Chuangxingwell

Cystatin C (Cys-C) Rapid Test Kit
Package Insert

CE

For in vitro diagnostic use only. For professional use only.

IVD

INTENDED USE

The Cystatin C Protein (Cys-C) Fluorescence ImmunoAssay (FIA) Test is a lateral flow chromatographic fluorescence immunoassay for the quantitative detection of Cys-C in human plasma or whole blood using the *FIA* system.

SUMMARY AND EXPLANATION OF THE TEST

The cysteine protease inhibitor Cys-C, also called gamma trace or post-gamma-globulin, is a valuable biomarker in diagnosing early kidney injury. Cys-C is removed from the bloodstream by glomerular filtration in the kidneys. The concentration of Cys-C in blood is only determined by glomerular filtration rates, not by age, gender, or diet. When both kidney function and glomerular filtration rates decrease, the levels of Cys-C in the blood elevate.

Cys-C is also used to detect kidney injury due to acute rejection reaction and medical treatment, making Cys-C a useful and sensitive biomarker for diagnosing diabetic nephropathy [1-3].

TEST PRINCIPLE

This test is a fluorescent lateral flow immunoassay. When the specimen and the buffer are mixed and applied into the test kit, the Cys-C present in the specimen will form an intermediate complex with the mouse anti-Cys-C monoclonal antibodies labeled with fluorescent reporters. The intermediate complex moves along the nitrocellulose membrane by lateral flow to a detection line (T line) coated with Cys-C specific monoclonal antibodies. The intermediate complex will be captured by the antibodies coated on the T line to form the final fluorescent reaction compound sandwich. Thus, the fluorescent signal on the detection line is positively correlated with the concentration of Cys-C in human plasma or whole blood.

The fluorescent signal from the reporters of the compound sandwich will be detected and calculated according to the calibration curve in the secure digital (SD) card provided with the reagents, to represent the concentration of Cys-C in human specimens.

REAGENTS AND MATERIALS PROVIDED

1. Individually sealed foil pouches containing:
   a. One test cassette
   b. One desiccant
2. Detection buffer tubes
3. SD card
4. Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED

1. Clock, watch or other timing device
2. *FIA* Immunofluorescence Analyzer
3. *FIA* Immunofluorescence Incubator

REAGENT PREPARATION AND STORAGE INSTRUCTIONS

All reagents are ready to use as supplied.

1. Store the test cassette and detection buffer at 2-30°C with a valid period of 24 months..
2. Use the test cassette within 30 minutes after opening the pouch.

SPECIMEN COLLECTION AND HANDLING

Consider any materials of human origin as infectious and handle them using standard biosafety procedures.

Step 1: Collect venous blood by venipuncture into a collection tube containing EDTA or heparin for plasma or whole blood specimens.

Step 2: **For whole blood:** Test immediately or store refrigerated at 2-8°C for up to 24 hours after collection. Do not freeze specimens.

For plasma: Centrifuge the collected specimen and carefully withdraw the plasma into a new pre-labeled tube.

Step 3: **For Plasma only:** Test specimens immediately after collection or store refrigerated at 2-8°C for up to 5 days. Specimens can be frozen at -20°C for longer storage. Avoid multiple freeze-thaw cycles.

Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing.

Note: Do not test specimens demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference with result interpretation.

ASSAY PROCEDURE

Read these instructions and the instrument manual carefully before testing.

Please refer to the operation manual of the *FIA* Immunofluorescence Analyzer and Incubator for details.

Step 1: Bring the specimen and detection buffer to room temperature. If the specimen is stored frozen, thaw and mix well prior to performing the assay.

Step 2: Turn on the incubator. Set the incubation temperature to 25°C and incubation time to 5 min.

Step 3: Turn on the analyzer and insert the SD card. Press “Test” and choose “Quick Test”. Input the patient information, then press “Confirm”.

Step 4: When ready to test, open the pouch and label the cassette with the specimen’s ID number. Ensure that the lot number of the buffer and the lot number of the test cassette match.

Note: *Complete steps 5 and 6 within 1 minute to ensure the accuracy of the test results.*

Step 5: Add 10 µL of plasma or 15 µL of whole blood into the buffer tube. Mix the specimen well with detection buffer by tapping or inverting the tube.

Step 6: Load 80 µL of specimen mixture into the sample well of the cassette. Ensure that there are no air bubbles. Immediately insert the cassette into the incubator and incubate for 5 minutes.

Step 7: After 5 minutes, pull out the test cassette, insert it into the analyzer and press “Start Test”. The test result will be shown on the screen and print automatically.

Step 8: Discard used kits after interpreting the result following local requirements governing the disposal of devices.

QUALITY CONTROL

Quality control tests are a part of the good testing practice to confirm the expected results and validity of the assay, and should be performed at regular intervals or:

- After opening a new test lot to ensure the test performance is not altered.
- Whenever there is any question concerning the validity of the test results.

Control materials are not provided with this kit. For more information regarding obtaining the control materials, contact our Sales Division for assistance (Please refer to the instructions for use of control material).

INTERPRETATION OF ASSAY RESULT

Expected Values

A normal range of < 1.2 mg/L Cys-C is recommended. However, laboratories should establish their own diagnostic cut-off concentration based on the clinical practice at their respective institutions.

PERFORMANCE CHARACTERISTICS

1. **Range**

   Working range: 0.2-8.0 mg/L

2. **Precision**

   Intra-lot Precision

   Intra-lot precision was determined by testing of Cys-C reference materials using 10 test kits from the same lot. CV ≤ 15%.

Inter-lot Precision

Inter-lot precision was determined by testing of Cys-C reference materials using 30 test kits from three consecutive lots randomly (10 test kits from each lot). CV ≤ 20%.

3. **Accuracy**

Cys-C control materials with three different concentrations were tested by every lot of test kit, and the deviations were within ±15%.

4. **Linearity**

A serial concentration of Cy s-C reference materials at 0.4-8.0 mg/ L was tested, and the correlation coefficient (R) is ≥ 0.9900.

WARNINGS AND PRECAUTIONS

For *in vitro* diagnostic use only. For professional use only.

1. Read these Instructions for Use completely before performing the test. Failure to follow the instructions could lead to inaccurate test results.
2. Do not open the sealed pouch unless ready to conduct the assay. Do not use if the pouch is damaged or not sealed. Do not use expired kits.
3. Lot number of buffer and test cassette must match.
4. Bring all reagents to room temperature (15-30°C) before use.
5. Do not use components from any other type of kit as a substitute for the components in this kit. Use the Cys-C FIA Test in conjunction with the *corresponding FIA* instruments only.
6. Do not use hemolyzed blood specimens for testing.
7. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
8. Follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other bloodborne pathogens.
9. Do not smoke, drink or eat in areas where specimens or kit reagents are being handled.
10. Dispose of all specimens and materials used to perform the test as bio-hazardous waste.
11. Read test results at 5 minutes after a specimen is applied to the sample well of the cassette.
12. Do not perform the test in a room with strong air flow, i.e. an electric fan or strong air-conditioning.

LIMITATIONS OF TEST

1. The test sample should be plasma or whole blood.
2. Follow the assay procedure and the interpretation of assay result sections closely when testing for the presence of elevated Cys-C in plasma or whole blood from individual subjects. Failure to follow the procedure may give inaccurate results.
3. Human anti-mouse antibody (HAMA) may be present in patients who have received immunotherapy with a murine monoclonal antibody. This kit has been specially designed to minimize the effect of these antibodies on the test results. However, the test result must be carefully evaluated when patients are known to have these antibodies [4, 5].
4. If symptoms are highly suspicious or persist while the result from the Cys-C FIA Test is normal or non-reactive, it is recommended to test with an alternative test method.
5. Some unknown factors may interfere with the test and cause erroneous results, such as technical/procedural errors, degradation of the test components/reagents or presence of interfering substances in the specimens.
6. The Cys-C FIA Test should be considered as preliminary diagnostic tool only. In case of an abnormal result, consult a physician to discuss the test result and decide further course of action.

REFERENCES

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2. Paola Lagos-ArevaloBSc, Ana Palijan, PhD, Laura Vertullo BSc, Prasad Devarajan, MD. Cystatin C in acute kidney injury diagnosis. Pediatr Nephrol. 2015-Apr, 30(4):665-676
3. Mohamed Fouad , Maher Boraie. Cystatin C as an early marker of acute kidney injury. Arab J Nephrol Transplant. 2016-Jan, 6(1):21-26
4. Boscato, L.M. and M.C. Stuart, Heterophilic antibodies: a problem for all immunoassays. J of Clin Chem, 1988. **34**(1): 27-33
5. Levinson,S.S., Antibody multispecificity in immunoassay interference. J of Clin Biochem, 1992. **25**(2): 77-87

Index of Symbols

	Caution	IVD	In Vitro Diagnostic Medical Device
	Manufacturer		Date of Manufacture
CE	CE Marking		Do Not Re-use
	Keep Dry		Keep Away From Sunlight
LOT	Batch Code		Do Not Use if Package is Damaged
REF	Catalogue Number	Σ	Contains Sufficient for <n> Tests
	Use-By Date		Temperature Limit
EC REP	Authorized representative in the European Community		

Manufacturer
Jinan Chuangxingwell Biotech Co., Ltd.
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