Cys-C FIA Rapid Test Device

(Whole Blood/Serum/Plasma)

FI2-CYSC-001

A rapid test for the quantitative detection of Cystatin C (Cys-C) in whole blood or serum or plasma that can be performed with the use of the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000).
For professional in vitro diagnostic use only.

INTENDED USE

The Cys-C FIA Rapid Test Device is based on Fluorescence Immunoassay for the quantitative determination of Cys-C in whole blood, serum or plasma as an aid in the diagnosis of renal function.

SUMMARY

Cystatin C or cystatin 3 (formerly gamma trace, post-gamma-globulin, or neuroendocrine basic polypeptide),[1] a protein encoded by the CST3 gene, 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. Cross-sectional studies (based on a single point in time) suggest that 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.[2,3] Longitudinal studies (following cystatin C over time) are sparse, but some show promising results.[4,5,6] Cystatin C levels are less dependent on age, gender, ethnicity and muscle mass compared to creatinine.

PRINCIPLE

The Cys-C FIA Rapid Test Device detects Cys-C based on Fluorescence Immunoassay. The sample moves through the strip from sample pad to absorbent pad. If the specimen contains Cys-C, it attaches to the Cys-C antibody which is conjugated with fluorescent microspheres. Then the complex will be captured by the capture antibodies coated on the nitrocellulose membrane (Test line). The concentration of Cys-C in the sample correlates linearly with the fluorescence signal intensity captured on the T line. According to the fluorescence intensity of the test and standard curve, the concentration of Cys-C in the sample can be calculated by the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000) to show Cys-C concentration in specimen.

REAGENTS

The test includes anti-Cys-C antibody coated particles and anti-Cys-C antibody coated on the membrane.

PRECAUTIONS

1. For professional *in vitro* diagnostic use only.
2. Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse.
3. This test contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious, and handled observing usual safety precautions (e.g., do not ingest or inhale).
4. Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
5. Do not eat, drink or smoke in the area where the specimens and tests are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
6. Do not interchange or mix reagents from different lots.
7. Humidity and temperature can adversely affect results.
8. Used testing materials should be discarded in accordance with local regulations.
9. Read the entire procedure carefully prior to any testing.
10. The Biopanda Cys-C FIA Rapid Test should only be used with the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000) by approved medical professionals.

STORAGE AND STABILITY

1. The kit should be stored at 4-30°C until the expiry date printed on the sealed pouch.
2. The test must remain in the sealed pouch until use.
3. Do not freeze.
4. Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

KIT COMPONENTS

- 25 x foil wrapped Cys-C test devices
- 25 x Specimen collection tubes with extraction buffer
- 1 x ID card (Cys-C)
- Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer
- Centrifuge
- Pipette
- Biopanda Fluorescence Immunoassay Device (BR-FIA-2000)

BLOOD SAMPLE TAKING

1. Collect the specimen according to standard procedures.
2. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Blood collected from fingerstick samples cannot be used.
3. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
4. EDTA, Heparin sodium, can be used as the anticoagulant tube for collecting the blood specimen.

DIRECTIONS FOR USE

Refer to the Biopanda Fluorescence Immunoassay Device Operation Manual for the complete instructions on use of the test. The test should be conducted at room temperature. Cold buffer solution or moisture condensation on the membrane can lead to invalid test results.

Note: There are two test modes for the Biopanda Fluorescence Immunoassay Device: Standard Test mode and Quick Test mode. *Standard Test* mode is a 'set and forget' method where the test will automatically be read after 10 minutes. *Quick* Test mode provides an instant result but the user must monitor the 10 minute test time themselves. It is suitable when running multiple tests concurrently.
Refer to the Biopanda Fluorescence Immunoassay Device Operation Manual for further details.

Allow the test cassette, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.

1. Turn on the Analyser. Then according to the user requirement, select "Standard test" or "Quick test" mode.
2. Take out the ID card and insert it into the Analyser port.
3. Remove the test cassette from the sealed foil pouch and start testing as soon as possible.
4. **Whole blood/Serum/plasma**: Transfer **20 µl of Whole blood, serum, or plasma** into the buffer tube, mix the specimen and the buffer well.
5. **Add diluted specimen with a Pipette**: Pipette 75 µl of diluted specimen into the sample well of the test cassette. Start the timer at the same time.
6. Test results should be read at **10 minutes** with the use of the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000).

INTERPRETATION OF RESULTS

The result of tests for Cys-C is calculated by the Biopanda Fluorescence Immunoassay Device and displays the result on the screen. For additional information, please refer to the user manual of the Biopanda Fluorescence Immunoassay Device.

Linearity range of the Biopanda Cys-C FIA Rapid Test is 0.1~9 mg/L.
Reference range: 0.5~1.1 mg/L.

QUALITY CONTROL

Each Biopanda Cys-C FIA Rapid Test Device contains an internal control that satisfies routine quality control requirements. This internal control is performed each time a patient sample is tested. This control indicates that the test device was inserted and read properly by the Biopanda Fluorescence Immunoassay Device. An invalid result from the internal control causes an error message on the Biopanda Fluorescence Immunoassay Device indicating that the test should be repeated. An invalid result from the internal control causes an "N/A" message on the Biopanda Fluorescence Immunoassay Device. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

LIMITATIONS

1. The Biopanda Cys-C FIA Rapid Test Device is for professional *in vitro* diagnostic use, and should only be used for the quantitative detection of Cys-C.
2. The Biopanda Cys-C FIA Rapid Test Device will only indicate the presence of Cys-C in the specimen and should not be used as the sole criterion for evaluating renal function.
3. As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
4. The results of the Biopanda Cys-C FIA Rapid Tests are based on measuring the levels of Cys-C in a specimen. It should not be used as the sole criterion for treatment decisions. If the result is positive, other clinical findings and alternative test methods are recommended to reach proper medical treatments.

EXPECTED RESULTS

Concentrations	Clinical Reference
≤1.1 mg/L	Negative
>1.1 mg/L	Positive

PERFORMANCE CHARACTERISTICS

1. **ACCURACY**: The test deviation is ≤±15%.
2. **SENSITIVITY**: The Biopanda Cys-C FIA Rapid Test Device can detect levels of Cys-C as low as 0.1 mg/L in whole blood, serum or plasma.
3. **DETECTION RANGE**: 0.1~9 mg/L
4. **LINEARITY RANGE**: 0.1~9 mg/L, R≥0.990
5. **PRECISION**

INTRA-LOT PRECISION

Within-run precision has been determined by using 10 replicates of 2 specimens containing 0.5 mg/L and 2 mg/L of Cys-C. C.V. is ≤ 15%.

INTER-LOT PRECISION

Between-run precision has been determined by using 10 replicates for each of three lots using 2 specimens containing 0.5 mg/L and 2 mg/L of Cys-C. C.V. is ≤15%.

7. **INTERFERING SUBSTANCES**

The following substances do not interfere with the test results at the indicated concentrations: Hemoglobin at 10g/l, Triglyceride at 30mg/ml, Bilirubin at 0.6mg/ml, cholesterol at 60mg/ml.

6. **METHOD COMPARISON**

The Cys-C Test Device was compared with the results obtained with Turbidimetric Inhibition Immunoassay for 104 samples. The correlation coefficient (r) is R=0.991.

REFERENCES

1. "Alzforum: AlzGene". Archived from the original on 2004-12-27.
2. Roos JF, Doust J, Tett SE, Kirkpatrick CM (March 2007). "Diagnostic accuracy of cystatin C compared to serum creatinine for the estimation of renal dysfunction in adults and children--a meta-analysis".
3. Dharnidharka VR, Kwon C, Stevens G (August 2002). "Serum cystatin C is superior to serum creatinine as a marker of kidney function: a meta-analysis".
4. ^ Premaratne E, MacIsaac RJ, Finch S, Panagiotopoulos S, Ekinci E, Jerums G (May 2008). "Serial measurements of cystatin C are more accurate than creatinine-based methods in detecting declining renal function in type 1 diabetes". Diabetes Care.
5. ^ Perkins BA, Nelson RG, Ostrander BE, et al. (May 2005). "Detection of renal function decline in patients with diabetes and normal or elevated GFR by serial measurements of serum cystatin C concentration: results of a 4-year follow-up study".
6. ^ Corrao AM, Lisi G, Di Pasqua G, et al. (January 2006). "Serum cystatin C as a reliable marker of changes in glomerular filtration rate in children with urinary tract malformations".

Index of Symbols

	Manufacturer		Tests per kit		Do not reuse test
IVD	*In vitro* diagnostic medical device		Expiration date	REF	Catalogue number
	Storage temperature	LOT	Lot Number		Consult instructions for use
	Do not use if package is damaged				

Thank you for purchasing Biopanda's Cys-C FIA Rapid Test Device. Please read this manual carefully before operating to ensure proper use.

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