Leading Technology in Fluid-Stable Reagents from DiaSys

- More than 25 years experience in development and production of clinical chemistry tests
- Premium service in technics, applications and after sales
- Quality products made in Germany
- High performance, ready-to-use reagents with minimized interferences, long shelf life and onboard stability as well as traceability to international references
- Perfectly matched fluid-stable reagents, calibrators and controls
- High grade raw materials from traceable origin
- Processes and resources certified according to ISO 13485, fulfilling highest quality standards
- Sustainable processes and products preserve the environment

DiaSys offers reagent kits for manual and automated use plus appropriate calibrators and controls. Detailed information about the Total bile acids 21 FS test is available on our microsite **www.total-bile-acids.com** and in the product catalog.

References

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CHOOSING QUALITY.

Total bile acids 21 FS

Reliable Assessment of Liver Function

FAST · ACCURATE · SENSITIVE

DiaSys. Total Confidence in Patient Results.
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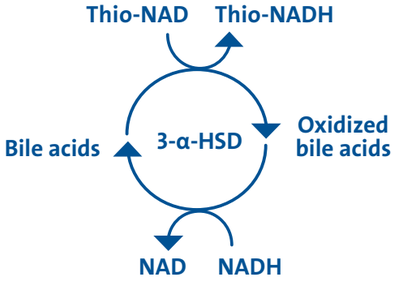
Clinical Significance [1, 2, 3]

Serum total bile acid (TBA) levels are a sensitive marker of liver function in all species reflecting hepatic synthesis, secretion and re-absorption. Serum TBA can be used to assess liver dysfunction that is not provided by conventional liver screening tests like alanine aminotransferase (ALT) and aspartate aminotransferase (AST), which correspond to liver damage rather than liver function. The sensitivity of TBA allows an early detection of liver malfunction which in turn can lead to rapid treatment and prevention of extensive and irreversible liver damage. TBA levels provide early diagnosis of hepatobiliary deficiencies but do not allow a differentiation between various diseases. The normal reference range is < 10 µmol/L (fasting). Abnormal levels in fasting patients are associated with diseases such as acute and chronic hepatitis, intrahepatic cholestasis of pregnancy (ICP), liver sclerosis, cirrhosis, and cancer.

TBA – Most Important Biomarker in ICP [4, 5, 6, 7]

The determination of TBA concentrations in pregnant women is considered the most important biomarker for diagnosis and monitoring of ICP. ICP is the most common liver disease in pregnant women; the incidence varies widely with geographical location and ethnicity. The prevalence of ICP has declined significantly in recent years, currently ranging from 1.5 to 4%. A high incidence is seen in twin pregnancies (20–22%) and following in vitro fertilization treatment. ICP occurs usually in the third trimester of pregnancy and is characterized by pruritus and an increase of serum bile acid concentration. It is caused by a reversible, hormonally mediated (induced) disturbance of bile secretion, leading to a restricted bile flow through the gallbladder, which in turn leads to an accumulation of bile acids in the liver and possibly in the bloodstream. In ICP, TBA levels can rise significantly (up to 220 µmol/L) resulting in an increased risk of fetal distress, premature birth or stillbirth. Levels above 40 µmol/L are potentially fetotoxic.

Method



Enzymatic cycling method
Two reactions are combined in the new generation enzymatic cycling method. In the presence of Thio-NAD, the enzyme 3-α-hydroxysteroid dehydrogenase (3-α-HSD) converts bile acids 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. 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. This cycling reaction leads to significant signal amplification.

Assay Features and Benefits

- Ready-to-use, liquid-stable reagents
- Wide measuring range: 220 µmol/L (may vary according to specific application)
- Excellent recovery of diagnostically relevant bile acids (target deviation ≤ 7%)
- Good precision
- Long onboard and calibration stability
- Dedicated calibrator for optimum performance
- Multi-parameter controls for a convenient workflow

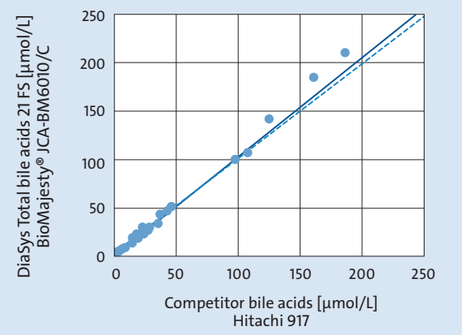
Performance Characteristics

Precision studies (on BioMajesty® JCA-BM6010/C) and method comparison to competitor bile acids.

Precision

Intra-assay	Mean [µmol/L]	SD [µmol/L]	CV [%]
Sample 1	5.41	0.129	2.38
Sample 2	10.2	0.085	0.83
Sample 3	199	1.19	0.60
Inter-assay	**Mean [µmol/L]**	**SD [µmol/L]**	**CV [%]**
Sample 1	5.39	0.076	1.42
Sample 2	10.4	0.159	1.54
Sample 3	201	1.64	0.82

Method Comparison



Recovery of Clinically Significant Bile Acids

Recovery in aqueous bile acids solution [50 µM]	DiaSys Cycling Method [µmol/L]	DiaSys Cycling Method [%]	Competitor A Cycling Method [µmol/L]	Competitor A Cycling Method [%]	Competitor B Cycling Method [µmol/L]	Competitor B Cycling Method [%]
Glycocholic acid	53.4	107	36.2	72	38.9	78
Glycochenodeoxycholic acid	48.9	98	49.4	99	67.0	134
Taurochenodeoxycholic acid	51.8	104	48.5	97	57.2	114
Taurocholic acid	50.3	101	34.0	68	34.6	69
Chenodeoxycholic acid	53.5	107	51.9	104	75.8	152
Cholic acid	51.6	103	35.6	71	38.4	77
Deoxycholic acid	50.1	100	61.8	124	74.6	149
Taurodeoxycholic acid	47.3	95	56.5	113	56.8	114
Lithocholic acid	48.4	97	–	–	–	–