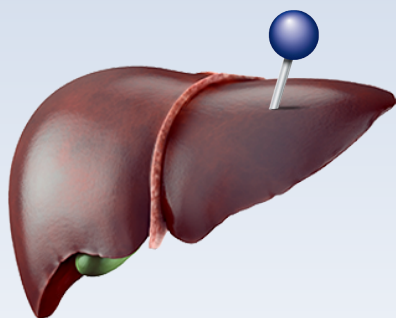


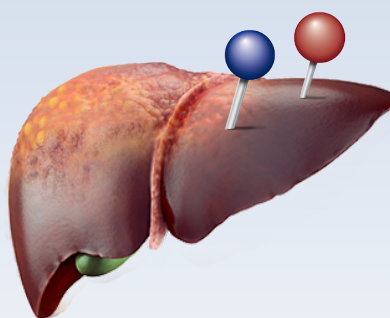
# HEPATIC BIOMARKERS LET'S GET SPECIFIC

Liver  
Marker

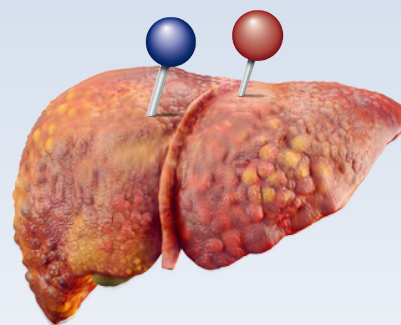
## Healthy Liver



## Progression to Disease



## Diseased Liver



### 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
- Diagnosis of Cholestasis can be made by doing a complete medical history, physical examination, and blood tests that evaluate liver function using total bile acids<sup>1</sup>

### 5' NUCLEOTIDASE – 5'NT

- A specific marker for assessing liver disease progression
- Liquid stable with improved on-board and calibration stability
- The diagnostic value of 5'-NT has been shown to be superior to other liver enzymes, especially in cases of liver metastasis<sup>2-7</sup>

|  | TBA  | 5'NT  |
|--|--|---|
| <b>Method</b>  | Enzyme Cycling   | Enzyme Cascade to Trinder Reaction  |
| <b>Traceability</b>  | UV spectrophotometric assay to predicate device  | k-factor based on the enzymatic hydrolysis of 5'-monophosphate to H <sub>2</sub> O <sub>2</sub> via an enzyme cascade |
| <b>Method Correlation to Predicate</b>   | R <sup>2</sup> = 0.9918<br>y = 1.1563x - 0.8567  | No higher order method  |
| <b>Precision</b>   | Intra-Assay Precision < 4% (CV)<br>Inter-Assay Precision < 3% (CV)   | Intra-Assay Precision < 2% (CV)<br>Inter-Assay Precision ≤ 4% (CV)  |
| <b>Reagent On-Board Stability*</b>   | Four Weeks   | Four Weeks  |
| <b>Calibrator</b>  | Liquid vial  | Lyophilized vial  |
| <b>Sample Type</b>   | Serum, EDTA Plasma, Lithium Heparin Plasma   | Serum, Plasma   |
| <b>Sample Volume</b>   | 4 µL   | 10 µL   |
| <b>Linearity</b>   | 1 to 180 µM  | 0 to 300 U/L  |
| <b>Regulatory Status</b>   | <ul style="list-style-type: none"> <li>• 510(k) Cleared</li> <li>• CE</li> <li>• Health Canada Registered</li> </ul> | <ul style="list-style-type: none"> <li>• 510(k) Exempt</li> <li>• CE</li> <li>• Health Canada Registered</li> </ul>   |
| <p>1. Palmer K. R., Liu X. &amp; Mol B. W. "Management of the Intrahepatic Cholestasis in Pregnancy." Lancet. 2019.<br/>                 2. Goldberg, D. M., Digestion 8, 87-99 (1973)<br/>                 3. Drummond, G. I. &amp; Masanobu, Y. In: The enzymes (boyer, P.D. (ed.), (3rd ed.), vol. 4, pp. 337 (1971)<br/>                 4. Kim, N. K., Yasmineh, W. G., Treier, E. F., Goldman, A. &amp; Theologides, A. Clin. Chem. 23, 2034-2038 (1977)<br/>                 5. Van der Hik, W., Persijn, J. P. et al. Clin. Biochem. 3: 59- 80 (1970)<br/>                 6. Heinz, F., Pilz, R., Reckel S.,Kalden JR., &amp; Haeckel R. J. Clin. Chem. Clin. Biochem. 18: 781-788 (1980)<br/>                 7. Bertrand A. and Buret J. Clin. Chim. Acta 119: 275-284 (1982)</p> |  |   |

\*Analyzer Dependent

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