Overview

Method Name
Automated ELISA Quantitative Stelara Comprehensive TDM Inform TX

NY State Available
No

Specimen

Specimen Type
Serum SST

Specimen Required
Specimen Type: SST Serum

Container/Tube: SST

Specimen Volume: 2-3 mL SST Serum

Collection Instructions: Collect 7 mL blood in a serum gel tube(s), plain red-top tube(s) is NOT acceptable. Centrifuge specimen and ship serum gel tube refrigerated (DO NOT ALIQUOT).

Specimen Minimum Volume
1.5 mL SST Serum

Reject Due To

<table>
<thead>
<tr>
<th>Condition</th>
<th>Acceptance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemolysis</td>
<td>Mild OK; Gross Reject</td>
</tr>
<tr>
<td>Thawing</td>
<td>Cold OK; Warm OK</td>
</tr>
<tr>
<td>Lipemia</td>
<td>Mild OK; Gross Reject</td>
</tr>
<tr>
<td>Icterus</td>
<td>Mild OK; Gross Reject</td>
</tr>
<tr>
<td>Other</td>
<td>Specimens other than SST serum; Specimen received in aliquot tube</td>
</tr>
</tbody>
</table>

Specimen Stability Information

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
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</thead>
<tbody>
<tr>
<td>Serum SST</td>
<td>Refrigerated (preferred)</td>
<td>7 days</td>
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<tr>
<td></td>
<td>Ambient</td>
<td>48 hours</td>
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</tbody>
</table>

Clinical and Interpretive

Reference Values
Clinically Reportable Ranges:

Ustekinumab 0.1 - 10 ug/mL

Anti-Ustekinumab antibody 5 - 100 AU/mL

Interpretation

Ustekinumab (UST)

- The maintenance study showed that both UST 90 mg IM q8w and q12w maintained clinical response and remission through Week 44. However, the q8w regimen more consistently demonstrated efficacy across the range of endpoints. 1

- In a sub study of patients (n=102) with endoscopy at baseline and Week 44, the proportions of patients achieving endoscopic response, endoscopic remission, and mucosal healing were higher in the 2nd (> 0.5 ug/ml - 1.39 ug/ml), 3rd (>1.39 ug/ml - 2.67 ug/ml), and 4th (>2.67 ug/ml) concentration quartiles. 2

- A second study of patients with CD treated with UST showed 78% of patients were receiving UST 90 mg IM every 4 weeks after > 6 months. 3

Antibodies to Ustekinumab

- In the phase II clinical trial, the incidence of antibodies to UST was 0.7% at week 36. 2 In the pooled results of the phase III clinical trial, the incidence of antibodies to UST was 2.3% through one year. 1

- Some patients on biologic therapy may develop antibodies that resolve over time. 7,8,9

Cautions

In cases in which a specimen received was outside specimen requirements and the validated range for specimen stability, INFORM DIAGNOSTICS, Inc will process, however, the results should be interpreted with caution.

These findings are not diagnostic. They should be independently evaluated by the treating physician and used to supplement clinical findings in accordance with the treating physician’s independent medical judgment.

Clinical Reference


San Diego, California. Abstract 696.


Performance

Method Description
Automated ELISA assay for simultaneous analysis of both drug and anti-drug antibody.

PDF Report
No

Day(s) and Time(s) Test Performed
Monday through Friday

Analytic Time
5 - 7 days

Maximum Laboratory Time
7 - 11 days

Performing Laboratory Location
Inform Diagnostics, Inc

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 by and its performance characteristics determined by Inform Diagnostics. The test has not been cleared or approved by the Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary. This test is used for clinical purposes. Inform Diagnostics is regulated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as qualified to perform high-complexity clinical testing. Test results are not diagnostic and should be used to supplement clinical findings from the ordering physician's workup.

CPT Code Information
### Test Definition: FUAUA

**Ustekinumab and Anti-Ustekinumab Ab**

### LOINC® Information

<table>
<thead>
<tr>
<th>Test ID</th>
<th>Test Order Name</th>
<th>Order LOINC Value</th>
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<tbody>
<tr>
<td>FUAUA</td>
<td>Ustekinumab and Anti-Ustekinumab Ab</td>
<td>In Process</td>
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<table>
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<tr>
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<td>Interval weeks</td>
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<td>Ustekinumab Drug Level</td>
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<td>Z4997</td>
<td>Anti-Ustekinumab Antibody</td>
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