Lab Dept: Chemistry
Test Name: INFLIXIMAB/HACA MEASUREMENT

General Information

Lab Order Codes: INHA

Synonyms: Infliximab concentration and Anti-Infliximab Antibody; Human Anti-Chimeric Antibodies

CPT Codes: 80299 – Quantitation of drug, NOS (Infliximab concentration)
              82397 – Chemiluminescent Ab (HACA measurement)

Test Includes: Serum Infliximab reported in ug/mL and HACA (Human Anti-Chimeric Ab) reported in ng/mL.

Logistics

Test Indications: Serum infliximab measurement is necessary when assessing the presence or absence of HACA. Serum infliximab concentrations may vary among equally dosed patient. Measuring serum infliximab levels can aid physicians in determining the dose of infliximab and guide infusion intervals. The HACA portion of the test detects Human Anti-Chimeric Antibodies (antibodies against infliximab). Patients that develop HACA may experience infusion reactions and/or a reduced duration of efficacy of infliximab.

Lab Testing Sections: Serology – Sendouts

Referred to: Esoterix Laboratory Services (ESL Test: 803770)

Phone Numbers:
MIN Lab: 612-813-6280
STP Lab: 651-220-6550

Test Availability: Daily, 24 hours

Turnaround Time: 8 – 10 days

Special Instructions: N/A

Specimen

Specimen Type: Blood

Container: SST (Marble, gold or red)
**Draw Volume:** 6 mL (Minimum: 3 mL) blood

**Processed Volume:** 2 mL (Minimum: 1 mL) serum
Note: Minimum volume does not allow for repeat testing.

**Collection:** Routine venipuncture. Specimen must be centrifuged within 45 minutes of collection.

**Special Processing:** Lab Staff: Centrifuge specimen, remove serum aliquot into a screw-capped round bottom plastic vial. Store and ship frozen. Forward promptly.

**Patient Preparation:** None

**Sample Rejection:** Mislabeled or unlabeled specimen

---

**Interpretive**

<table>
<thead>
<tr>
<th>Reference Range:</th>
<th>Infliximab:</th>
<th>≥0.4 ug/mL indicated detection of Infliximab</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Note: In the presence of anti-infliximab antibodies, the infliximab drug level reflects the antibody-unbound fraction of the infliximab concentration in serum.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Human Anti-Chimeric Ab (HACA):</td>
<td>Result ≥22 ng/mL indicates detection of anti-infliximab antibodies.</td>
</tr>
</tbody>
</table>

**Critical Values:** N/A

**Limitations:** Detection limit: Infliximab concentration = <0.4 ug/mL
Detection limit: HACA = <22 ng/mL

**Methodology:** Electrochemiluminescence Immunoassay (ECLIA)

**References:** [Esoterix Laboratory Services](#) August 2016

**Updates:** 8/3/2016: Updated tube SST.