Cat. No 4-597

DIAGNOSTIC KIT FOR DETERMINATION OF BILE ACIDS CONCENTRATION

CE CORMAY

HC – BILE ACIDS

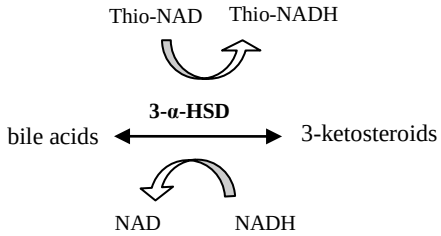
INTRODUCTION

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

1-Reagent	1 x 36.62 ml
2-Reagent	1 x 11.76 ml

The reagents when stored at 2-8°C are stable up to expiry date printed on the package. The reagents are stable for 12 weeks on board the analyser at 2-10°C. Protect from light and avoid contamination!

Concentrations in the test

1-Reagent	
Thio-NAD	> 0.1 mmol
buffer	
2-Reagent	
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.
- Do not mix or use reagents with different lot numbers.
- 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 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!

PROCEDURE

The reagents are ready to use.

These reagents may be used in automatic analyser Hitachi 911/912.

Application should be entered using handheld barcode scanner and attached barcodes sheet, according to procedure described below:

1. Delete previous version of application and calibrators assigned to it and restart the analyser.
2. Enter codes of calibrators according to the attached list.
3. Enter barcoded application and assign proper values to calibrators.
4. To activate entered application go to the tab UTILITY | APPLICATION | RANGE and change value of field DATA MODE from INACTIVE to ON BOARD. Confirm the change using UPDATE button.
5. Put reagents on board the analyser – they will be assigned to relevant tests automatically. Perform also measurement of level of reagents inside the bottles.
6. After calibration analyser is ready to use.

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 the calibration of automatic analysers systems the CORMAY MULTICALIBRATOR LEVEL 2 (Nr kat. 5-175; 5-177). **Calibrator and 0.9 % NaCl** should be used for calibration.

The calibration curve should be prepared every 4 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 the automatic analysers Hitachi 912 and Hitachi 717. Results may vary if a different instrument or a manual procedure is used.

- **Sensitivity:** 4.2 µmol/l (2,1 µg/ml).
- **Linearity:** up to 180 µmol/l (90 µg/ml).
  For higher 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 = 6	Mean [µmol/l]	SD [µmol/l]	CV [%]
level 1	30.56	0.31	3.9
level 2	97.18	0.30	1.3

Reproducibility (day to day) n = 20	Mean [µmol/l]	SD [µmol/l]	CV [%]
level 1	8.12	0.24	2.9
level 2	23.0	0.61	2.6

- **Method comparison**

A comparison between bile acids values determined at Hitachi 912 (y) and at OLYMPUS AU400 (x) using 69 samples gave following results:
y = 0.9238 x + 0.4708 µmol/l;
R = 0.9998 (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. DembińskaKieć A., Naskalski J.W.: Diagnostyka laboratoryjna z elementami biochemii klinicznej, Volumed, 261-262, (1998).

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