Test Description

Serum concentrations of ustekinumab (UST) may vary among equally dosed patients which can ultimately affect patient outcomes. Some patients may develop immunogenicity to UST by producing antibodies to ustekinumab (ATU) and the presence of persistent ATU has been observed to substantially reduce serum concentrations of ustekinumab. The quantitative measurement of UST and ATU levels in serum provides healthcare providers with valuable information to help them gain a better understanding of the factors that may be affecting a patient's loss of response.

The PROMETHEUS Anser UST test is a next generation and more sensitive quantitative monitoring assay that allows healthcare providers to measure and monitor serum UST and ATU levels at any time during therapy. Incorporating therapeutic drug monitoring may clarify what factors are contributing to a patient's loss of response and help guide treatment decisions by providing information to help determine an appropriate course of action.

- A quantitative monitoring analysis of UST and ATU levels
- PROMETHEUS Anser UST is only offered by Prometheus
- Specimen Requirements - 2.0 ml Serum, SST or Red Top Tube
- Shipping Requirements - Ambient or cold pack
- Storage/Stability – 7 days ambient, 9 days refrigerated
- Turn Around Time - 3 business days from date of receipt

Test Information

<table>
<thead>
<tr>
<th>Catalog Number</th>
<th>Test Name</th>
<th>Assay</th>
<th>Lower Limit of Quantification</th>
<th>Result Identifier*</th>
</tr>
</thead>
<tbody>
<tr>
<td>3190</td>
<td>Anser UST</td>
<td>Serum ustekinumab concentration (UST)</td>
<td>&lt; 1.6 ug/mL</td>
<td>A00111</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Antibodies to ustekinumab (ATU)</td>
<td>&lt; 1.6 U/mL</td>
<td>A00113</td>
</tr>
</tbody>
</table>

*Result identifier provided for use in HL7 applications.

Laboratory Description

- Prometheus is located in San Diego, CA. Tax ID# 33-0685754 NPI# 1073642641.
- Licensed in all states including New York and California.
- This test was developed and its performance characteristics determined by Prometheus Laboratories Inc. It has not been cleared or approved by the U.S. Food and Drug Administration. Prometheus Laboratories Inc. is a CAP-accredited CLIA laboratory.

CPT Codes (as applied by Prometheus)

84999 (x1), Unlisted Chemistry Procedure (Quantitative assay that simultaneously measures serum ustekinumab UST) and antibodies to ustekinumab (ATU) concentrations).

Literature References

2. Stelara (ustekinumab) Prescribing Information.

Assays and methods within this test may be covered by one or more US pending patents. For details, please visit www.prometheuslabs.com

PROMETHEUS, the Link Design, Anser, and the Anser design mark are trademarks or registered trademarks of Société des Produits Nestlé S.A. Vevey, Switzerland. STELARA is a registered trademark of Janssen Biotech, Inc. All rights reserved.

UST17003 9/17