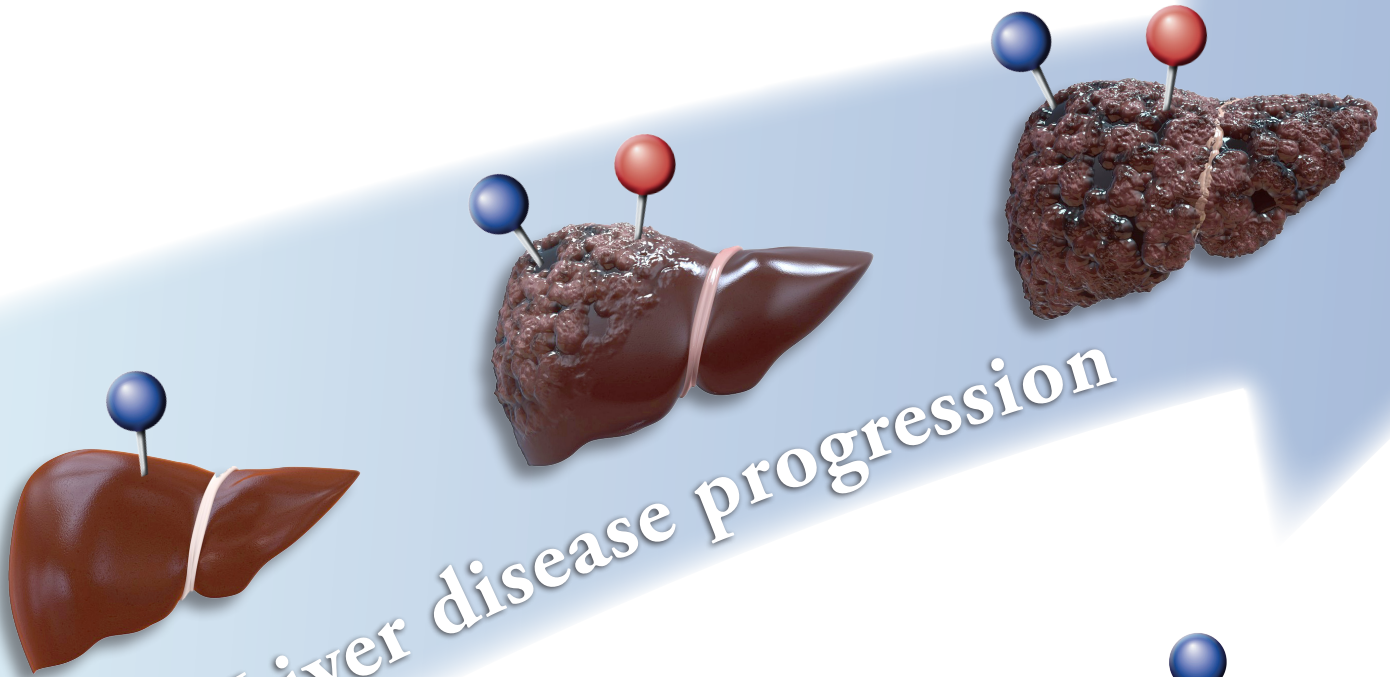


HEPATIC BIOMARKERS

LET'S GET SPECIFIC



Liver disease progression

TOTAL SERUM BILE ACIDS - TBA

- A sensitive and specific liver function test that can be used to analyze the early stages of impaired liver function
- Significantly reduced interference compared to NBT methods
- Two reagent liquid stable advanced enzyme cycling method

5' NUCLEOTIDASE - 5'NT

- A specific marker for assessing liver disease progression
- Superior specificity when compared to both Alkaline Phosphatase (ALP) and Gamma-glutamyl transferase (GGT)
- Liquid stable with improved on-board calibration stability when compared to (ALP) and (GGT)

 **DIAZYME LABORATORIES**

INNOVATIONS IN CLINICAL DIAGNOSTICS

DIAZYME HEPATIC BIOMARKERS

	TBA	5'NT
Method	Enzyme Cycling	Enzyme Cascade to Trinder Reaction
Traceability	UV spectrophotometric assay to predicate device	k-factor based on the enzymatic hydrolysis of 5'-monophosphate to H ₂ O ₂ via an enzyme cascade
Method Correlation to Predicate	R ² = 0.9918 y = 1.1563x - 0.8567	There is no high sensitivity competitor method
Precision	Intra-Assay Precision < 4 CV% Inter-Assay Precision < 3 CV%	Intra-Assay Precision < 2 CV% Inter-Assay Precision ≤ 4 CV%
On-Board Stability*	Four Weeks	Three Weeks
Calibrator	Liquid vial	Lyophilized vial
Sample Type	Serum, EDTA Plasma, Lithium Heparin Plasma	Serum, Plasma
Sample Volume	4 µL	10 µL
Assay Range	1 to 180 µM	0 to 300 U/L
Instrument Specific Packaging	<ul style="list-style-type: none"> • Beckman - Synchron - AU Series • Roche - Hitachi 	Universal Packaging
Regulatory Status	<ul style="list-style-type: none"> • 510 (k) Cleared • CE • Health Canada 	<ul style="list-style-type: none"> • 510 (k) Cleared • CE • Health Canada

*Analyzer Dependent



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