Overview

Useful For
Screening for bile acid malabsorption in patients with irritable bowel syndrome-diarrhea (IBS-D)

Method Name
Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS)

NY State Available
Yes

Specimen

Specimen Type
Serum

Specimen Required

Patient Preparation:
1. Patient must be fasting for at least 12 hours; fasting morning specimen is preferred.
2. Patient should not be taking bile acid sequestrants or statins.

Collection Container/Tube:

Preferred: Serum gel

Acceptable: Red top

Submission Container/Tube: Plastic vial

Specimen Volume: 1 mL

Collection Instructions:
1. Centrifuge and aliquot 1 mL of serum into plastic vial.
2. Send specimen frozen.

Forms
If not ordering electronically, complete, print, and send a Gastroenterology and Hepatology Client Test Request (T728) with the specimen.

Specimen Minimum Volume
0.5 mL

Reject Due To
All specimens will be evaluated at Mayo Clinic Laboratories for test suitability.
**Test Definition: 7AC4**

7AC4, Bile Acid Synthesis, S

---

### Specimen Stability Information

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum</td>
<td>Frozen (preferred)</td>
<td>90 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Refrigerated</td>
<td>72 hours</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ambient</td>
<td>24 hours</td>
<td></td>
</tr>
</tbody>
</table>

---

### Clinical and Interpretive

#### Clinical Information

Bile acids are synthesized from cholesterol in the liver and released into the digestive tract where they function to emulsify dietary fats and facilitate lipid absorption in the small intestine. More than 95% of bile acids are then reabsorbed primarily by active uptake in the distal ileum, while less than 5% are excreted in stool. The synthesis of bile acids in the liver is regulated by a negative feedback mechanism from the bile acids reabsorbed from the intestine. 7 Alpha-hydroxy-4-cholesten-3-one (7aC4) is an intermediate in the biosynthesis pathway of cholesterol to bile acids. The concentration of 7aC4 in serum is a surrogate for the amount of bile acid synthesis in the liver. There is some diurnal variation in 7aC4 serum concentrations, so measurement should be performed on a fasting morning sample.

Patients with increased bile acid in their stool suffer from chronic diarrhea termed bile acid diarrhea (BAD). Approximately 10% to 33% of patients with irritable bowel syndrome with primarily diarrhea (IBS-D) have BAD. Identifying patients with BAD can be done by measuring total and fractionated bile acids in stool. The increased bile acids in feces can be caused by an inability to reabsorb bile acids in the terminal ileum (bile acid malabsorption: BAM). The loss of intestinal reabsorption leads to increase synthesis of bile acids in the liver. Recent studies have shown that serum concentrations of 7aC4 are elevated in patients with BAD and can be used as a surrogate to the timed fecal collection. Several intestinal diseases or functional abnormalities can lead to BAD. Identification of these patients can influence treatment decisions that could include the use of bile acid sequestrants.

Conversely, patients with IBS with predominately constipation (IBS-C) may have lower circulating 7aC4 as compared to healthy individuals.

#### Reference Values

> or =18 years: 2.5-63.2 ng/mL

Reference values have not been established for patients who are <18 years of age.

#### Interpretation

In patients with irritable bowel syndrome-diarrhea (IBS-D), elevated 7alpha-hydroxy-4-cholesten-3-one (7aC4) is consistent with bile acid diarrhea (BAD). A result of 17.6 ng/mL or greater is 83% sensitive and 53% specific for BAD. In these cases, a confirmatory 48-hour fecal bile acid test could be considered. A result above 52.5 ng/mL is 40% sensitive and 85% specific for BAD.

Interpretation in patients with chronic diarrhea (bile acid malabsorption: BAM):

```
----------------------------------17.6------------------------------------------52.5--------------------------
BAM unlikely                     Indeterminate                             BAM likely
```
Test Definition: 7AC4
7AC4, Bile Acid Synthesis, S

(consider other (consider confirmatory (consider bile acid conditions) fecal bile acids test or trial sequestrant therapy) of bile acid sequestrant)

**Cautions**
Testing should not be performed on individuals with liver disease or dysfunction.

**Supportive Data**
From an internal study of 55 patients with irritable bowel syndrome-diarrhea (IBS-D), a fasting serum 7 alpha-hydroxy-4-cholesten-3-one (7aC4) result of > or =17.6 ng/mL was 83% sensitive and 53% specific for identifying patients with elevated fecal bile acids (eg, patient with bile acid diarrhea).(1) In a different study, a result of 52.5 or greater resulted in 40% sensitivity and 85% specificity for bile acid malabsorption.(2)

**Clinical Reference**


**Performance**

**Method Description**
7 Alpha-hydroxy-cholesten-3-one (7aC4) isÂ extracted from the sample. After addition of a deuterium-labeled 7aC4 internal standard, 7aC4 is measured by liquid chromatography-tandem mass spectrometry (LC-MS/MS).(Donato LJ, Lueke A, Kenyon SM, Meeusen JW, Camilleri M: Description of analytical method and clinical utility of measuring serum 7-alpha-hydroxy-4-cholesten-3-one (7aC4) by mass spectrometry. Clin Biochem. 2018;52:106-111)

**PDF Report**
No

**Day(s) Performed**
Wednesday

**Report Available**
2 to 9 days

**Specimen Retention Time**
14 days

**Performing Laboratory Location**
Fees and Codes

Fees

- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their Regional Manager. For assistance, contact Customer Service.

Test Classification

This test was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration.

CPT Code Information

82542

LOINC® Information

<table>
<thead>
<tr>
<th>Test ID</th>
<th>Test Order Name</th>
<th>Order LOINC Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>7AC4</td>
<td>7AC4, Bile Acid Synthesis, S</td>
<td>94866-1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Result ID</th>
<th>Test Result Name</th>
<th>Result LOINC Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>65504</td>
<td>7AC4, Bile Acid Synthesis, S</td>
<td>94866-1</td>
</tr>
</tbody>
</table>