Nonfasting PROMETHEUS® 7C4 Diagnostic Test for bile acid malabsorption (BAM) \(^1\)

Helps determine if BAM may be a cause of gastrointestinal-related symptoms in patients with inflammatory bowel disease (IBD), or diarrhea-predominant irritable bowel syndrome (IBS-D)

- Serum test measures 7α-hydroxy-4-cholesten-3-one (7C4) levels with liquid chromatography-tandem mass spectrometry
  - 7C4 is a biomarker for measuring the activity of the major rate-limiting enzyme in the hepatic bile acid biosynthesis pathway \(^2\)
  - Correlation of 7C4 with bile acid synthesis has been validated in multiple studies \(^3,4\)
  - Increased 7C4 serum levels can be used to help diagnose BAM \(^3\)
- In validation testing, the 7C4 Diagnostic test demonstrated\(^1,*\):
  - 94% specificity, 65% sensitivity, and 71% positive predictive value
  - No reported interference \(^**\)
- In a clinical study, 7C4 concentrations were associated with bile acid diarrhea regardless of IBD disease activity or length of ileal resection \(^5,***\)

\(^*\) In laboratory testing using a cutoff of 55 ng/mL 7C4.

\(^**\) When the 7C4 analyte was tested with multiple cross-reactants and interfering substances, all test samples recovered below the lower limit of quantitation (< 1.5 ng/mL) with no spiked 7C4 and recovered within 15% bias (85%-115% recovery) when 7C4 was spiked to target concentrations.

\(^***\) In a prospective study of IBD patients where serum samples from 26 Crohn’s disease patients with ileal resection (97 serum samples) and 11 ulcerative colitis patients (13 serum samples, no ileal resection) were analyzed with the 7C4 Diagnostic test. Diarrhea was defined as > 3 bowel movements a day.
PROMETHEUS®
7C4 Diagnostic Test

Prevalence of BAM

- Catalog number: #8205
- CPT® Code (as applied by Prometheus): 82542
- Specimen requirements: Serum separator tube or red top tube. Cold pack required
- Storage: Room temperature or refrigerated

Stability:
- Room temperature: 3 days
- Refrigerated: 7 days
- Turnaround time: 3-4 business days from receipt of sample

Ordering the PROMETHEUS® 7C4 Diagnostic Test:

References:

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