfer the data to analyzers via touch.

2. The standard curve data for Getein 1150 is written to the QR code on the outer packaging box.

3. Do not mix or interchange different batches of kits.

APPLICABLE DEVICES

Getein 1100 Immunofluorescence Quantitative Analyzer
Getein 1150 Immunofluorescence Quantitative Analyzer
Getein 1160 Immunofluorescence Quantitative Analyzer
Getein 1180 Immunofluorescence Quantitative Analyzer
Getein 1200 Immunofluorescence Quantitative Analyzer
Getein 1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Realtime stability:

Store the kit at 4–30°C with a valid period of 24 months. The test kits are stable until the expiry date printed on the labels.

In-use stability:

For the test card of Getein 1100/Getein 1150/Getein 1160/Getein 1180: Use the test card within 1 hour once the foil pouch is opened.

For test card of Getein 1200/Getein 1600: 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.

PRECAUTIONS

- For *in vitro* diagnostic use only.
- For professional and laboratory use only, not for near-patient test and self-testing.
- Do not use the test card if the foil pouch or the cartridge is damaged.
- Do not open pouches until performing the test.
- Do not reuse the test card and disposable pipet.
- Handle all specimens as potentially infectious. The foil bag is non-degradable. Proper handling and disposal methods should be followed in accordance with local regulations.
- It is recommended that operators take necessary self-protection measures (work clothes and disposable gloves, etc) when touching kits or samples.

SPECIMEN COLLECTION AND PREPARATION

- This test can be used for serum and plasma samples. Heparin, EDTA and sodium citrate should be used as the anticoagulant for plasma. Samples should be free of hemolysis.
- It is recommended to test the sample within 4 hours after collection. Stable in serum and plasma for 7 days when stored at 2–8°C and 6 months when stored at -20°C.
- Refrigerated or frozen sample should reach room temperature before testing. Avoid multiple freeze-thaw cycles.
- SAMPLE VOLUME (for Getein 1100/Getein 1150/Getein 1160/Getein 1180):** 100 μL .

TEST PROCEDURE

- User must carefully read and operate in strict accordance with the instructions for use before testing, otherwise reliable results cannot be guaranteed.
- Test kit and sample should be brought to room temperature before testing.

For Getein 1100:

- Confirm SD card lot No. in accordance with test kit lot No. Perform "SD card" calibration when necessary.
- Select the corresponding "Sample" on the analyzer according to the sample type (see the user manual of analyzer for details).
- Remove the test card from the sealed pouch immediately before use and put the test card on a clean table, horizontally placed.
- Use disposable pipet or pipette, deliver **100 μL** of sample into the sample well on the test card.
- Reaction time: 15 minutes.** After reaction time is elapsed, insert the test card into Getein1100 and press "ENT" button (click on "Start" icon for Android Getein 1100). The result will be shown on the screen and printed automatically.

For Getein 1160/Getein 1180:

- Confirm SD card lot No. in accordance with test kit lot No. Perform "SD card" calibration when necessary.
- Select the corresponding "Sample" on the analyzer according to the sample type (refer to the analyzer user manual for details).
- Remove the test card from the sealed pouch immediately

before use and put the test card on a clean table, horizontally placed.

4) Use disposable pipet or pipette, deliver **100 μ L** of sample into the sample well on the test card.

5) Insert the test card into Getein 1160/Getein 1180 **immediately** after sample loading. The analyzer will count down the reaction time (**15 minutes**) and automatically test the card after reaction time is elapsed. The result will be shown on the screen and displayed automatically.

For Getein 1150:

1) Turn on the instrument and enter the sample test interface. Insert the test card and scan the QR code (**On the outer packaging box**) to complete calibration as prompted by the instrument.

2) Select the corresponding "Sample" mode on the analyzer (refer to the analyzer user manual for details).

3) Use disposable pipet or pipette, deliver **100 μ L** of sample into the sample well on the test card.

4) Press the "Start" button immediately after sample loading. The analyzer will initiate a 15-minute reaction countdown, and the test results will be automatically displayed on the screen upon completion.

For Getein 1200/Getein 1600:

1) Each cartridge for Getein 1200/Getein 1600 contains a specific RFID card which can calibrate automatically.

2) Place the sample diluent at the correct position of Getein 1200/Getein 1600.

3) Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein 1200/Getein 1600 will do the testing and print the result automatically.

TEST RESULTS

Measuring range of the tPSA test kit is 0.40–100.00 ng/mL. Dilute the sample which concentration is higher than the upper limit with female samples, and the dilution ratio should be less than 4 times.

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) | 5 g/L | 25 g/L | 0.1 g/L |

EXPECTED VALUE

The expected normal value for tPSA was determined by testing samples from 1000 apparently healthy individuals. The reference range of tPSA is 4.0 ng/mL calculated by using normal distribution methods (95% confidence interval).

Each laboratory should verify the transferability of the expected values to its own population, and if necessary, determine its own expected values according to good laboratory practice.

PERFORMANCE CHARACTERISTICS

Measuring Range 0.40–100.00 ng/mL

Limit of Detection \leq 0.40 ng/mL

Within-run Precision: Test tPSA with same batch for 10 times using tPSA control 1 (3.20–4.80 ng/mL) and tPSA control 2 (24.00–36.00 ng/mL) respectively, then calculate within-run precision which should not greater than 10%.

Between-lot Precision: Randomly select 3 consecutive batches of tPSA products, and take 10 strips for each batch to test the quality control (24.00–36.00 ng/mL), calculate between-lot precision which should not greater than 15%.

Method Comparison: Perform clinical comparison study on 231 clinical serum samples from 231 patients. Concordance between tPSA Fast Test Kit (Immunofluorescence Assay) and Elecsys® tPSA were evaluated. The following regression data were obtained: N=231; y=0997x+0.0471; r=0,9984.

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












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DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on tPSA 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 ISO 15223-1:2021.

| Key to symbols used | | | |
|--|---|---|---|
|  | Manufacturer |  | Use-by date |
|  | Do not re-use |  | Date of manufacture |
|  | Consult instructions for use or consult electronic instructions for use |  | Batch code |
|  | Temperature limit |  | In vitro diagnostic medical device |
|  | Contains sufficient for <n> tests |  | Unique device identifier |
|  | Keep away from sunlight |  | Do not use if package is damaged and consult instructions for use |
|  | Catalogue number |  | Keep dry |
|  | Caution | | |

Thank you for using tPSA Fast Test Kit (Immunofluorescence Assay). Please read the instructions for use carefully before operating to ensure proper use.

Version: WIF48-S-14



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TSH

Fast Test Kit

(Immunofluorescence Assay)

Instructions for Use

INTENDED USE

TSH Fast Test Kit (Immunofluorescence Assay) is designed for *in vitro* quantitative determination of thyroid-stimulating hormone (TSH) in human serum and plasma samples. This test is used as an aid in the screening, diagnosis, prognosis, and therapeutic efficacy evaluation of thyroid diseases.

For professional and laboratory use only.

SUMMARY

TSH is the main regulator of thyroid cell growth, thyroid hormone synthesis and secretion. TSH (MW 30 kDa) is synthesized and secreted by TSH cells of pituitary gland, it has negative feedback to the synthesis and secretion process. The fluctuation of TSH is faster and more significant than thyroid hormones when thyroid function was changed, it is a sensitive biomarker of hypothalamic-pituitary-thyroid function.

PRINCIPLE

TSH Fast Test Kit (Immunofluorescence Assay) is a lateral flow immunoassay in a sandwich design. After the sample has been applied to the test strip, the fluorescence labeled TSH monoclonal antibody binds with the TSH in sample and forms a marked antigen-antibody complex. This complex moves to the detection zone of the test card by capillary action, where it is captured on the test line by another TSH monoclonal antibody. The fluorescence intensity of the test line increases in proportion to the amount of TSH in the sample. The intensity of the fluorescent signals can be analyzed with an appropriate

device, enabling the quantitative detection of TSH in the sample.

CONTENTS

| Materials provided | Getein 1100/ Getein 1160/ Getein 1180 | | Getein 1150 | | Getein 1200/Getein 1600 | | |
|----------------------|---|----------|-------------|----------|------------------------------------|------------------------------------|------------------------------------|
| | 10 T/kit | 25 T/kit | 10 T/kit | 25 T/kit | 2×12 T/kit | 2×24 T/kit | 2×48 T/kit |
| TSH test card* | 10 pcs | 25 pcs | 10 pcs | 25 pcs | 2 cartridges, 12 pcs in each | 2 cartridges, 24 pcs in each | 2 cartridges, 48 pcs in each |
| Disposable pipet | 10 pcs | 25 pcs | 10 pcs | 25 pcs | / | / | / |
| Instructions for use | 1 pc | 1 pc | 1 pc | 1 pc | 1 pc | 1 pc | 1 pc |
| SD card | 1 pc | 1 pc | / | / | 1 pc in each cartridge | 1 pc in each cartridge | 1 pc in each cartridge |

* TSH test card

A test card mainly consists of: Fluorescence labeled TSH monoclonal antibody and TSH monoclonal antibody.

Consumables for Getein 1200/Getein 1600:

-Box with pipette tips (96 tips/box)

-Mixing plate (1 piece/box)

Note:

- The SD card, also known as the standard curve data card, stores standard curve data for the specific test items and uses RFID technology to transfer the data to analyzers via touch.
- The standard curve data for Getein 1150 is written to the QR code on the outer packaging box.
- Do not mix or interchange different batches of kits.

APPLICABLE DEVICES

Getein 1100 Immunofluorescence Quantitative Analyzer

Getein 1150 Immunofluorescence Quantitative Analyzer

Getein 1160 Immunofluorescence Quantitative Analyzer

Getein 1180 Immunofluorescence Quantitative Analyzer

Getein 1200 Immunofluorescence Quantitative Analyzer

Getein 1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Realtime stability:

Store the kit at 4–30°C with a valid period of 24 months. The test kits are stable until the expiry date printed on the labels.

In-use stability:

For the test card of Getein 1100/Getein 1150/Getein 1160/Getein 1180: Use the test card within 1 hour once the foil pouch is opened.

For test card of Getein 1200/Getein 1600: 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.

PRECAUTIONS

- For *in vitro* diagnostic use only.
- For professional and laboratory use only, not for near-patient test and self-testing.
- Do not use the test card if the foil pouch or the cartridge is damaged.
- Do not open pouches until performing the test.
- Do not reuse the test card and disposable pipet.
- Handle all specimens as potentially infectious. The foil bag is non-degradable. Proper handling and disposal methods should be followed in accordance with local regulations.
- It is recommended that operators take necessary self-protection measures (work clothes and disposable gloves, etc) when touching kits or samples.

SPECIMEN COLLECTION AND PREPARATION

- Serum and plasma can be used as samples in this assay.
- Heparin, sodium citrate and EDTA can be used as the anticoagulants for plasma. Hemolyzed specimens should not be used.
- It is recommended to test the sample within 4 hours after collection. Stable in serum and plasma for 7 days at 2–8°C and 6 months at -20°C.
- Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid

multiple freeze-thaw cycles.

- SAMPLE VOLUME (for Getein 1100/ Getein 1150/Getein 1160/Getein 1180): **100 µL**.

TEST PROCEDURE

- User must carefully read and operate in strict accordance with the instructions for use before testing, otherwise reliable results cannot be guaranteed.
- Test kit and sample should be brought to room temperature before testing.

For Getein 1100:

- Confirm SD card lot No. in accordance with test kit lot No. It is required to perform "SD card" calibration when using a new batch of kits.
- Select the corresponding "Sample" on the analyzer according to the sample type (see the user manual of analyzer for details).
- Remove the test card from the sealed pouch before use. Horizontally place the test card.
- Use disposable pipet or pipette to drop 100 µL of sample into the sample well on the test card.
- Reaction time: 15 minutes.** After reaction time is elapsed, insert the test card into Getein1100 and press "ENT" button (click on "Start" icon for Android Getein 1100). The result will be shown on the screen and printed automatically.

For Getein 1160/Getein 1180:

- Confirm SD card lot No. in accordance with test kit lot No. It is required to perform "SD card" calibration when using a new batch of kits.
- Select the corresponding "Sample" on the analyzer according to the sample type (see the user manual of analyzer for details).
- Remove the test card from the sealed pouch before use. Horizontally place the test card.
- Use disposable pipet or pipette to drop 100 µL of sample into the sample well on the test card.
- Insert the test card into Getein 1160/Getein 1180 **immediately** after sample loading. The analyzer will count down the reaction time (15 minutes) and automatically test the card after reaction time is elapsed. The result will be shown on the screen and printed

automatically.

For Getein 1150:

- 1) Turn on the instrument and enter the sample test interface. Insert the test card and scan the QR code (**On the outer packaging box**) to complete calibration as prompted by the instrument.
- 2) Select the corresponding "Sample" mode on the analyzer (refer to the analyzer user manual for details).
- 3) Use disposable pipet or pipette to drop 100 µL of sample into the sample well on the test card.
- 4) Press the "Start" button immediately after sample loading. The analyzer will initiate a 15-minute reaction countdown, and the test results will be automatically displayed on the screen upon completion.

For Getein 1200/Getein 1600:

- 1) Each cartridge for Getein 1200/Getein 1600 contains a specific RFID card (SD card) which can calibrate automatically.
- 2) Place consumables at the correct position in Getein 1200/Getein 1600.
- 3) Place samples in the designed area of the sample holder, insert the holder, set parameters (more operational details refer to the user manual of analyzer) and run the instrument, Getein 1200/Getein 1600 will do the testing and print the result automatically.

RESULTS

TSH Fast Test Kit (Immunofluorescence Assay) results are provided in µIU/mL

Others: Measuring range of the test kit is 0.10–50.00 µIU/mL, dilute the sample which concentration is higher than the upper limit, the dilution ratio should be less than 4 times.

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. Some substances in blood as listed below may interfere

with the test and cause erroneous results. The maximum allowance concentration of each is as follows:

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

EXPECTED VALUE

The expected normal value for TSH was determined by testing samples from serum of 391 apparently healthy individuals. The reference range of TSH is 0.27–4.20 µIU/mL calculated by using normal distribution methods (95% confidence interval).

Each laboratory should verify the transferability of the expected values to its own population, and if necessary, determine its own expected values according to good laboratory practice.

PERFORMANCE CHARACTERISTICS

| | |
|-----------------------|-------------------|
| Measuring Range | 0.10–50.00 µIU/mL |
| Limit of Detection | ≤ 0.10 µIU/mL |
| Within-Run Precision | ≤ 10% |
| Between-Lot Precision | ≤ 15% |


















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5. EN ISO 18113-1:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
6. 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.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on TSH Fast Test Kit (Immunofluorescence Assay) are the most common ones appearing on medical devices and their packaging. They are explained in more detail in the European Standard EN ISO 15223-1:2021.

| Key to symbols used | | | |
|--|---|---|---|
|  | Manufacturer |  | Use-by date |
|  | Do not re-use |  | Date of manufacture |
|  | Consult instructions for use or consult electronic instructions for use |  | Batch code |
|  | Temperature limit |  | In vitro diagnostic medical device |
|  | Contains sufficient for <n> tests |  | Authorized representative |
|  | CE mark |  | Do not use if package is damaged and consult instructions for use |
|  | Catalogue number |  | Keep dry |
|  | Keep away from sunlight |  | Caution |
|  | Unique device identifier | | |

Thank you for using TSH Fast Test Kit (Immunofluorescence Assay). Please read the instructions for use carefully before operating to ensure proper use.

Version: WIF26-S-14



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| Catalogue number | Applicable analyzer | Package specification |
|------------------|---------------------|-----------------------|
| IF1024-10T | Getein 1100 | 10 T/kit |
| IF1024 | Getein 1100 | 25 T/kit |
| IF8024-10T | Getein 1150 | 10 T/kit |
| IF8024 | Getein 1150 | 25 T/kit |
| IF5024-10T | Getein 1160 | 10 T/kit |
| IF5024 | Getein 1160 | 25 T/kit |
| IF3024-10T | Getein 1180 | 10 T/kit |
| IF3024 | Getein 1180 | 25 T/kit |
| IF4024-24T | Getein 1200 | 2×12 T/kit |
| IF4024 | Getein 1200 | 2×24 T/kit |
| IF4024-96T | Getein 1200 | 2×48 T/kit |
| IF2024-24T | Getein 1600 | 2×12 T/kit |
| IF2024 | Getein 1600 | 2×24 T/kit |
| IF2024-96T | Getein 1600 | 2×48 T/kit |