Cholyglycine Assay Kit （CG）

Method: Immunoturbidimetric

Cat . No.	Size	Instrument
GSCG	R1:1×60 ml R2:1×20 ml	For Hitachi917 OlympusAU640/400/600
GSCG/B	R1:2×60 ml R2:2×20 ml	For Hitachi917 OlympusAU640/400/600
GBCG	R1:1×60 ml R2:1×20 ml	For Hitachi 717 &ShimadzuCL7200/8000
GBCG/B	R1:2×60 ml R2:2×20 ml	For Hitachi 717 &ShimadzuCL7200/8000
GXCG	R1:1×60 ml R2:1×20 ml	For Beckman
GTCG	R1:1×45 ml R2:1×15 ml	For TOSHIBA 40
GHCG	R1:1×45 ml R2:1×15 ml	For Hitachi7020
GDCG	R1:12×3.8 ml R2:6×2.6 ml	For DATE DIMENSION

INTENDED USE

For the quantitative in vitro determination of Cholyglycine (CG) in human serum.

CLINICAL SIGNIFICANCE

Serum Cholyglycine (Cholyglycine, CG) is one of the binding cholic acid combined by cholic acid and glycine, within the liver cells, cholesterol transformed into the primary bile acid through the extremely complex enzymatic reaction. Including cholic acid (CA) and chenodeoxycholic acid (CD - CA). there are three hydroxyl (C3, C7, C12) in the steroid nucleus of cholic acid, the hydroxyl at the end of side chains using peptide bonds with glycine, the molecular weight is 462 u [1].

Under normal circumstances, the cholic acid content in the peripheral blood is very little, no matter on an empty stomach or after eating, the concentration of serum CG is stable at a low level of a normal adult. When the liver cell is damaged, liver cells' ability of absorbing CG will drop, cause the increase of the CG content in the serum; When the bile stasis, the liver's excretion of bile acid occurs disorder, and the CG content in the reflux circulated blood is increse, also makes the blood CG content increased [1].

Cholestasis syndrome during pregnancy (ICP), at present, the recognized index of ICP is CG values, which sensitivity is much higher than that of TBA, so at present's clinic, the TBA can not replace CG at all.

ASSAY PRINCIPLES

CG and super sensitized CG antibody latex particle reagent react and appear agglutination, test the absorbance at the wavelength of 600 nm, the changing degree is proportional to the CG content of the sample.

REAGENT COMPOSITION

Contents	Concentration of Solutions
R1： Amino acid buffer	0.1mmol/L
R2： 0.12 w/v % of latex particles of sensitizing CG fluid resistance	0.12 w/v %

SAMPLE COLLECTION AND PREPARATION

Fresh serum. Please centrifuge as soon as possible after samples' collection.

Serum samples are stable for a week at 2-8 ℃.

STABILITY AND PREPARATION OF REAGENTS

All reagents are ready to use.

Stable up to the expiry date when stored at 2-8℃.

The reagents are stable for 1 month on-board the analyzer after opening and kept at 2-8℃.

ASSAY PROCEDURE

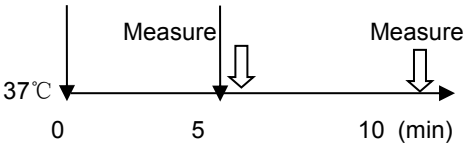
Test Procedure for Analyzers (Hitachi917)

Assay Mode: 2 POINT END,19-34

Wave Length (main/sub): 600 nm

Sample: 6 µl

R1: 150 µl R2: 50 µl



1. Mix 6µl sample with 150µl R1 and incubate at 37℃ for 5 minutes.
2. Add 50µl R2 into cuvette, mix and read initial absorbance A_1
3. Incubate at 37℃ for 5 minute, read final absorbance A_2.
4. Calculate absorbance change ($\Delta A=A_2-A_1$).

CALIBRATION

Recommend that this assay should be calibrated using Gcell Calibration.

CALCULATION OF RESULTS

$$\text{Concentration} = \frac{\Delta A_{\text{sample}}}{\Delta A_{\text{calibrator}}} \times \text{calibrator value}$$

QUALITY CONTROL

Gcell quality control are recommended for daily quality control. Controls should be assayed at least once a day. Values obtained should fall within a specified range. If these values fall outside the range and repetition excludes error, the following steps should be taken:

1. Check instrument settings and light source.
2. Check reaction temperature.
3. Check expiration date of kit and contents.

NORMAL VALUE

Serum or plasma: 0.00 mg/L-2.70mg/L.

It is recommended that each laboratory establish its own reference range to reflect the age, sex, diet and geographical location of the population.

Beijing Strong Biotechnologies, Inc.
Add: 5/F Kuang Yi Building, No. 15 Hua Yuan Dong Lu, Haidian District, Beijing 100191 P. R. China
Tel: +86 10 8201 2486 Fax: +86 10 8201 2812

Web: www.bsbe.com.cn Email: jq.tech@bsbe.com.cn

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SPECIFIC PERFORMANCE CHARACTERISTICS

LINEARITY

Linear range [2.5， 80.0] mg/L, the linear correlation coefficient r should be≥0.990, in [2.5，25.0] mg/L range, the mesured linear deviation should be no more than±2.5mg/L, in [25.0，80.0] mg/L range, the mesured linear deviation should be no more than±10%.

PRECISION

The CV of the test should be CV <10%

Intra assay precision		
N=20	level 1	level 2
Mean(mg/L)	5.00	15.00
SD	0.16	0.28
CV(%)	3.2%	1.9%

Inter assay precision			
N=5	Batch 1	Batch 2	Batch 3
Mean(mg/L)	10.30	10.12	10.24
$\bar{x}$	10.22		
(Xmax-Xmin)/ $\bar{x}$	7.01%		

INTERFERENCE

The following analytes were tested up to the levels indicated and found not to interfere:

bilirubin: up to 40 mg/dL
Hemoglobin: up to 500 mg/dL
Intralipid: up to 250 mg/dL
RF up to 400 IU/mL

SAFETY PRECAUTIONS AND WARNINGS

1. For in vitro diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.
2. Reagent contains Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes or if ingested, seek immediate medical attention.
3. Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents flush with large volumes of water to prevent azide from building up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.
4. Specimens should be treated as potentially infectious (HIV, Hepatitis B virus, Hepatitis C virus, etc.) and handled with appropriate caution.
5. Reagents with different lot numbers should not be interchanged or mixed.

REFERENCES

Dehui Wan, Duniju Liu. The clinical analysis of the serum liver serum chileglycine levels in chronic liver disease patients, The practical clinical medicine, 2012, 13 (4) : 5-6.

Xiao-ling Hu, Wei-guang Wang, Wei Wu. Pregnant women. The clinical significance of testing the serum acid and chileglycine, Radiation immunology journal. 2004 (4) : 294-295.

INDEX OF SYMBOLS

	Manufacture
REF	Catalogue Number
LOT	Lot number
	Date of manufacture
	Use by(Expiration date)
IVD	For In-Vitro Diagnostic use only
2℃ 8℃	Stored at 2-8℃
	Attention:See instruction for use
EC REP	Authorized Representative in the European Company

Beijing Strong Biotechnologies, Inc.
Add: 5/F Kuang Yi Building, No. 15 Hua Yuan Dong Lu, Haidian District, Beijing 100191 P. R. China
Tel: +86 10 8201 2486 Fax: +86 10 8201 2812

Web: www.bsbe.com.cn Email: jq.tech@bsbe.com.cn

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