Total bile acid Assay Kit (TBA)

Method: Enzymatic Cycling

Cat. No.	Size	Instrument
GB060G	R1: 6×60 ml R2: 6×20 ml	For Hitachi 717 & ShimadzuCL7200/8000
GB060G/S	R1: 2×60 ml R2: 2×20 ml	For Hitachi 717 & ShimadzuCL7200/8000
GS061G	R1: 6×60 ml R2: 6×20 ml	For Hitachi917& OlympusAU 640/400/600
GS061G/S	R1: 2×60 ml R2: 2×20 ml	For Hitachi917& OlympusAU 640/400/600
GH061G	R1: 2×48 ml R2: 2×16 ml	For Hitachi902
GX061G	R1: 2×60 ml R2: 2×20 ml	For SYNCHRON CX4-5-7-9/LX20/DXC600-800
GT061G	R1: 5×42 ml R2: 2×35 ml	For TOSHIBA
GD061G	R1:24×3.8 ml R2: 12×2.6 ml	For DATE DEMENSION

INTENDED USE

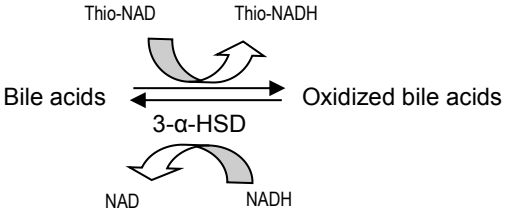
For the *in vitro* quantitative determination of bile acid in serum or plasma.

CLINICAL SIGNIFICANCE[1,2,3,4]

The assay kit is for determination of serum total bile acids (TBA). Total bile acids are metabolized in the liver and hence serve as a marker for normal liver function. Serum total bile acids are increased in patients with acute hepatitis, chronic hepatitis, liver sclerosis and liver cancer.

ASSAY PRINCIPLE[5,6,7]

The reagents of the assay kit are stable liquid formulation that allows ease of use coupled with enhanced performance characteristics. In the presence of Thio-NAD, the enzyme 3-α-hydroxysteroid dehydrogenase (3α-HSD) converts bile acids to 3-keto steroids and Thio-NADH. The reaction is reversible and 3α-HSD can convert 3-keto steroids and Thio-NADH to bile acids and Thio-NAD. In the presence of excess NADH, the enzyme cycling occurs efficiently and the rate of formation of Thio-NADH is determined by measuring specific change of absorbance at 405 nm.



SAMPLE COLLECTION AND PREPARATION

Serum or plasma samples.
Use fresh patient serum or EDTA treated plasma samples. TBA concentration is increased after meals, hence sample should be collected under fasting condition.
Serum or plasma samples are stable for a week at 2-8 ℃, or for 3 months at -20 ℃.

REAGENT COMPOSITION

Contents	Concentration of Solutions
Reagent 1 (R1)	
Goods buffer	5mmol/L
Oxidized-thio niacinamide urea purine two	952.9 mg/dl
Reagent 2 (R2)	
Goods buffer	300mmol/L
NADH	6.1 g/L
3α-HSD	12500 U/L
Sodium azide	

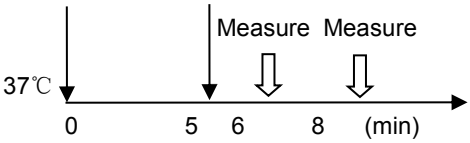
STABILITY AND PREPARATION OF REAGENTS

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 analyser after opening and kept at 2-8℃.

ASSAY PROCEDURE

Test Procedure for Analyzers (Hitachi 7180)
Assay Mode: 2 Point Rate, 22-30
Wave Length (main/sub): 405 nm/600 nm

Sample: 3 μl
R1: 225 μl R2: 75 μl



CALIBRATION

Recommend that this assay should be calibrated using Gcell Calibrator (Cat.No. GC-TBA).

CALCULATION OF RESULTS

Calculate the concentration in sample by the following formula:

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

QUALITY CONTROL

Randox Assayed Multi-sera, Level 2 and Level 3 are recommended for daily quality control. Two levels of 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[8]

Serum or plasma: 0.5-10 μmol/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,KuangYi 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

CE Revised 2014 version 1102

SPECIFIC PERFORMANCE CHARACTERISTICS

LINEARITY

The method is linear up to 200 μmol/L.
When the concentration is above the limitation,please dilute the sample with 0.9% NaCl and reassay. Multiply the result by dilution factor.

PRECISION

The CV of the test should be less than 5%.

Intra assay precision		
N=20	Level 1	Level 2
Mean (μmol/L)	25.8	40.94
SD	0.33	0.39
CV	1.30%	0.96%

Inter assay precision			
N=5	Batch 1	Batch 2	Batch 3
Mean(μmol/L)	26.14	25.97	25.82
$\bar{x}$	25.98		
(Xmax-Xmin)/$\bar{x}$	(26.14-25.82)/25.98*100=1.23%		

INTERFERENCE

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

Hemoglobin:	up to 500 mg/dl
Intrlipid:	up to 2000 mg/dl
Direct bilirubin:	up to 50 mg/dl
Ascorbic Acid (VC):	up to 10 mg/dl

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

1. Samuel J. Levin and Morton K. Schwartz. Serum Bile Acids in Patients with Liver Disease. CLIN.CHEM. Vol. II, No. 5, 196
2. Sverre Skrede, Helge Erik Solberg, Jan Petter Biomhoff, and Egli Gjone Bile Acids Measured in Serum during Fasting as a Test for Liver Disease CLIN.CHEM.24/7, 1095-1099 (1978)
3. Kaplowitz, N., Kok, E., and Javitt, N. B., Postprandial serum bile acid for the detection of hepatobiliary disease. J. Am. Med. Assoc. 225, 292 (1973)
4. Kitazima, K., and Shibata, S., Determination of serum bile acids and its use as a hepatic function test. Kawasaki Med. J. 1, 55 (1975)
5. Naomi Quast Hanson and Esther F. Freler. Effect of Protein on the Determination of Total Bile Acids in Serum. CLIN. CHEM. 29/1, 171-1 75 (1983)
6. Stephen D. Turley and John M. Dietschy Re-evaluation of the 3α-hydroxysteroid dehydrogenase assay for total bile Pseudomom testosteroni. acids in bile. Journal of Lipid Research Volume 19, 1978 Notes on Methodology
7. Michael J. Croweli and Ian A. Macdonald1 Enzymic Determination of 3a-, 7a-, and 12a-Hydroxyl (loups of Fecal Bile Salts. CLIN. CHEM. 26/9,1298-1300 (1980)1298
8. Barnes, S., Gab, G. A., Trash, D. B., and Morris, J. S., Diagnostic value of serum bile acid estimations in liver disease. J. Clin. Pat hol. 28, 506 (1975)

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,KuangYi 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

CE Revised 2014 version 1102