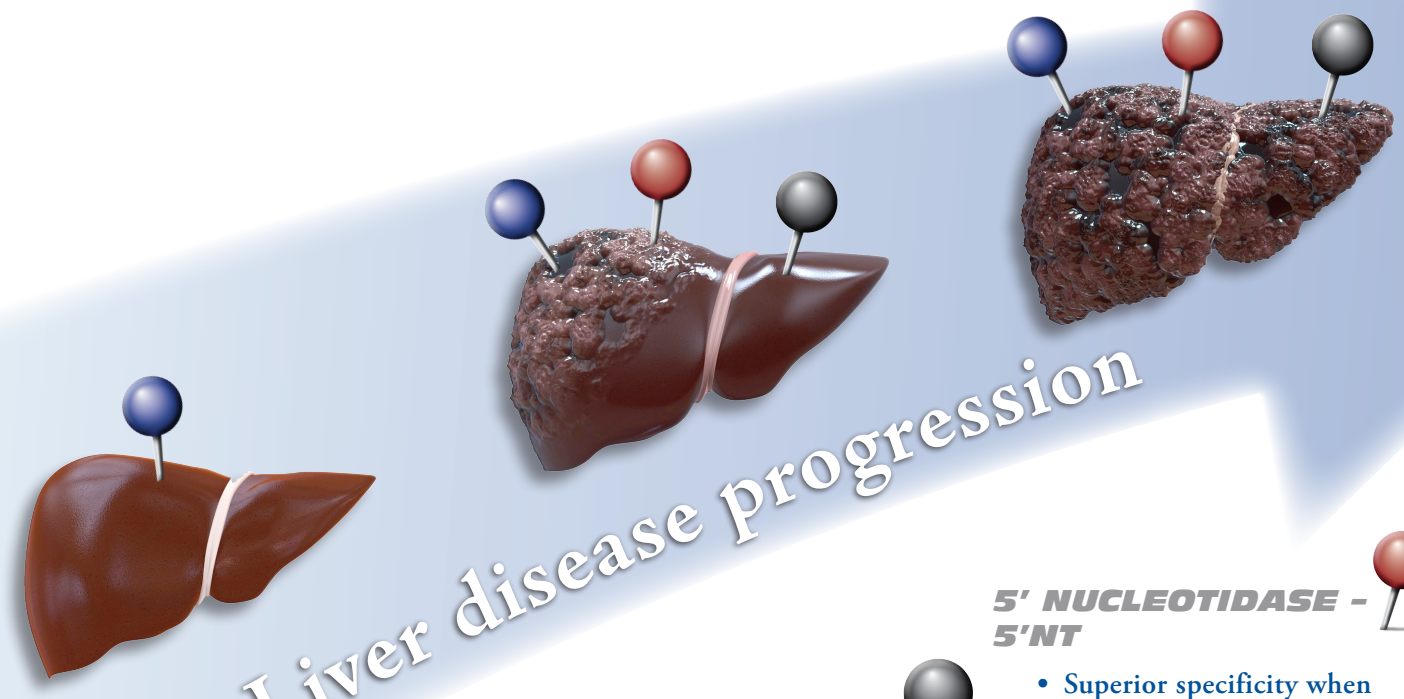
HEPATIC BIOMARKERS

LET'S GET SPECIFIC



TOTAL SERUM BILE ACIDS – TBA

- A sensitive marker 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

TOTAL AND DIRECT BILIRUBIN

- Virtually no interference from hemolysis and lipemia
- Superior performing vanadate method
- Liquid stable two vial system

5' NUCLEOTIDASE – 5'NT

- 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

INNOVATIONS IN CLINICAL DIAGNOSTICS

DIAZYME HEPATIC BIOMARKERS

	TBA	5'NT	Direct Bilirubin	Total Bilirubin
Method	Enzyme Cycling	Enzyme Cascade to Trinder Reaction	Vanadate Oxidation Bilirubin concentration in the sample can be obtained by measuring the absorbances at 450 nm before and after vanadate oxidation	
Traceability	UV spectrophotometric assay to predicate device	k-factor based on the enzymatic hydrolysis of 5'-monophosphate to H_2O_2 via an enzyme cascade	NIST Bilirubin (SRM916a)	NIST Bilirubin (SRM916a)
Method Correlation to Predicate	Fifty-two (52) serum samples ranging from 0.47 – 131.25 µmol/L gave a correlation coefficient of 0.9918. Linear regression analysis gave the following equation: This method = 1.1536 (reference method) – 0.8567 µmol/L	There is no high sensitivity competitor method	R^2 = 0.9989 y = 0.905x + 0.045	R^2 = 0.9993 y = 0.959x + 0.140
Precision	Intra-Assay Precision < 4 CV% Inter-Assay Precision < 3 CV%	Intra-Assay Precision < 2 CV% Inter-Assay Precision < 4 CV%	Within-Run Precision < 3 CV% Within-Laboratory Precision < 4 CV%	Within-Run Precision < 8 CV% Within-Laboratory Precision < 2 CV%
On-Board Stability*	Four Weeks	Four Weeks	Four Weeks	Four Weeks
Calibration Interval*	One Week	One Week	One Week	One Week
Calibrator	Liquid vial	Lyophilized vial	Lyophilized vial Same calibrator for both assays	
Sample Type	Serum, Lithium Heparin Plasma	Serum, Plasma	Serum	Serum
Sample Volume	4 µL	10 µL	10 µL	10 µL
Assay Range	0 to 180 µM	0 to 300 U/L	0.1 to 20 mg/dL	0.1 to 40 mg/dL
Instrument Specific Packaging	• **Beckman** - Synchron - AU Series • **Roche** - Hitachi	**Universal Packaging**	**Universal Packaging**	**Universal Packaging**
Regulatory Status	• 510 (k) Cleared • CE • Health Canada	• 510 (k) Cleared • CE • Health Canada	• 510 (k) Cleared • CE	• 510 (k) Cleared • CE

****Analyzer Dependent***

DIAZYME

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