Pariksha Biotech
A game changer in IVD

Total Bile Acids
High-Q Total Bile Acids
Enzymatic Cyclic Method

HIGH Q
Command on Quality

Intended Use:
For the Quantitative Determination of Bile Acids in Human Serum

Clinical Significance:
Bile acids and their salts, usually sodium ones, are steroid acids found found predominantly in the bile of mammals. In humans, bile acid synthesis begins when liver cells synthesize the two primary bile acids, cholic and chenodeoxycholic acids by the cytochrome P450-mediated oxidation of cholesterol. The rate-limiting step is the addition of a hydroxyl group on position 7 of cholesterol by the enzyme cholesterol 7 alpha hydroxylase.

This enzyme is down-regulated by cholic acid and up-regulated by cholesterol. When these two bile acids are secreted into the lumen of the intestine, intestinal bacteria dehydroxylate a portion of each of them to form the secondary bile acids, deoxycholic acid (from cholic acid) and lithocholic acid (from chenodeoxycholic acid). All four of these bile acids can be taken back up into the blood stream, return to the liver, and be re-secreted in a process known as enterohepatic circulation.

All bile acids are found in human intestinal bile. The main function of bile acids is to facilitate the formation of micelles, which promotes processing of dietary fat; but also to eliminate cholesterol from body and driving the flow of bile to eliminate catabolites from the liver. Tests for bile acids are useful to diagnose a number of conditions, including cholestase, portosystemic shunt and hepatic microvascular dysplasia. Excess concentrations of bile acids in the colon are a cause of chronic diarrhea. It is well-documented
that bile acids are carcinogens and tumor promoters in experimental models. Their role in carcinogenesis is best documented in Barrett's esophagus and adenocarcinoma at the gastroesophageal junctions.

Principle:
Bile Acids are converted by 3-□-HSDH (3-□-Hydroxysteroid dehydrogenase) into the corresponding ketons, in presence of thio-NAD. The thio-NAD reacts with NADH, giving thio-NADH yellow colour, with a max. absorbance at 405 nm.
The intensity of colour at the reaction conditions is directly proportional to the Bile Acids in the sample. Using the Calibrator contained in the kit it is possible to prepare a Calibration Curve to refer. Plotting on the Calibration Curve absorbance values and concentration for each single sample, may be determined the concentration of each sample.

Precautions for use:
1. This product has been formulated for in vitro diagnostic use.
2. A proportional variation of the reaction volumes does not change the result.
3. DO NOT mix Reagents from different Production lots.
4. For concentration of bile acids higher than 200 □mol/L, dilute the sample 1:4 with saline solution, repeat the determination and multiply the result by 4.
5. In addition to the possible risk indications, the Reagent cancontain preservatives (as sodium azide or others), which total concentration is lower than the limits mentioned in Dir. 67/548/CEE e 88/379/CEE and following modifications regarding classification, labelling and packaging of dangerous preparations (Reagents). However it is recommended to handle the reagentscarefully, avoiding ingestion and contact with eyes, mucous membranes and skin; to use reagents according to good laboratory practice. On the material safety data sheet are detailed the operating procedures for the manipulation of this product. Material safety data sheet should be supplied on request.

Reagents:
Components of the kit:

R1 - BUFFER	(READY TO USE)	Phosphate buffer	> 10 mmol/L
		Thio-NAD	> 0.1 mmol/L
R2 - 3-Alpha-HSDH	(READY TO USE)	3-Alpha-HSDH	> 50 U/L
		NADH	> 0.1 mmol/L
R3 - CAL	(READY TO USE)	Solution of Bile Acids = 100 µMol/L	
		NaN3 < 0.1%	

Quality Control Materials:
BILE ACIDS NORMAL CONTROL (Optional)
BILE ACIDS ELEVATED CONTROL (Optional)

Stability:
All the Reagents are stable up to the expiry date mentioned on the labels when properly stored at stored at 2-8°C.

Specimen:
Serum (Fasting minimum 8 hours) .Sample Stability: 2 weeks at 2 – 8°C, 1 year at –20°C
Samples from patients under bile acid analogues treatment such as fusidic acid, ursodeoxycholic acid or obeticholic acid are unsuitable for analysis

System Parameters:

Reaction Type (Mode) :	Fixed Time
Reaction Direction :	Increasing
Wave Length :	405 nm
Flow Cell Temp. :	37°C
Zero Setting with :	Distilled Water
Delay Time :	60 Seconds (A1)
Measuring Time :	120Seconds (A2)
Reagent Volume : R1	360 µl
Reagent Volume : R2	120 µl
Calibrator / Sample Volume :	5 µl
Calibrator Concentration :	**50 µMol/L**
Linearity :	200 µMol/L
Low Normal	2 µMol/L
High Normal :	12 µMol/L

Test Procedure:

Reagent	Calibrator	Serum
Reagent-1	360 µL	360 µL
Calibrator	5 µL	——
Serum	——	5 µL
Reagent-2	120 µL(Derive the Factor)	——
Reagent-2	——	120 µL

Mix well and immediately aspirate in to the analyzer. Record the first absorbance (A1) at 60 seconds . Exactly 120 Seconds after the first reading record the absorbance (A2) at 37 °C.

Calculate the change in absorbance for the Calibrator and Serum Samples.

Calculations with calibrator:

$$\text{TBA}\ (\mu\text{Mol/L}) = \frac{\text{A2-A1 Sample}}{\text{A2-A1 Calibrator}} \times 50\ (\text{Conc. of Calibrator}\ \mu\text{Mol/L})$$

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Reference Values:
Normal Values Bile Acids: Up to 0-12 µMol/L
Since the normal values depend on age, sex, diet, geographic area and other factors, each laboratory should establish its own normal values for this procedure.

Analytical Performance: (validate on MINDRAY Bs300)
The performances of the Reagent BILE ACIDS liquid have been tested with a MINDRAY BS300 analyzer. The data, while representing the characteristics of the product, could be different for each laboratory and for different analyzers.

Attention:
The kit is tested for a manual spectrophotometer and for HITACHI, COBAS and MINDRAY systems. The applications on automatic analyzers could be completely different by what has been developed as manual determination

Method Linearity:
The test is linear up to 200 µMol/L
For concentration of bile acids higher than 200 µMol/L, dilute the sample 1:4 with saline solution, repeat the determination and multiply the result by 4.

Method Sensitivity (LoD):
The sensitivity limit, that is the minimum concentration that can be distinguished by zero, is µMol/L

Interferences:
Interference test criterion: recovery ± 10% of initial value.
No interference found on samples with: -
total bilirubin up to 40 mg/dL;
haemoglobin up to 600 mg/dL,
lipemia [Intralipid ®] up to 4000 mg/dL;
ascorbic acid up to 50 mg/dL.

Accuracy:
A group of 20 sera has been tested using this procedure and using a similar reagent available on the market.

The comparison gave these results:
Linear regression equation y = 1.0140 x - 1
Correlation coefficient r = 0.9997 n = 20

References:

1.Textbook of Clinical Chemistry, Ed. by N.W. Tietz,W.B. Saunders Co., Philadelphia (1999).
2.Young D.S., Effect of drugs on Clinical Lab. Test,5th Ed. AACC Press (2000).
3. Mashige F. et al., Clin. Chem. 27/8, 1352 (1981)

Order Information:

Ref./Cat. No.	Pack Size	Presentation
P-TBA-30	30 ml	Two reagents with calibrator

Product Features:

- **Two reagents with calibrator.**
- **Serum is the Specimen.**
- **Linear up to 200 µMol/L**
- **3 Minutes Fixed Time Assay**
- **Adaptable to Semi and Fully Auto Analyzers**

Symbols used with IVD devices

Date of manufacture	Manufactured by
In vitro diagnostic medical device	Keep away from sunlight
Do not freeze	This way up
Use-by date	Do not use if package is damaged
Keep dry	Batch Code
Consult instructions for use	Reagent
Consult electronic instructions for use	Calibrator Material
Catalogue number	
Caution	

eIFU Indicator

Pariksha's world inside
SCAN TO EXPLORE MORE

Manufactured in India by :
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