Cystatin C Test Kit (FIA) Package Insert

REF VID03-02-011	English

INTENDED USE

VivaDiag Cystatin C Test Kit (FIA) is a fluorescence immunoassay (FIA) for the quantitative determination of Cystatin C (Cys C) in human whole blood, serum, or plasma. It is useful as an aid in management and monitoring of renal disease.
For *in vitro* diagnostic use only.
For professional use only.

INTRODUCTION

Cystatin C is a proteinase inhibitor with a low molecular mass of 13Kda that is produced at a constant rate in all nucleated cells and appears in human plasma and serum. Cystatin C is freely filtered through the glomerulus, is not secreted by the tubule or eliminated via any extra-renal route, and is almost completely absorbed and catabolized by proximal tubular cells. Therefore, the plasma concentration of Cystatin C is almost exclusively determined by the glomerular filtration rate (GFR), making Cystatin C an excellent indicator of GFR. A number of clinical studies have shown that Cystatin C is more accurate than plasma creatinine and the Cockcroft-Gault estimation of creatinine clearance and is more reliable than the 24-h creatinine clearance. There is a growing body of evidence that suggests that Cystatin C can be used to detect kidney disease at earlier stages than serum creatinine which may help facilitate prevention efforts in the elderly and those with diabetes, hypertension, or cardiovascular disease.[1,2]

PRINCIPLE

VivaDiag Cystatin C Test Kit (FIA) is based on fluorescence immunoassay technology, specifically the sandwich immunodetection method. When the sample is added into sample well of the test device, Cys C binds to the fluorescence-labeled antibody to form immune complexes. Then the immune complexes migrate on the membrane, and bind specially to antibody coated on the test line. The intensity of fluorescence signal reflects the amount of Cys C in the sample, which then is processed by VivaDiag POCT Analyzer to show the Cys C concentration.

TRACEABILITY

Each VivaDiag Cystatin C Test Kit (FIA) has the ID Card containing specific information for calibration of the particular reagent lot. The predefined calibration curve is adapted to VivaDiag POCT Analyzer.
The metrological traceability of values assigned to trueness-control materials can be traced to Certified Reference Material (ERM-DA471).

COMPONENT

VivaDiag Cystatin C Test Kit (FIA) contains the 'Test Device (packaged in pouch with desiccant)', 'ID Card', 'Buffer Tube (prefilled with buffer)', and 'Package Insert'.

- Test Device: It is composed of glass fiber, nitrocellulose membrane, plastic backer, absorbent paper and plastic cassette.
- ID Card: Calibration information.
- Buffer Tube: Sample diluent.
- Package Insert: Instruction for use.

MATERIALS SUPPLIED

Each VivaDiag Cystatin C Test Kit (FIA) contains:

- 25 Test Devices
- ID Card
- 25 Buffer Tubes
- 1 Package Insert

MATERIALS REQUIRED BUT NOT SUPPLIED

- VivaDiag POCT Analyzer
- VivaDiag Cystatin C Control Solution (FIA)
- Timer
- Pipettes with pipette tips for 5 μL, 10 μL and 75 μL.

STORAGE AND STABILITY

- Store the test kit in a cool, dry place between 2 ~ 30°C. Keep away from light. Exposure to temperature and/or humidity outside the specified conditions may cause inaccurate results.
- Do not freeze.
- Do not open the pouch until ready to perform the assay.
- Once the pouch is opened, the test device should be used in 1 hour.
- All expiration dates are printed in Year-Month-Day format. Example: 2026-06-18 indicates June 18, 2026.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- For professional use only. Testing should be applied by well-trained healthcare professionals, and conducted in central laboratories, GP offices, clinics, pharmacy and medical examination centers etc.
- Please follow the Package Insert when testing.
- The Test Device should remain sealed in its original pouch until just before use. Do not use the Test Device, if pouch is damaged or has already been opened.
- Do not reuse the Test Device and do not use your test kits beyond the expiration date. Biological materials used beyond their expiry date can become unstable and fail.
- It is recommended to use an anticoagulant blood collection tube (EDTA, heparin, or citrate). Other anticoagulants have not been evaluated in VivaDiag Cystatin C Test Kit (FIA) and thus should not be used.
- Use the test kits at temperatures between 18 ~ 25°C.
- Use the test kits between 10 ~ 90% humidity.
- Do not use the Test Device in extremely temperature. If the Test Device has been stored refrigerated, bring to the ambient temperature (18 ~ 25°C) prior to testing and avoid moisture absorption.
- Keep the test kit away from direct sunlight.
- All parts of kit are considered biohazardous and can potentially transmit infectious diseases from blood borne pathogens, even after you have performed cleaning and disinfection. Follow proper precautions and all local regulations when disposing of the used test kits and other accessories.
- Do not interchange the test components between different lots or use the test components after the expiration date, either of which might yield incorrect test result(s).
- Please contact your local distributor to solve problems timely if you have any questions or need help.
- VivaDiag Cystatin C Test Kit (FIA) will provide accurate and reliable results subject to the below conditions:
  a) VivaDiag Cystatin C Test Kit (FIA) should be used combined with VivaDiag POCT Analyzer.
  b) Whole blood or plasma samples should be collected with a suitable anticoagulant blood collection tube (EDTA, heparin, or citrate is recommended).

SAMPLE COLLECTION AND PROCESSING

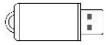
The sample type for VivaDiag Cystatin C Test Kit (FIA) is human

whole blood/serum/plasma.

- For serum sample, separate the serum from the clot as soon as possible to avoid hemolysis.
- For whole blood or plasma sample, collect the blood with a suitable anticoagulant blood collection tube (EDTA, heparin, or citrate is recommended).
- The serum/plasma can be stored at 2 ~ 8°C for 7 days, or frozen at -20°C for 6 months; the whole blood can be stored at 2 ~ 8°C for 2 days, and avoid frozen.
- Once the serum/plasma sample was frozen, it should be thawed only once. As a repeated freeze-thaw cycle may affect the test result, do not refreeze previously frozen samples.

PREPARE FOR TEST

- Turn on the Analyzer for at least 5 minutes before testing.
- If the test kit has been stored in a refrigerator, place it on a clean and flat surface at 18 ~ 25°C for at least 30 minutes before testing.
- Check the contents of VivaDiag Cystatin C Test Kit (FIA): 'Test Device (packaged in pouch with desiccant)', 'ID Card', 'Buffer Tube (prefilled with buffer)', and 'Package Insert'.
- Check the label information of the ID Card to make sure that the ID Card matches the Test Device.
- Select the ID card that matches the current Analyzer being tested, according to the User's Manual of VivaDiag POCT Analyzer.

ID Card Type	
Code Chip	USB Flash Drive
	

TEST PROCEDURE

Input Information

1. Insert the ID Card into the port on the Analyzer
2. When the information is read successfully, the test item will change to "**Cys C**".
3. Select the correct sample type.

Note: *Please refer to the User's Manual of VivaDiag POCT Analyzer for complete information and operating instructions.*

Run Test (Standard Test Model)

1. Take the Test Device out of the foil pouch and place it on a clean, dust-free and flat surface.
2. Pipette **10 µL** human whole blood or **5 µL** serum/plasma to the Buffer Tube.
3. Gently invert and mix the solution well. Avoid bubbles. Use the mixed solution within one hour.
4. Pipette **75 µL** mixed solution from the Buffer Tube to the sample well of the Test Device. Avoid bubbles.
5. Insert the Test Device into the holder of VivaDiag POCT Analyzer. Ensure proper orientation of the Test Device before pushing it into the holder. An arrow has been marked on the Test Device especially for this purpose.
6. Click the button to start the test. The Analyzer will scan the sample-loaded Test Device after **3 minutes**.
7. Read the test result on the display screen of VivaDiag POCT Analyzer, or print it by clicking the "**Print**" button on the display screen.

Run Test (Quick Test Model)

1. Take the Test Device out of the foil pouch and place it on a clean, dust-free and flat surface.
2. Pipette **10 µL** human whole blood or **5 µL** serum/plasma to the Buffer Tube.
3. Gently invert and mix the solution well. Avoid bubbles. Use the mixed solution within one hour.
4. Pipette **75 µL** mixed solution from the Buffer Tube to the sample well of the Test Device. Avoid bubbles.
5. Place the sample-loaded Test Device on a clean, dust-free and flat surface and reaction for **3 minutes**.
6. Insert the Test Device into the holder of VivaDiag POCT Analyzer. Ensure proper orientation of the Test Device before pushing it into the holder. An arrow has been marked on the Test Device especially for this purpose.
7. Click the button to start the test. The Analyzer will scan the sample-loaded Test Device in seconds.
8. Read the test result on the display screen of VivaDiag POCT Analyzer, or print it by clicking the "**Print**" button on the display screen.

INTERPRETATION OF TEST RESULT

The Analyzer calculates the Cys C test result automatically and displays "Cys C" concentration on the screen.

Reference Interval:

Cys C: ≤1.00 mg/L

Note: *Each laboratory should establish a reference interval that is representative of the population to be evaluated. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.*

QUALITY CONTROL

- Users should follow government guidelines and/or accreditation requirements for 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.
- Quality control tests should be performed immediately after opening a new test lot to ensure the test performance is not altered.
- Quality control tests should also be performed if the result and the symptoms are not consistent or if there are doubts about their accuracy.
- Control materials are not provided with VivaDiag Cystatin C Test Kit (FIA). For more information regarding obtaining the control materials, contact with your local distributor for assistance.

Note: *Please refer to the Package Insert of VivaDiag Cystatin C Control Solution (FIA) for detailed information.*

LIMITATIONS OF THE PROCEDURE

- The performance of this product has been established for human whole blood/serum/plasma only. Other specimen types have not been evaluated.
- The test may yield false negative result. The non-responsiveness of the antigen to the antibodies is most common where the epitope is masked by some unknown components, so as not to be detected or captured by the antibodies. The instability or degradation of the antigen with time and/or temperature may cause the false negative as it makes antigen unrecognizable by the antibodies.
- There is a possibility that substances and/or factors may interfere with the test and cause false results. Technical or procedural errors can also contribute to erroneous results.
- The false positive results may be caused by the cross-reactions and/or other non-specific adhesion of certain sample components to the capture/detector antibodies.
- Test results must always be evaluated with other data available to the physician. Any clinical diagnosis based on the test result must be supported by a comprehensive judgment of the concerned physician including clinical symptoms and other relevant test results. The test result cannot be used for diagnosis. If the result is not matched the clinical evaluation,

please do more testing.

PERFORMANCE CHARACTERISTICS

· Measuring Range and Detection Capability

Measuring Range: 0.50 ~ 10.00 mg/L
Limit of Blank (LoB): 0.20 mg/L
Limit of Detection (LoD): 0.40 mg/L

· Precision

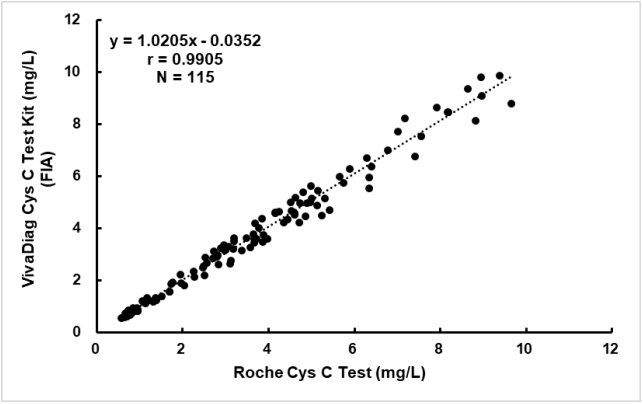
Repeatability: On the one analyzer, the specified 3 levels of samples were tested for one day, measured 20 times a day.
Reproducibility: In three laboratories, on the 3 analyzers, the specified 3 levels of samples were tested for 5 days by 3 operators, measured 5 times a day.

Sample	Cys C (mg/L)	Repeatability		Reproducibility	
		SD	CV (%)	SD	CV (%)
1	2	0.11	5.67	0.17	8.34
2	4	0.41	10.11	0.27	6.62
3	8	0.64	7.78	0.75	9.40

· Accuracy

A comparison study using 115 human serum samples, demonstrated good correlation with a commercially available kit. Comparison between VivaDiag Cystatin C Test Kit (FIA) and Roche Cys C Test is summarized in the following table and figure:

Method	Number	Intercept	Slope	Correlation Coefficient
Ordinary Linear Regression	115	-0.0352	1.0205	0.9905



· Specificity

The following substances do not interfere with the test results at the indicated concentrations:

Interfering Substance	Concentration
Bilirubin	1 g/L
Triglyceride	40 mg/L
Hemoglobin	10 g/L
Rheumatoid Factors	200 IU/mL

LITERATURE REFERENCES

[1] Randers E, Erlandsen EJ. Serum Cystatin C as an endogenous marker of the renal function-a review. Clin Chem Lab Med, 1999, 37: 389-395.

[2] Jung K, Jung M. Cystatin C: a promising marker of glomerular filtration rate to replace creatinine. [J] Nephron, 1995, 70: 370-1.

INDEX OF SYMBOLS

	Consult instructions for use or consult electronic instructions for use
	Use-by date
	Contains sufficient for <n> tests
IVD	In vitro diagnostic medical device
LOT	Batch code
REF	Catalogue number
	Manufacturer
	Date of manufacture
	Temperature limit
	Do not re-use
EC REP	Authorized representative in the European Community/European Union

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Number: 1604144901
Effective date: 2024-11-25