

Cardiac
Markers

Coagulation
Markers

Diabetes
Mellitus

Inflammation

Thyroid
Function

Metabolic
Marker

Renal
Function

Tumor
Markers

Reproduction
/Fertility

Infectious
Disease



Getein
Biotech, Inc.

Stock Code: 603387

OPTIMIZED POINT-OF-CARE SOLUTION

MAKING TEST EASY

Getein 1100

Immunofluorescence Quantitative Analyzer



Getein 1100

Immunofluorescence Quantitative Analyzer



HIGHLY EFFICIENT & ACCURATE

Advanced fluorescence immunoassay

Multiple quality control



REAL-TIME AND RAPID TEST

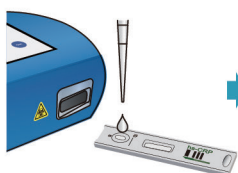
One-step test

3-15 min/test

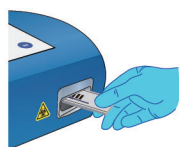
5 sec/test for multiple tests

OPERATION MODES

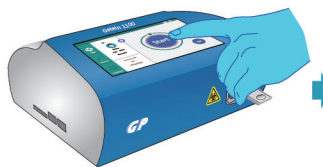
Inside Mode (Single sample rapid test mode)



Sample Transfer



Test Card Insert

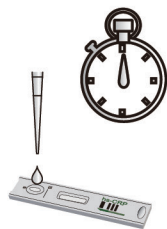


Click "Start" Icon



Result Show and Print

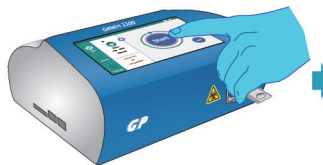
Outside Mode (Mass samples rapid test mode)



Sample Transfer



Timing the Reaction Manually



Click "Start" Icon



Result Show and Print



CONVENIENT OPERATION

RFID card calibration

Keyboard and mouse connectivity through USB port

Handwriting input available

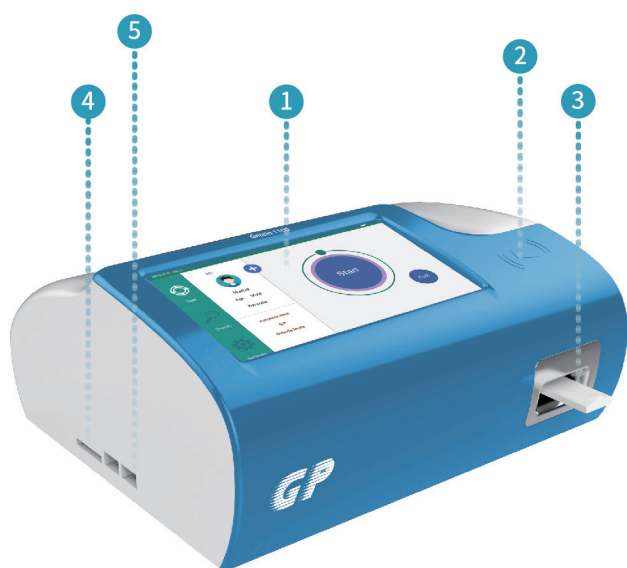
Continuous test for 3 hours with optional lithium battery



USER-FRIENDLY INTERFACE

Android system

7-inch touch screen



① 7-inch Touch Screen

② SD Card 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 $\leq$ 70%
Air pressure 70.0 ~ 106.0 kpa

Dimensions

261 mm*241 mm*115 mm (D*W*H)

Weight

2.0 kg

TEST ITEMS

Cat. #	TEST ITEMS	DISEASES	CUT-OFF VALUE	SAMPLE TYPES	MEASURING RANGE	SAMPLE VOLUME	REACTION TIME	QUALIFICATION	
Cardiac Markers									
IF1001	cTnI	Myocardial infarction	0.10 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
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
IF1004	NT-proBNP/cTnI	Heart failure/acute myocardial infarction/acute coronary syndrome	NT-proBNP: 185 pg/mL cTnI: 0.10 ng/mL	S/P/WB	100-15000 pg/mL 0.10-50.00 ng/mL	100 µL	10 min	NMPA	CE
IF1005	CK-MB/cTnI/Myo	Myocardial damage /infarction	CK-MB: 5.00 ng/mL cTnI: 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
IF1012	CK-MB/cTnI	Myocardial damage /infarction	CK-MB: 5.00 ng/mL cTnI: 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
IF1014	H-FABP	Myocardial damage	6.36 ng/mL	S/P/WB	1.00-120.00 ng/mL	100 µL	3 min	NMPA	CE
IF1016	CK-MB/cTnI/H-FABP	Myocardial damage /infarction	CK-MB: 5.00 ng/mL cTnI: 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
IF1018	CK-MB	Myocardial injury	5.00 ng/mL	S/P/WB	2.50-80.00 ng/mL	100 µL	10 min	NMPA	CE
NEW IF1087	ST2	AMI and chronic heart failure	35.0 ng/mL	S/P/WB	3.0-200.0 ng/mL	100 µL	15 min		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									
IF1003	hs-CRP+CRP	Cardiovascular inflammation /normal 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
IF1007	PCT	Sepsis, bacterial infection	0.10 ng/mL	S/P/WB	0.05-50.00 ng/mL	100 µL	15 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
IF1044	SAA	Bacterial/Virus infection	10.0 mg/L	S/P/WB/ Fingertip blood	5.0-200.0 mg/L	10 µL	5 min	NMPA	CE
IF1090	SAA/CRP	Neonatal sepsis, Bacterial/virus infection	SAA: 10.0 mg/L CRP: 10.0 mg/L	S/P/WB/ Peripheral blood	5.0-200.0 mg/L 0.5-200.0 mg/L	10 µL	5 min	NMPA	CE
IF1088	IL-6	Acute inflammation	7.0 pg/mL	S/P/WB/ Peripheral blood	1.5-4000.0 pg/mL	40 µL	15 min	NMPA	CE
IF1096	hs-CRP	Cardiovascular disease, routine inflammation	Refer to user manual	S/P	0.5-200.0 mg/L	100 µL	3 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
Renal Function									
IF1008	CysC	Acute and chronic 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, hypertensive nephropathy	20.0 mg/L	Urine	10.0-200.0 mg/L	100 µL	3 min	NMPA	CE
IF1010	NGAL	Acute kidney injury	Serum: 200.0 ng/mL Urine: 100.0 ng/mL	S/Urine	50.0-5000.0 ng/mL	10 µL	10 min	NMPA	CE
IF1011	β ₂ -MG	Acute and chronic kidney diseases/tumours	0.80-3.00 mg/L	S/P/WB	0.50-20.00 mg/L	10 µL	3 min	NMPA	CE
Diabetes Mellitus									
IF1017	HbA1c	Diabetes mellitus	3.80%-5.80%	WB	2.00%-14.00%	10 µL	5 min	NGSP IFCC	NMPA CE
Metabolic Marker									
IF1031	25-OH-VD	Osteomalacia, osteoporosis	30.00-50.00 ng/mL	S/P/WB/ Capillary blood	8.00-70.00 ng/mL	20 µL	20 min	NMPA	CE
NEW IF1112	Osteocalcin	Osteoporosis	Male: 14-70 ng/mL Female:11-48 ng/mL	S/P/WB	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	Hyperthyroidism, hypothyroidism	1.30-3.10 nmol/L	S/P	0.30-10.00 nmol/L	100 µL	15 min	NMPA	CE
IF1023	T4	Hyperthyroidism, hypothyroidism	59.00-154.00 nmol/L	S/P	5.40-320.00 nmol/L	100 µL	15 min	NMPA	CE
IF1067	fT3	Hyperthyroidism, hypothyroidism	3.10-6.80 pmol/L	S/P/WB	0.60-50.00 pmol/L	100 µL	15 min	NMPA	CE
IF1068	fT4	Hyperthyroidism, hypothyroidism	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
Reproduction/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 and pituitary disorders	Refer to User Manual	S/P	0.20-150.00 mIU/mL	100 μL	15 min	NMPA CE
IF1066	AMH	Fertility, PCOS, gonadal function, precocious/late puberty	Refer to User Manual	S/P	0.10-20.00 ng/mL	100 μL	15 min	NMPA CE
IF1048	PRL	Infertility, gonadal disorders	Refer to User Manual	S/P	0.50-200.00 ng/mL	100 μL	15 min	NMPA CE
IF1071	Prog	Infertility, evaluation of ovulation	Refer to User Manual	S/P	0.10-40.00 ng/mL	100 μL	15 min	CE
NEW IF1073	Testosterone	Female polycystic ovary syndrome, male testosterone insufficiency	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
NEW IF1138	Estradiol	Ovarian function	Refer to User Manual	S/P	40.0-4800.0 pg/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, cancer of ovaries or testicles, etc.	7.0 ng/mL	S/P	2.0-500.0 ng/mL	100 μL	15 min	NMPA CE
IF1051	CEA	Cancer marker: colon cancer etc.	4.7 ng/mL	S/P	2.0-500.0 ng/mL	100 μL	15 min	NMPA CE
NEW IF1079	CA125	Ovarian cancer	35.0 U/mL	S/P/WB	2-500.0 U/mL	100 μL	15 min	CE
NEW IF1080	CA19-9	Pancreatic cancer	27.0 U/mL	S/P/WB	2-1000.0 U/mL	100 μL	15 min	CE
NEW IF1081	CA15-3	Breast cancer	26.2 U/mL	S/P/WB	1.5-300.0 U/mL	100 μL	15 min	CE
Infectious Disease								
IF1057	Anti-HCV	Hepatitis C	1.00 S/CO	S/P	1.00-20.00 S/CO	100 μL	15 min	
IF1058	Anti-TP	Syphilis	1.00 S/CO	S/P	1.00-50.00 S/CO	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	1.00-100.00 IU/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	<i>H. pylori</i>	<i>H. pylori</i> 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
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	Rheumatic fever, acute glomerulonephritis, group A streptococcal infection	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								
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
IF1069	Total IgE	Allergic disorders	Refer to User Manual	S/P/WB	1.00-2000.00 IU/mL	100 μL	15 min	CE
NEW IF1052	PG I/PG II	Atrophic gastritis, stomach cancer	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	CE
IF1110	Cortisol	Adrenal cortex function	Refer to User Manual	S/P	11-1655 nmol/L	100 μL	15 min	CE

Coming soon: VB12, Folate...





mAlb Fast Test Kit (Immunofluorescence Assay)

IF1009 for Getein1100
IF5009 for Getein1160
IF2009 for Getein1600
IF3009 for Getein1180
IF4009 for Getein1200

REF

User Manual

INTENDED USE

mAlb Fast Test Kit (Immunofluorescence Assay) is intended for in vitro quantitative determination of microalbuminuria (mAlb) in human urine samples. An elevated mAlb concentration below the proteinuric level has long been recognized as a marker of kidney disease and increased cardiovascular risk in diabetic nephropathy.

SUMMARY

Albumin is one of the major plasma proteins. In normal circumstances, albumin molecules are too large to cross the glomerular basement membrane. Therefore, albumin is usually present in very low concentration in urine. Damage to the glomerular basement membrane can alter its permeability. Albumin is then able to enter the urine. Sustained elevation of urinary albumin concentration is called microalbuminuria (mAlb). mAlb arises from increased leakage of glomerular basement membrane. So, mAlb is recognized as a marker of kidney damage. The epidemiology of microalbuminuria reveals a close association between systemic endothelial dysfunction and vascular disease, also implicating glomerular endothelial dysfunction in microalbuminuria.

Recent years, determination of mAlb is linked with increased risk for cardiovascular events rather than progression to endstage kidney diseases. It is a valuable tool for the detection of cardiovascular risk in diabetic nephropathy. Early detection of microalbuminuria in diabetics is critical because immediate intervention can slow the progression of disease.

PRINCIPLE

The test is based on the competition immune-detection method and uses an anti-human mAlb monoclonal antibody conjugated with fluorescence latex and recombi-

nant mAlb antigen coated on the test line. After the sample has been applied to the test strip, mAlb in the sample will compete with recombinant mAlb antigen on nitrocellulose matrix for fluorescence latex-labelled mAlb monoclonal antibody. As a result, the concentration of mAlb antigen in specimen shows inverse proportionally with the fluorescence intensity of mAlb.

Insert test card into Getein1100/Getein1160/Getein1180 Immunofluorescence Quantitative Analyzer/Automatically inserted by Getein1200/Getein1600 Immunofluorescence Quantitative Analyzer (hereafter referred to as Getein1100, Getein1160, Getein1180, Getein1200 and Getein1600), the concentration of mAlb in sample will be measured and displayed on the screen. The value will be stored in Getein1100/Getein1160/Getein1180/Getein1200/Getein1600 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

CONTENTS

1. A kit for Getein1100/Getein1160/Getein1180 contains:

- Package specifications: 25 tests/box, 10 tests/box
- 1) mAlb test card in a sealed pouch with desiccant
- 2) Disposable pipet
- 3) User manual: 1 piece/box
- 4) SD card: 1 piece/box

2. A kit for Getein1200/Getein1600 contains:

- Package specifications: 2x24 tests/kit, 2x48 tests/kit
- 1) Sealed cartridge with 24/48 Getein mAlb test cards
- 2) User manual: 1 piece/box

Materials required for Getein1200/Getein1600:

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

3. Sample diluent:

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

4. A test card consists of:

A plastic shell and a reagent strip which is composed of a sample pad, nitrocellulose membrane (one end of the membrane is coated with a fluorescence latex-labelled anti-human mAlb monoclonal antibodies, the test line is coated with mAlb recombinant antigen, and the control line is coated with rabbit anti-mouse IgG antibody), absorbent paper and liner.

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

APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer
Getein1160 Immunofluorescence Quantitative Analyzer
Getein1180 Immunofluorescence Quantitative Analyzer
Getein1600 Immunofluorescence Quantitative Analyzer
Getein1200 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

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

Use the test card for Getein1100/Getein1160/Getein1180 within 1 hour once the foil pouch is opened. For test card of Getein1200/Getein1600: if the cartridge is opened, it could be stable within 24 hours once exposed to air. If the test cards can't be used up at a time, please put the cartridge back to the foil pouch and reseal along the entire edge of zip-seal. The remaining test cards should be used up within 7 days.

PRECAUTIONS

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

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for **urine sample**.
2. **Urine sample** can be preserved at room temperature for 4 hours, please test it as soon as possible. If testing is delayed, urine sample may be stored up to 3 days at 2–8°C before testing.
3. Do not use frozen urine sample.
4. Samples should be brought to room temperature before testing.
5. Do not use heat-inactivated samples.
6. **SAMPLE VOLUME (for Getein1100/Getein1160/Getein1180): 100 μ L.**

TEST PROCEDURE

1. Collect specimens according to user manual.

2. Test card, sample and reagent should be brought to room temperature before testing.

For Getein1100:

3. Confirm SD card lot No. in accordance with test kit lot No.. Perform "SD card" calibration when necessary.
4. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
5. Put the test card on a clean table, horizontally placed.
6. Using sample transfer pipette, deliver **100 μ L** of sample into the sample port on the test card.
7. **Reaction time: 3 minutes.** Insert the test card into Getein1100 and press "ENT" button or click on "Start" icon (for Android Getein 1100) after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein1160/Getein1180:

8. Confirm SD card lot No. in accordance with test kit lot No.. Perform "SD card" calibration when necessary.
9. Enter testing interface of Getein 1160/Getein1180.
10. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
11. Put the test card on a clean table, horizontally placed.
12. Using sample transfer pipette, deliver **100 μ L** of sample into the sample port on the test card.
13. **Reaction time: 3 minutes.** Insert the test card into Getein1160/Getein1180 immediately after sample loading. The analyzer will count down the reaction time and automatically test the card after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein1200/Getein1600:

14. Each cartridge for Getein1200/Getein1600 contains a specific RFID card which can calibrate automatically.
15. Place the sample diluent at the correct position in Getein1200/Getein1600.
16. Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein1200/Getein1600 will do the testing and print the result automatically.

Notes:

1. It is required to perform "SD card" calibration when using a new batch of kits for Getein1100/Getein1160/Getein1180.
2. It is suggested to calibrate once for one batch of kits for Getein1100/Getein1160/Getein1180.
3. Make sure the test card and the sample insertion is

correct and complete.

TEST RESULTS

Getein1100/Getein1160/Getein1180/Getein1200/Getein1600 can scan the test card automatically and display the result on the screen. Please follow the procedure in user manual of Getein1100/Getein1160/Getein1180 for result printing. For additional information, please refer to the user manual of Getein1100/Getein1160/Getein1180/Getein1200/Getein1600.

EXPECTED VALUE

The expected normal value for mAlb was determined by testing samples from 500 apparently healthy individuals. The 95th percentile of the concentration for mAlb is 20.0 mg/L. (The probability that value of a normal person below 20.0 mg/L is 95%.) It is recommended that each laboratory establish its own expected values for the population it serves.

PERFORMANCE CHARACTERISTICS

Measuring Range	10.0~200.0 mg/L
Lower Detection Limit	≤10.0 mg/L
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.
- Samples containing interferents may influence the results. The table below listed the maximum allowance of these potential interferents.

Interferent	Creatinine	Glucose	Urea
Concentration (Max)	10 g/L	10 g/L	100 g/L

REFERENCES

- Cöi M, Ocaktan E, Ozdemir O, et al. Microalbuminuria: prevalence in hypertensives and diabetics. Acta Med Austriaca. 2004, 31(1):23-29.
- McTaggart MP, Price CP, Pinnock RG, et al. The diagnostic accuracy of a urine albumin - creatinine ratio point-of-care test for detection of albuminuria in primary

- care. Am J Kidney Dis. 2012, 60(5):787-794.
- Denis Sviridov, Glen L. Hortin. Urine albumin measurement: Effects of urine matrix constituents. Clinica Chimica Acta. 2009, 404(2):140-143.
 - Reboldi G, Gentile G, Angeli F, et al. Microalbuminuria and hypertension. Minerva Med. 2005, 96(4):261-75.
 - EN ISO 18113-1:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
 - EN ISO 18113-2:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on mAlb 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 <i>instructions for use</i> or consult <i>electronic instructions for use</i>		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 <i>instructions for use</i>
	Catalogue number		

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

Version: WIF10-S-11

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