Liquick Cor-BILE ACIDS

DIAGNOSTIC KIT FOR DETERMINATION OF TOTAL BILE ACIDS CONCENTRATION

Kit name	Cat. No
Liquick Cor-BILE ACIDS 500	2-341
Liquick Cor-BILE ACIDS "bulk"	2-342

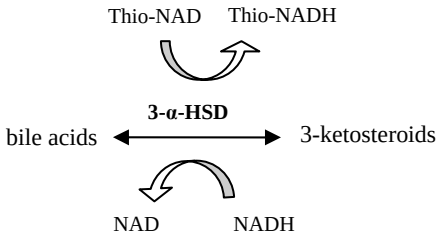
INTRODUCTION

Bile acids are the main product of degradation of endogenous cholesterol formed in the liver. Total bile acids are metabolized in the liver and are a valuable indicator of normal or abnormal liver function. Serum total bile acids are increased in patients with viral hepatitis, liver cirrhosis and liver cancer.

METHOD PRINCIPLE

Enzymatic method with 3-α-hydroxysteroid dehydrogenase (3-α-HSD).

Bile acids under the influence of 3-hydroxysteroid dehydrogenase (3-α-HSD) in the presence of thio-NAD are converted to 3 - ketosteroids and thio-NADH. The reaction is reversible and 3-α-HSD can convert 3-ketosteroids and NADH to bile acids and NAD.



The rate of thio-NADH formation can be monitored at 405 nm and is proportional to the bile acids activity.

REAGENTS

Package

	Liquick Cor-BILE ACIDS 500	Liquick Cor- BILE ACIDS "bulk"
1-BILE ACIDS	3 x 300 ml	--*
2-BILE ACIDS	1 x 300 ml	--*

* reagent volume is printed on the label.

The reagents when stored at 2-8°C are stable up to expiry date printed on the package. The reagents are stable for 7 weeks on board the analyser at 2-10°C. Protect from light and avoid contamination!

Concentrations in the test

1-BILE ACIDS

Thio-NAD	> 0.1 mmol
Buffer	

2-BILE ACIDS

3-α-HSD	> 2 kU/l
NADH	> 0.1 mmol
Buffer	

Warnings and notes

- Product for in vitro diagnostic use only.
- Avoid contact with skin and mucous membranes.
- Yellow or yellow-brown color of the reagent does not affect the reagents performance.
- Reagents from different lots must not be interchanged.
- Samples from patients treated with ursodeoxycholic acid (UDCA) are not suitable for the determination of total bile acid concentrations.

SPECIMEN

Serum.

Total bile acids concentration is increased after meals, therefore samples should be collected under fasting conditions. Serum and plasma samples are stable for a 7 days at 4 °C or for 3 month at -20 °C.

Nevertheless it is recommended to perform the assay with freshly collected samples!

ADDITIONAL EQUIPMENT

- automatic analyser or photometer able to read wavelength at 405 nm;
- thermostat at 37ºC;
- general laboratory equipment;

PROCEDURE

These reagents may be used both for manual assay and in several automatic analysers. Applications for them are available on request.

Manual procedure

wavelength	405 nm
temperature	37°C
cuvette	1 cm

Pipette into the cuvettes:

	test (T)	calibrator (C)
1-BILE ACIDS	900 µl	900 µl
2-BILE ACIDS	300 µl	300 µl

Bring up to the temperature of determination. Then add:

calibrator	-	20 µl
sample	20 µl	-

Mix well and after 2 min. of incubation read the absorbance of calibrator (C) and test (T) against water or air. After next 1, 2, and 3 minutes repeat absorbance reading and calculate the mean absorbance change (ΔA) for calibrator and sample.

Calculation

$$\text{bile acids concentration} = \frac{\Delta A(T)}{\Delta A(C)} \times \text{calibrator concentration}$$

REFERENCE VALUES [3]

serum	2.5 – 6.8 µmol/l (1.25 – 3.4 µg/ml)

It is recommended for each laboratory to establish its own reference ranges for local population.

QUALITY CONTROL

For internal quality control it is recommended to use the CORMAY BILE ACIDS CONTROLS (Cat. No 5-149) with each batch of samples.

For calibration CORMAY MULTICALIBRATOR LEVEL 2 (Cat No. 5-175; 5-177) is recommended.

The calibration curve should be prepared every 7 weeks, with change of reagent lot number or as required e.g. quality control findings outside the specified range.

PERFORMANCE CHARACTERISTICS

These metrological characteristics have been obtained using automatic analyser Biolis 24i Premium and Hitachi 717. Results may vary if a different instrument or a manual procedure is used.

- **Sensitivity:** 2.9 µmol/l (1.45 µg/ml).

- **Linearity:** up to 180 µmol/l (90 µg/ml).
  For higher total bilirubin concentrations dilute the sample with 0.9% NaCl and repeat the assay. Multiply the result by dilution factor.

- **Specificity / Interferences**
  Haemoglobin up to 0.5 g/dl, bilirubin up to 50 mg/dl, ascorbic acid up to 50 mg/dl and triglycerides up to 750 mg/dl do not interfere with the test.

- **Precision**

Repeatability (run to run) n = 20	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	30.72	0.34	1.11
level 2	47.96	0.64	1.34

Reproducibility (day to day) n = 80	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	8.12	0.24	2.9
level 2	23.0	0.61	2.6

- **Method comparison**

A comparison between bilirubin values determined at Biolis 24i Premium (y) and at OLYMPUS AU400 (x) using 45 samples gave following results:
y = 1.0813 x - 0.0198 µmol/l;
R = 0.9997 (R – correlation coefficient)

WASTE MANAGEMENT
Please refer to local legal requirements.

LITERATURE

1. LaRusso, N.F. et al., Dynamics of Enterohepatic Circulation of Bile Acids, New Engl J M, 291, 689-692, (1974).
2. Skrede S. et al: Bile acids measured in serum during fasting as a test for liver disease, Clin Chem 24: 1095-1099, 1978
3. Wu, Alan H.B. Tietz Clinical Guide to Laboratory Tests. 4th ed. St. Louis, MO: Saunders/Elsevier, 2006. 170-171.
4. Dembińska-Kieć A., Naskalski J.W.: Diagnostyka laboratoryjna z elementami biochemii klinicznej, Volumed, 261-262, (1998).

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