Bioway Chemistry Reagent Series
Cholyglycine Assay Kit
Detection of Cholyglycine in Human Serum on Chemistry Analyzers

Cat. No. R016K11 ***CG Reagent Kit***

SUMMARY OF TEST PROCEDURE

Figure 1: Procedure Diagram

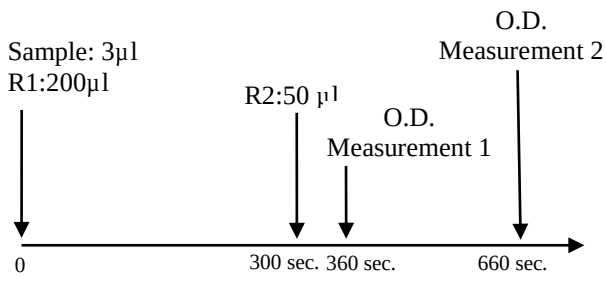

Table 1: Instrument Parameters*

Calibration method	6 point non-linear	Slope of reaction	increase
Wavelength	600nm / 700nm	Sample volume	3 µl
Test method	2 point end	R1 volume	200 µl
Reaction temperature	37℃	R2 volume	50 µl

*Refer to Figure 1 and the package insert for detail

INTENDED USE

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

SUMMARY AND EXPLANATION

Cholyglycine is formed by the conjugation of cholic acid and glycine. It plays a role of detergent to solubilize fats in intestine. Recently doctors has used it as a sensitive marker to evaluate the function of hepatocyte in patients.

TEST PRINCIPLES

The Kit utilizes latex-enhanced immunoturbidimetry to measure the CG level in human serum or plasma. During the test, CG in the sample binds with the specific CG antibody which 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 CG in the sample. The actual concentration is obtained by comparing with a calibration curve with known concentrations.

MATERIALS PROVIDED

Reagents:

R1	Tris buffer solution	10mM
R2	Latex particles coated with CG antibody	1%

MATERIALS NEEDED BUT NOT PROVIDED

1. Automated chemistry analyzer.
2. CG 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°C. 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°C 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.
5. Reagents contain less than 0.1% sodium azide as preservative; avoid contact with skin and eyes, flush with copious amounts of water when disposing.

SPECIMEN COLLECTION AND HANDLING

Follow standard laboratory procedures to collect urine samples and store them at 2- 4° C for up to 2 days or at -20° C for up to 1 months. Avoid repeated freezing and thawing.

TEST PROCEDURE (see Figure 1)

No pretreatment required for reagents and samples.

Calibration: 6 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 3 µl of sample and 200 µl of R1; mix well and incubate at 37°C for 300 seconds.
2. Add 50 µl of R2, mix well and incubate at 37°C for 1 minutes.
3. Take optical density measurement OD 1.
4. Take optical density measurement OD 2 at 660 seconds.
5. Calculate ΔOD = OD 2 – OD 1

RESULT

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

EXPECTED VALUES

0.00~2.70 mg/L

It is recommended for each laboratory to establish its own expected values. CG levels can be influenced by hereditary factors and vary with geographical location and ethnic population.

QUALITY CONTROL

Using commercially available 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.

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LIMITATIONS

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 – 80 mg/L (R^2≥0.990)

Precision: Within Run: CV≤6%;
Run-to-Run: CV≤10%

Reagent Blank Absorbance: at 600nm wavelength and 10 mm optical diameter, O.D. ≤ 1.2.

REFERENCES

1. Comparative sensitivity of serum cholylglycine concentration and bromsulphalein retention in patients with early and late alcoholic liver disease. Aust N Z J Med. 1986 Dec;16(6):785-7.
2. Determination of cholylglycine in alcoholic hepatopathies. Clinical usefulness. Minerva Dietol Gastroenterol. 1985 Jan-Mar;31(1):25-31.
3. Serum cholylglycine in the evaluation of impaired hepatic function. Minerva Med. 1986 Apr 21;77(17):687-91. Italian.

Not Intended for Sale in the United States.

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