Total Bile Acids (TBA) Diagnostic Reagent Kit (Enzymatic Method) Product Instruction

Product name
Generic Name: Total Bile Acids (TBA) Diagnostic Reagent Kit (Enzymatic Method)
Abbreviation: TBA

Package Specifications

R1	R2
60ml×2	20ml×2
300ml×2	200ml×1
300ml×1	100ml×1

Calibrator:
Specification 1 (1.0mL×1; 1 level).

Intended use
Total bile acids (TBA) diagnostic reagent is used for quantitative in vitro determination of total bile acids in human serum on photometric systems.

Clinical significance
Total bile acids are metabolized in the liver and hence serve as a marker for normal liver function. Total bile acids are increased in patients with acute hepatitis, chronic hepatitis, liver sclerosis and liver cancer.

Principle
In the presence of Thio-NAD, the enzyme 3-α hydroxysteroid dehydrogenase (3-α HSD) converts bile acids to 3-keto steroids and Thio-NADH. The reaction is reversible and 3-α HSD can convert 3-keto steroids and Thio-NADH to blie 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 405nm.

Main ingredient

Name	Ingredient	Concentration
R1	Buffer	65mmol/L, pH 7.0
	Thio-NAD	1g/L
R2	Buffer	65mmol/L, pH 7.0
	NADH	6g/L
	Sodium azide	0.6mmol/L
	3α-hydroxysteroid dehydrogenase	≥5000U/L

Composition of calibrator: single level liquid calibrator, sodium cholate added in glycine buffer, stabilizer <0.1%; fixed value range: (40-60) μmol/L.

Storage and stability
This kit stays stable for 18 months when stored in a dark condition at 2-8°C (do not freeze). After being opened for the first time, the kit can be stored at 2-8°C in an anti-pollution environment and stays stable for 14 days.

Specimen preparation
Fresh serum.
2-8°C, stable for 3 days.
-70°C, stable for 3 months.

Assay procedure
1. Reagent preparation
This reagent is liquid and can be used directly.

Main wavelength	405nm	Sample	4μl
Subwavelength	660 nm	Reagent 1	270μl
Reation temperature	37°C	Reagent 2	90μl
Cuvette light path	1cm	Reaction type	rate method
Reation direction	+		

2. Operation steps

Add to the cuvette:	
Sample (S)	4μl
R1	270μl
Mix well, incubate at 37°C for 5 minutes, then add	
R2	90μl
Mix well, incubate at 37°C for 60 seconds, absorbance A1; incubate at 37°C for 2 minutes, absorbance A2 △A= A2- A1	

Calculations

$$\text{Conc. of TBA} = \frac{A(\text{sample}) - A(\text{blank})}{A(\text{Cal.}) - A(\text{blank})} \times \text{conc. of Cal.}$$

Reference interval
0-15μmol/L
It is recommended that each laboratory should establish its own reference interval.

Quality control
The control intervals and limits should be adapted to each laboratory's individual requirements. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the limits.

Performance characteristics
Measuring range：
0μmol/L-200μmol/L
Samples above this concentration should be diluted 1+1 with 0.9% NaCl solution and the result multiplied by 2.

Interference
The effect of the following substances can be neglected if the concentrations of the following substances are at or below the given values.

Substances	Concentrations
Bilirubin	30mg/dl
Haemoglobin	150mg/dl
Intralipid	2.0 %
VC	0.5g/l
Heparin Sodium	100U/ml

Automation
Special adaptations for automatic analyzers can be made on request.

General precautions
For in vitro diagnostic use only.
Diagnosis should only be made after taking clinical symptoms and the results of other tests into consideration.
Exercise the normal precautions required for handling all laboratory reagents.
Disposal of all waste material should be in accordance with local guidelines.

Precautions for measurement
Specimens should be treated as potentially infectious (HIV, Hepatitis B virus, Hepatitis C virus, etc.) and handled with appropriate caution.
Reagents with different lot numbers should not be interchanged or mixed.
For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.
Material safety data sheet available for professional user on request.

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