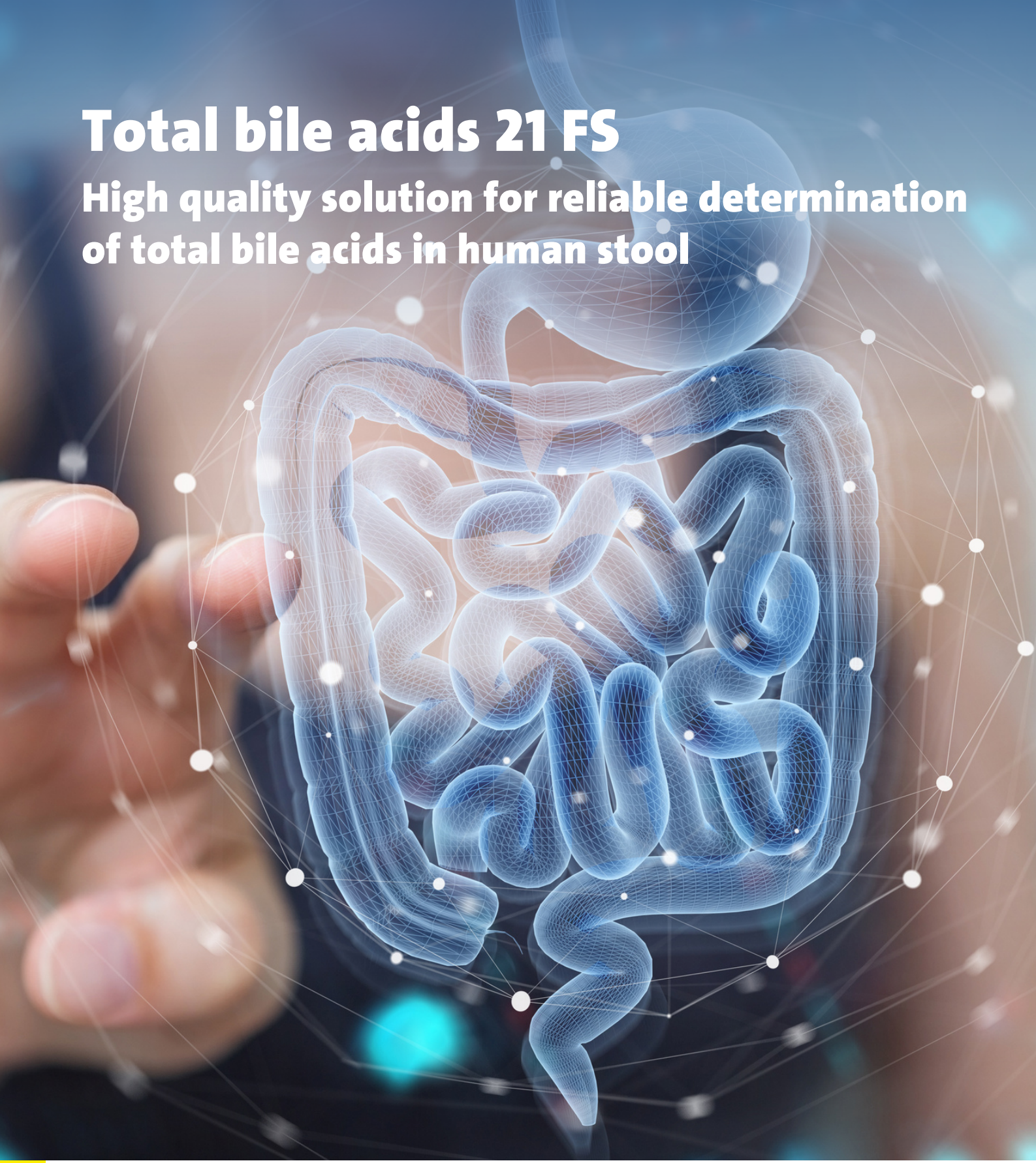
Total bile acids 21 FS

High quality solution for reliable determination of total bile acids in human stool



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Clinical significance[1-5]

Determination of total bile acids in human stool plays a major role in diagnosis of bile acid malabsorption leading to various gastrointestinal tract disorders, such as irritable bowel syndrome with diarrhea (IBS-D), bile acid diarrhea (BAD) or Crohn's disease. Approximately 25 – 50% of IBS-D patients and 1% of the population in Western countries suffer from bile acid malabsorption.

DiaSys Total bile acids 21 FS in stool diagnostics[6-12]

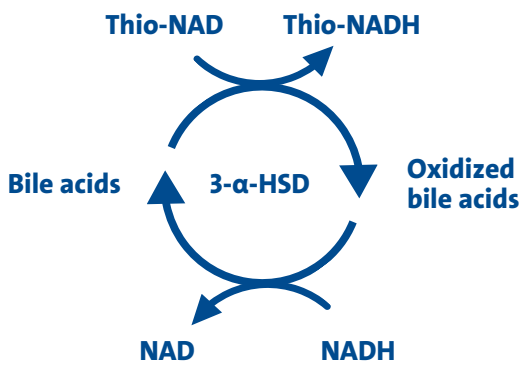
The gold standard to determine total bile acids in stool, the 7-days ^{75}selenotaurohomocholic acid retention test (^{75}SeHCAT), and other currently applied methods, such as liquid and gas chromatography - mass spectrometry (LC-MS and GC-MS) and enzyme-linked immunosorbent assay (ELISA), display many disadvantages.

Disadvantages of currently applied methods	Advantages of DiaSys Total bile acids 21 FS
Highly complex	Uncomplicated widely used method
Expensive	Cost-efficient
Time-consuming	Extremely timesaving
Labor-intensive	Convenient and fast workflow
Require special equipment & specialized staff	Applicable on various common clinical analyzers
^{75}SeHCAT includes ingestion of radioactive substance	Non-invasive

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.



Performance characteristics*

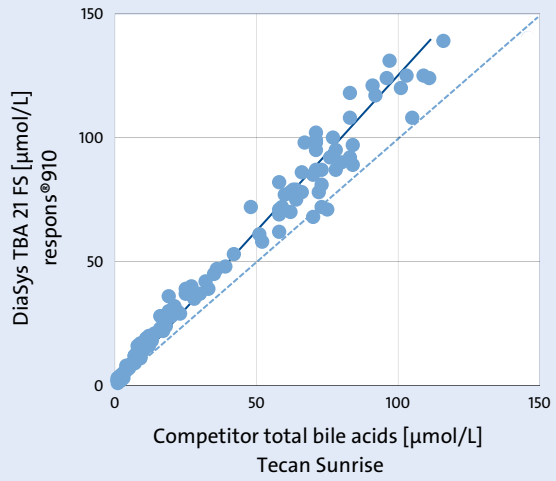
Precision

Within run N = 20	Mean [µmol/L]	SD [µmol/L]	CV [%]
Sample 1	14.7	0.222	1.50
Sample 2	70.8	0.770	1.09
Sample 3	115	2.37	2.06

Total precision N = 80	Mean [µmol/L]	SD [µmol/L]	CV [%]
Sample 1	14.8	0.607	4.09
Sample 2	72.5	2.54	3.51
Sample 3	120	4.13	3.44

*Data collection performed in diluted human stool extract samples (1:100)

Method comparison



n = 122; Passing/Bablok: Slope: 1.22; Intercept: 1.89 µmol/L; r: 0.988

Reference ranges

Female	4.51 – 70.3 µmol/L
Male	4.34 – 83.8 µmol/L

Assay features and benefits

1. Innovative cycling method
2. Ready-to-use, liquid-stable reagents
3. Dedicated calibrator for optimal performance
4. Multi-parameter controls for convenient workflow
5. Wide measuring range (3.5 µmol/L – 130 µmol/L)
6. Excellent precision
7. Long onboard and calibration stability
8. No prolonged sample collection
9. Faster than current gold standard
10. Dedicated CE application for respons®910

Leading technology in fluid-stable reagents from DiaSys

- More than 30 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

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