

TOTAL BILE ACIDS ASSAY



Liver
Marker

The Diazyme Total Bile Acids assay is intended for the in vitro quantitative determination of total bile acids (TBA) in human serum samples. Total bile acids are metabolized in the liver and serve as a marker for normal and abnormal liver function. Serum total bile acids are increased in patients with liver disease.

DIAZYME TOTAL BILE ACIDS ASSAY ADVANTAGES

- Advanced enzymatic cycling method
- Interference from triglycerides, bilirubin and hemolysis has been virtually eliminated
- Results in as little as eight (8) minutes
- Liquid stable reagents
- Wide range of instrument parameters available for simplifying implementation

REGULATORY STATUS

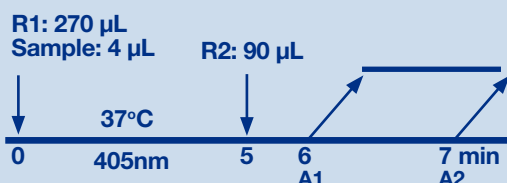
510(k) Cleared; EU:  

Health Canada Registered

ASSAY SPECIFICATIONS

Method	Enzyme Cycling
Sample Type & Volume	<ul style="list-style-type: none"> • Serum • Plasma <ul style="list-style-type: none"> - Heparin - EDTA Sample Volume 4 μ L
Method Correlation to Predicate	$R^2 = 0.9918$ $y = 1.1563x - 0.8567$
Linearity	1 to 180 μ M
Traceability	UV spectrophotometric assay to predicate device
Calibrator	Liquid Vial
Calibration Interval*	One week
Reagent On-Board Stability	Four Weeks

TBA Assay Procedure*



*Analyzer Dependent

Parameter questions for Total Bile Acids Assay should be addressed to Diazyme Technical Support. Please call 858.455.4768 or email support@diazyme.com

ASSAY PRECISION

The intra-assay precision and inter-assay precision were evaluated in samples containing two different bile acid levels (8 μ M and 23 μ M). The inter-assay precision was evaluated by testing these two level specimens (low = 8 μ M and high = 23 μ M) in 20 runs. All tests were done using the Hitachi 717 Auto-analyzer instrument. Precision data is summarized in the table below:

Intra-Assay Precision

	Level 1 8 μ M	Level 2 23 μ M
Number of Replicates	20	20
Mean	7.93	23.5
SD	0.31	0.3
CV (%)	3.9	1.3

Inter-Assay Precision

	Level 1 8 μ M	Level 2 23 μ M
Number of Replicates	20	20
Mean	8.12	23.0
SD	0.24	0.61
CV (%)	2.9	2.6

ASSAY INTERFERENCE

The following substances normally present in serum produced less than 10% deviation at the listed concentrations:

Hemoglobin:	up to 500 mg/dL
Bilirubin:	up to 50 mg/dL
Triglycerides:	up to 750 mg/dL
Ascorbic Acid:	up to 50 mg/dL

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