Getein Biotech, Inc.

CE

CysC Fast Test Kit (Immunofluorescence Assay)
For *in vitro* Diagnostic Use

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 and another anti-human CysC monoclonal antibody coated on the test line. After the sample has been applied to the test strip, the fluorescence-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 (hereafter referred to as Getein1100), the concentration of CysC in sample will be measured and displayed on the screen. The value will be stored in Getein1100 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

CONTENTS

A kit contains:

1. Getein CysC test card in a sealed pouch with desiccant ····· 25
2. Disposable pipet ····· 25
3. User manual ····· 1
4. SD card ····· 1
5. Blood sample diluent ····· 25

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.

Blood sample diluent:

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

Note: Components from different batches must not be interchanged.

APPLICABLE DEVICE

Getein1100 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 within 1 hour once the foil pouch is opened.
Store the blood sample diluent at 0~30°C with a valid period of 24 months.
Store the blood sample diluent at 2~8°C for better results.

PRECAUTIONS

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

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for serum, plasma and whole blood samples. Sodium citrate or EDTA should be used as the anticoagulant for plasma and whole blood. Samples should be free of hemolysis.
2. Suggest to use serum or plasma for better results.
3. Serum or plasma can be used directly. For whole blood sample, one drop of blood sample diluent must be added before testing.
4. If testing will be delayed, serum and plasma samples may be stored up to 7 days at 2~8 °C or stored at -20 °C for 6 months prior to being tested (whole blood sample may be stored up to 3 days at 2~8 °C).
5. Refrigerated or frozen sample should reach room temperature and be homogeneous prior to testing. Avoid multiple freeze-thaw cycles.
6. Do not use heat-inactivated samples.
7. SAMPLE VOLUME: 10 µl.

TEST PROCEDURE

1. Collect specimen according to manual.
2. Test card, sample and reagent should be brought to room temperature prior to testing.
3. Confirm SD card lot No. in accordance with test kit lot No.. Perform “SD Card Calib” calibration when necessary (Details refer to 8.5.2 of Getein1100 User Manual).
4. On the main interface of Getein1100, press "ENT" button to enter testing interface.
5. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
6. Put the test card on a clean table, horizontally placed.
7. Using sample transfer pipette, deliver 10 µl of sample into one tube of sample diluent, mix gently and thoroughly. Then drop 100 µl of sample mixture (or 3-4 drops of sample mixture when using disposable pipet) into the sample port on the test card.
8. After 3 minutes, insert the test card into Getein1100 and press "ENT" button. The result will be shown on the screen and printed automatically

Notes:

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

TEST RESULTS

Getein1100 can scan the test card automatically and display the result on the screen. Please follow the procedure in user manual of Getein1100 for result printing.

For additional information, please refer to the user manual of Getein1100.

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.

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

LIMITATIONS

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

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

REFERENCES

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

DESCRIPTION OF SYMBOLS USED

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

Key to symbols used			
	Manufacturer		Expiration Date
	Do not re-use		Date of manufacture
	Consult instructions for use	LOT	Batch code
	Temperature limitation	IVD	In vitro diagnostic medical device
	Sufficient for	EC REP	Authorized representative in the European Community
CE	CE marking		

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

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