HEPATIC BIOMARKERS
LET’S GET SPECIFIC

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)
<table>
<thead>
<tr>
<th></th>
<th>TBA</th>
<th>5’NT</th>
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<tbody>
<tr>
<td><strong>Method</strong></td>
<td>Enzyme Cycling</td>
<td>Enzyme Cascade to Trinder Reaction</td>
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<td><strong>Traceability</strong></td>
<td>UV spectrophotometric assay to predicate device</td>
<td>k-factor based on the enzymatic hydrolysis of 5’-monophosphate to H₂O₂ via an enzyme cascade</td>
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| **Method Correlation to Predicate** | R² = 0.9918  
  y = 1.1563x - 0.8567                                                  | There is no high sensitivity competitor method                        |
| **Precision**            | Intra-Assay Precision  
  < 4 CV%                                           | Intra-Assay Precision  
  < 2 CV%                                           |
|                          | Inter-Assay Precision  
  < 3 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** | • Beckman  
  - Synchron  
  - AU Series  
  • Roche  
  - Hitachi                                                                 | Universal Packaging                                                  |
| **Regulatory Status**    | • 510 (k) Cleared  
  • CE  
  • Health Canada                                                     | • 510 (k) Exempt  
  • CE  
  • Health Canada                                                     |

*Analyzer Dependent