Bioway Chemistry Reagent Series
Cystatin C Test Kit

Detection of Cystatin C in Human Serum or Plasma on Chemistry Analyzers

Cat. No. R025K11 ***Cystatin C Test Kit***

SUMMARY OF TEST PROCEDURE

Figure 1: Procedure Diagram

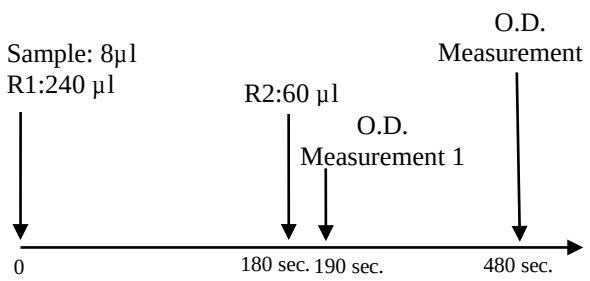

Table 1: Instrument Parameters*

Calibration method	5 point non-linear	Slope of reaction	increase
Wavelength	Pr:340 nm Se: 700 nm	Sample volume	3 µl
Test method	2 point end	R1 volume	240 µl
Reaction temperature	37℃	R2 volume	80 µl

*Refer to Figure 1 and the package insert for detail

INTENDED USE

Bioway Chemistry Reagent Series **Cystatin C Reagent Kit** (the Kit) is a latex-enhanced immunoturbidimetric assay intended for *in vitro* quantitative detection of Cystatin C in human serum or plasma on automated clinical chemistry analyzers.

SUMMARY AND EXPLANATION

Cystatin C is a small cysteine proteinase inhibitor produced by all nucleated cells that can be freely filtered by the glomerular membrane and then nearly completely reabsorbed and degraded by the renal tubular cells. Thus, plasma concentration of cystain C can be used as an indicator of glomerular filtration rate (GFR). Cystatin C levels are less dependent on age, sex, race and muscle mass compared to creatinine, making it a better assessment for kidney functions.

TEST PRINCIPLES

The Kit utilizes latex-enhanced immunoturbidimetry to measure the Cystatin C level in human serum or plasma. During the test Cystatin C in the sample binds with the specific anti-Cystatin C antibody that is coated on latex particles to cause agglutination. The turbidity caused by agglutination is detected optically by chemistry analyzer. The change in absorbance is proportional to the level of Cystatin C in the sample. The actual concentration is obtained by comparing with a calibration curve with known concentrations.

MATERIALS PROVIDED

Reagents:

R1	Glycine buffer solution
R2	Latex particles coated anti-Cys C antibodies

MATERIALS NEEDED BUT NOT PROVIDED

1. Automated chemistry analyzer.
2. Cystatin C calibrator set and control set (available for purchase).

INSTRUMENT

The Kit is applicable on most automated chemistry analyzers. Refer to specific instrument application for suggested settings.

STORAGE AND STABILITY

Store the reagents at 2-8℃. Avoid direct sunlight. The Kit is stable through the expiration date when stored properly. R1 and R2 reagents are stable for 1 month at 2-8℃ after opening.

PRECAUTIONS

1. The Kit is for *in vitro* diagnostic use only. Not for use in humans or animals.
2. The instructions must be followed to obtain accurate results.
3. Do not use the reagents beyond the expiration date.
4. Treat all specimens as infectious. Proper handling and disposal procedures of specimens and test materials should be strictly followed.

SPECIMEN COLLECTION AND HANDLING

Follow standard laboratory procedures to collect samples.
It is recommended to perform test immediately after sample collection. If the test cannot be done immediately, store sample at 2- 8° C for up to 2 days or at -20° C for up to 6 months. Avoid repeated freezing and thawing. **Do not use haemolysed samples.**

TEST PROCEDURE (see Figure 1)

No pretreatment required for reagents and samples.

Calibration: 5 level calibrator set available for purchase. Recommend using Bioway calibrators for optimal results. Use multi-point non-linear calibration method.

Test procedure: see Figure 1 and Table 1 for instrument parameter setup. Refer to specific instrument application for suggested setting.

1. Add 8 µl of sample and 240 µl of R1; mix well and incubate at 37℃ for 180 seconds.
2. Add 60 µl of R2, mix well and incubate at 37℃ for 10 seconds.
3. Take optical density measurement OD 1
4. Incubate at 37 ℃ and take optical density measurement OD 2 at 480 seconds.
5. Calculate ΔOD = OD 2 – OD 1

RESULT

The Cystatin C value can be obtained by using the calculated ΔOD to find the corresponding value on a calibration curve prepared with known values.

EXPECTED VALUES

0.57 – 1.12 mg/L.
It is recommended for each laboratory to establish its own expected values.

QUALITY CONTROL

Using Bioway controls with known concentration is recommended before each batch of tests to ensure the test is properly performed and all reagents and the instrument are functional as specified.

LIMITATIONS

Cystatin C Test Kit

Detection of Cystatin C in Human Serum or Plasma on Chemistry Analyzers

1. The Kit is for *in vitro* use on automated chemistry analyzers only.
2. Hemolysis samples may cause inconsistent results.
3. The test result from the Kit should not be used as the only basis for definite diagnosis.

PERFORMANCE CHARACTERISTICS

Linearity: 0 – 7.5 mg/L (R≥0.990)

Precision: Within Run: CV≤8%;
Run-to-Run: CV≤10%

Interference: no interference detected for: Ascorbic acid (500g/L), Bilirubin (18 mg/dL), triglycerides (1000 mg/dL), hemoglobin (460 mg/dL), and RF (240 U/mL).

Reagent Blank Absorbance: at 546nm wavelength and 10 mm optical diameter, O.D. ≤ 1.50

REFERENCES

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Not Intended for Sale in the United States.

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