



# CysC Fast Test Kit

(Immunofluorescence Assay)

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

## User Manual

## INTENDED USE

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

## SUMMARY

Cystatin C (CysC) is mainly used as a biomarker of kidney function. Cystatin C has a low molecular weight (approximately 13.3 kilodaltons), and it is removed from the bloodstream by glomerular filtration in the kidneys. If kidney function and glomerular filtration rate decline, the blood levels of cystatin C rise. Serum levels of cystatin C are a more precise test of kidney function (as represented by the glomerular filtration rate, GFR) than serum creatinine levels.

This finding is based mainly on cross-sectional studies (on a single point in time). Longitudinal studies (that follow cystatin C over time) are scarcer; some studies show promising results. Cystatin C levels are less dependent on age, sex, race and muscle mass compared to creatinine. Cystatin C measurement alone has not been shown to be superior to formula-adjusted estimations of kidney function. As opposed to previous claims, Cystatin C has been found to be influenced by body composition. It has been suggested that cystatin C might predict the risk of developing chronic kidney disease, thereby signaling a state of 'preclinical' kidney dysfunction.

## PRINCIPLE

The test uses an anti-human CysC monoclonal antibody conjugated with fluorescence latex and another anti-human

CysC monoclonal antibody coated on the test line. After the sample has been applied to the test strip, the fluorescence latex-labelled anti-human CysC monoclonal antibody binds with the CysC in sample and forms a marked antigen-antibody complex. This complex moves to the test card detection zone by capillary action, then be captured on the test line by another anti-human CysC monoclonal antibody. The fluorescence intensity of the test line increases in proportion to the amount of CysC in sample.

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

## CONTENTS

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

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

## APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer  
Getein1600 Immunofluorescence Quantitative Analyzer

## STORAGE AND STABILITY

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

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

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

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

## PRECAUTIONS

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

## SPECIMEN COLLECTION AND PREPARATION

- This test can be used for **serum, plasma and whole blood samples**. **Sodium citrate** should be used as the anticoagulant for plasma and whole blood. Samples should be free of hemolysis.
- Suggest using serum or plasma for better results.
- If testing will be delayed, serum and plasma samples may be stored up to 7 days at 2~8°C or stored at -20°C for 6

months before testing (whole blood sample may be stored up to 3 days at 2~8°C).

- Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
- Do not use heat-inactivated samples.
- SAMPLE VOLUME (for Getein1100): 10 µl.

## TEST PROCEDURE

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

### For Getein1100:

- Confirm SD card lot No. in accordance with test kit lot No.. Perform "SD Card Calib" calibration when necessary (Details refer to 8.5.2 of Getein1100 User Manual).
- On the main interface of Getein1100, press "ENT" button to enter testing interface.
- 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 10 µl of sample into one tube of sample diluent, mix gently and thoroughly. Then drop 100 µl of sample mixture (or 3~4 drops of sample mixture when using disposable pipet) into the sample port on the test card.
- Reaction time: 3 minutes. Insert the test card into Getein1100 and press "ENT" button after reaction time is elapsed. The result will be shown on the screen and printed automatically.

### For Getein1600:

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

## Notes:

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

## TEST RESULTS

Getein1100/Getein1600 can scan the test card automatically

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

## EXPECTED VALUE

The expected normal value for CysC was determined by testing samples from 233 apparently healthy individuals. The reference range of CysC is 0.51 mg/L~1.09 mg/L calculated by using normal distribution methods.

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

## PERFORMANCE CHARACTERISTICS

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

### Method Comparison:

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

## LIMITATIONS

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

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

## DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on CysC Fast Test Kit (Immunofluorescence Assay) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN 980:2008 and International Standard ISO 15223-1:2007.

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

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

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