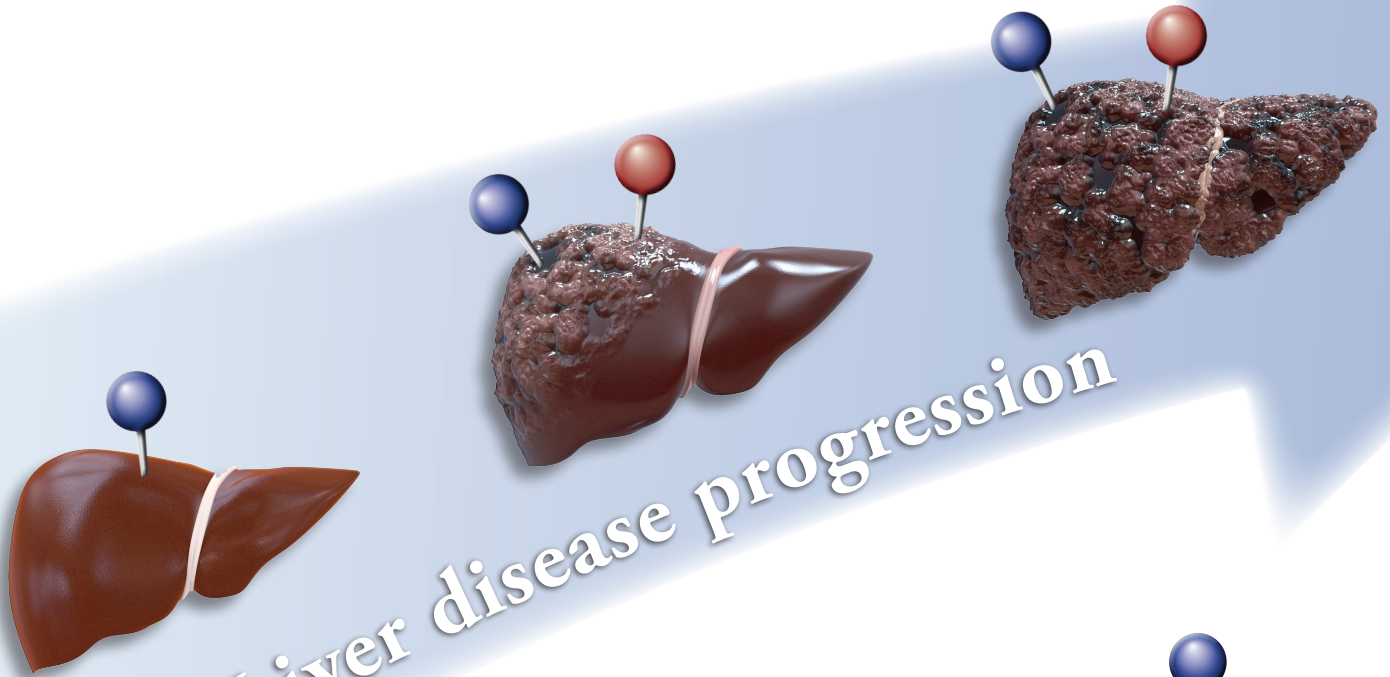


HEPATIC BIOMARKERS

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)



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) Exempt • CE • Health Canada

*Analyzer Dependent



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