TOTAL BILE ACID

(Kinetic method)

Intended Use

Total Bile acid assay kit is intended for the In-vitro quantitative determination of Total bile acid (TBA) in human serum sample.

Principle

The reagent of the assay kit are in a liquid formulation that allows for ease couple with enhanced performance characteristics in the presenceThio-NAD, The enzyme 3-α- Hydroxysteroid Dehydrogenase (3-α- HSD) convert bile acids to 3- keto steroid and ThioNADH.The reaction is reversible and 3-α- HSD can convert 3-keto steroids and Thio-NADH. Bile acid 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.

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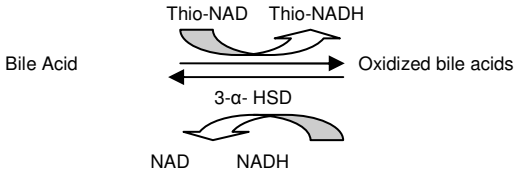


Reagent provided

1. Reagent R1
2. Reagent R2
3. Calibrator:

Working Reagent Preparation

Total bile acid reagent are ready to use liquid reagent. The Intrinsic yellow to yellow-brown color of the TBA reagent does not interfere with test.

Reagent storage and stability

The reagent kit should be stored at 2-8°C and is stable till the expiry date indicated on the label.

Specimen collection and preservation

Blood should be collected in a clean dry container. Although serum is preferred, plasma with heparin or EDTA can be used. The assay should be carried out as far as possible on the same day. Serum and plasma samples are stable for 1 week at 4°C and 1 month at -10°C. The samples should be brought to room temperature prior to use. Avoid use of haemolysed and grossly contaminated samples.

Assay guidelines for Analyzers

Reaction type	Kinetic Reaction
Reaction Slope	Increasing
Wavelength	405 nm
Flow cell Temperature	37°C
Incubation	5 min. 37°C
Delay time	90 seconds
Reading time	150 Seconds
Blank with	Distilled water
Sample volume	6 µl (0.006 ml)
Reagent 1 volume	450 µl (0.450 ml)
Reagent 2 volume	150 µl (0.150 ml)
Calibrator conc.	As on vial
Lower limit	0
Higher limit	10
Linearity	180µmole/L

Assay guidelines for Manual procedure

Pre warm the required amount of working reagent at 37°C before use. Perform the assay as given below:

Reagents	Calibrator	Test
Reagent 1	450 µl (0.450 ml)	450 µl (0.450 ml)
Calibrator	6 µl (0.006 ml)	-
Serum/Plasma	-	6 µl (0.006 ml)
Mix and Incubate at 37°C for 5 minutes Than Add Reagent 2		
Reagent 2	150 µl (0.150 ml)	150 µl (0.150 ml)

1. Mix thoroughly and transfer the assay mixture immediately to the thermo stated cuvette and start the stop watch simultaneously.
2. Record the first reading at 90th second and subsequently 1 more readings with 150 seconds at 405 nm.

Calculation

$$\text{TBA µmole/L} = \frac{\text{Sample } \Delta\text{Abs/min.}}{\text{Std}\Delta\text{Abs/min.}} \times \text{Conc. of std.}$$

Note: Since temperature conversion factors are given only as an approximate conversion, it is suggested that values be reported at the temperature of measurement.

Normal Range

Serum or Plasma : 0 – 10µmole/L

Note: Expected range varies from population to population and each laboratory should establish its own normal range.

Limitations

A Sample with a bile acid level exceeding(180 µmole/L) The linearity limit should be diluted with 0.9% saline and reassayedincorporating the dilution factor in the calculation of the value.

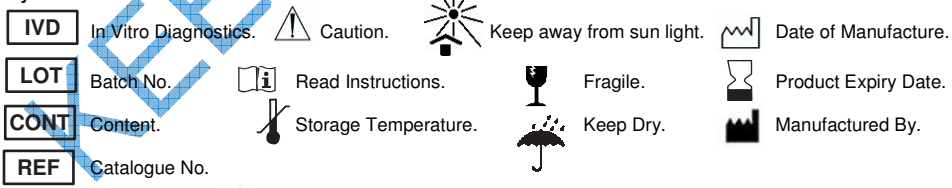
Quality Control

To ensure adequate quality control, it is recommended that each batch should include a normal and an abnormal commercial reference control serum. It should be realized that the use of quality control material checks both instrument and reagent functions together. Factors which might affect the performance of this test include proper instrument function, temperature control, and cleanliness of glassware and accuracy of pipetting.

References

1. LaRussoN.F. et .al . Dynamics of Enterohepatic Circulation of Bile acid, New Engl J M,291,689-692,(1974) t
2. SkredsS.et,al: Bile acid measured in serum during fasting as a test for liver disease,ClinChem 24:1095-1099(1978
3. Wu Alan H.B. Tietz Clinical guide to Laboratory test 4thed.St Louis, M.O:Saunders/Elsevier,2006 .170-1711976

Symbols



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