



# CysC

## Fast Test Kit

### (Immunofluorescence Assay)

#### User Manual

#### INTENDED USE

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

#### SUMMARY

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

#### PRINCIPLE

CysC 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 fluorescently labeled CysC monoclonal antibody specifically binds to target CysC molecules in the sample, forming a labeled antigen-antibody complex. The complex through capillary action to the detection zone, where it is captured by another CysC monoclonal antibody coated on the detection area of nitrocellulose membrane, ultimately forming a fluorescent double-antibody sandwich complex. The test line fluorescence intensity demonstrates proportional correlation with CysC concentration in the sample. Fluorescent signals intensity can be analyzed by applicable device thus the CysC 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
CysC 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 tubes	25 tubes	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

\* CysC test card

A test card mainly consists of: Fluorescently labeled CysC monoclonal antibody, CysC monoclonal antibody.

\*\* Sample diluent

(1) Sample diluent for Getein 1100/Getein 1160/Getein 1180 in each tube mainly consists of: phosphate buffer (20 mmol/L), NaN<sub>3</sub> (<0.1%).

(2) Sample diluent for Getein 1200/ Getein 1600 is an independent packing box mainly consists of: -Phosphate buffer (20 mmol/L), NaN<sub>3</sub> (<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 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.
- Sodium citrate and EDTA can be used as the anticoagulant for plasma and whole blood. Do not use hemolysis specimens.
- 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: **10 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.
- Using disposable pipet or pipette, deliver **10 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: **3 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. 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.
- Using disposable pipet or pipette, deliver **10 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.
- Insert the test card into Getein 1160/Getein 1180 immediately after sample loading. The analyzer will count down the reaction time (**3 minutes**) and automatically test the card after reaction time is elapsed. The result will be

shown on the screen and displayed automatically.

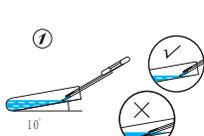
**For Getein 1200/Getein 1600:**

- Each cartridge for Getein 1200/Getein 1600 contains a specific RFID card (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.

**Note:**

- It is required to perform "SD card" calibration when using a new batch of kits for Getein 1100/Getein 1160/Getein 1180.
- The directions for using disposable pipet are as follows:

**Directions to use disposable pipet**

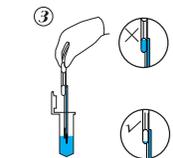


Insert the disposable pipet into the sample tube, gently touch the liquid surface with the capillary tip, and draw the sample.

**Note: Do not immerse the exhaust pipe below the liquid level.**



Insert the disposable pipet (including the exhaust tube) into the dilution liquid, gently squeeze the suction bulb to perform 2-3 aspiration washing cycles, then mix the dilution manually.



Insert the disposable pipet (including the exhaust tube) into the dilution liquid, firmly squeeze the suction bulb to aspirate the mixed sample.



Squeeze the suction bulb and drop the mixed sample vertically into the sample well on the test card.

**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 user manual of Getein 1100/Getein 1160/Getein 1180/Getein 1200/Getein 1600.

**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	10g/L
Bilirubin	0.2g/L
Hemoglobin	10g/L

**EXPECTED VALUE**

The expected normal value for CysC was determined by testing samples from 233 apparently healthy individuals. The reference range of CysC is 0.51mg/L~1.09mg/L calculated by using normal distribution methods. 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	0.50-10.0mg/L
Limit of Detection	≤0.50mg/L
Within-Run Precision	≤10%
Between-Lot Precision	≤15%

**REFERENCES**

- Björman C, Snygg-Martin U, Olaison L, et al. Cystatin C in a composite risk score for mortality in patients with infective endocarditis: a cohort study. *BMJ Open*. 2012, Jul 12, 2(4).
- Chae HW, Shin JI, Kwon AR, et al. Spot urine albumin to

- creatinine ratio and serum cystatin C are effective for detection of diabetic nephropathy in childhood diabetic patients. *J Korean Med Sci*.2012, 27(7):784-787.
- Odutayo A, Cherney D, Cystatin C and acute changes in glomerular filtration rate. *Clin Nephrol*. 2012, 78(1):64-75.
  - EN ISO 18113-1:2011 In vitro diagnostic medical devices- Information supplied by the manufacturer (labelling)- Part1: Terms, definitions and general requirements.
  - EN ISO 18113-2:2011 In vitro diagnostic medical devices- Information supplied by the manufacturer (labelling)- Part2: In vitro diagnostic reagents for professional use.

**DESCRIPTION OF SYMBOLS USED**

The following graphical symbols used in or found on CysC Fast Test Kit (Immunofluorescence Assay) are the most common ones appearing on medical devices and their packaging. They are explained in more 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		Caution

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

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Catalogue number	Applicable analyzer	Package specification
IF1008-10T	Getein 1100	10 T/kit
IF1008	Getein 1100	25 T/kit
IF5008-10T	Getein 1160	10 T/kit
IF5008	Getein 1160	25 T/kit
IF3008-10T	Getein 1180	10 T/kit
IF3008	Getein 1180	25 T/kit
IF4008	Getein 1200	2*24 T/kit
IF4008-96T	Getein 1200	2*48 T/kit
IF2008	Getein 1600	2*24 T/kit
IF2008-96T	Getein 1600	2*48 T/kit