Lab Dept:	**Chemistry**
Test Name:	**INFLIXIMAB QUANTITATION WITH REFLEX TO ANTIBODIES TO INFLIXIMAB, SERUM**

General Information

Lab Order Codes:	INFX
Synonyms:	Infliximab concentration and Anti-Infliximab Antibody; Human Anti-Chimeric Antibodies
CPT Codes:	80230 – Infliximab concentration 82397 – Chemiluminescent Ab (HACA measurement) (if appropriate)
Test Includes:	Infliximab will be performed by liquid chromatography-tandem mass spectrometry (LC-MS/MS). When infliximab results are below 5.1 mcg/mL, testing for antibodies to infliximab will be performed at an additional charge.

Logistics

Test Indications:	Trough level quantitation for evaluation of patients undergoing therapy with infliximab, infliximab-dyyb, infliximab-abda or infliximab-axxq.
Lab Testing Sections:	Serology – Sendouts
Referred to:	Mayo Clinic Laboratories (MML test: INFXR)
Phone Numbers:	MIN Lab: 612-813-6280 STP Lab: 651-220-6550
Test Availability:	Daily, 24 hours (Reference lab test performance schedule INFX: Monday, Wednesday, Thursday; INXAB: Monday, Wednesday, Friday)
Turnaround Time:	3-6 days
Special Instructions:	Draw blood immediately before next scheduled dose (trough specimen). See Patient Preparation.

Specimen

Specimen Type:	Blood
Container:	Red NO GEL

Draw Volume: 3 mL (Minimum: 1.5 mL) blood

Processed Volume: 1 mL (Minimum: 0.5 mL) serum

Collection: Routine blood collection. Specimen must be centrifuged within 2 hours of collection.

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

Specimen stable refrigerated (preferred) or frozen for 28 days.

Patient Preparation: For 12 hours before specimen collection do not take multivitamins or dietary supplements containing biotin (vitamin B7), which is commonly found in hair, skin, and nail supplements and multivitamins.

Sample Rejection: Gross hemolysis; gross icterus; mislabeled or unlabeled specimen; SST specimen

Interpretive

Reference Range:

Infliximab:	Limit of quantitation is 1.0 mcg/mL. Therapeutic ranges are disease specific. Pediatric reference ranges are not established.
Infliximab Ab/ Human Anti-Chimeric Ab (HACA):	Absence of antibodies to infliximab (ATI) is defined as <50U/mL. Presence of ATI is reported as positive when concentrations are > or =50 U/mL.
Interpretation: Low trough concentrations may be correlated with loss of response to infliximab. For infliximab trough concentrations5.0 mcg/mL or less, testing for antibodies is suggested. For infliximab trough concentrations above 5.0 mcg/mL, the presence of ATI is unlikely; patients experiencing loss of response to infliximab may benefit from an increased does or a shorter infusion level. Results above 35 mcg/mL are suggestive of a blood draw at a time-point in treatment other than trough.	

Critical Values: N/A

Limitations: Toxicity effects other than acute hypersensitivity infusion reactions have not been described nor correlated with infliximab concentrations.

During the initial induction phase of treatment (weeks 0, 2, and 6), steady-state has not been achieved and concentrations of infliximab may vary significantly between infusions.

Therapeutic concentrations of infliximab may vary according to the disease (eg, Crohn disease versus ulcerative colitis versus rheumatoid arthritis).

Samples containing more than 12.5 ng/mL biotin (vitamin B7) may interfere (in the form of depressed signal) with INXAB/Infliximab Antibodies, Serum.

For antibodies-to-infliximab (ATI), pediatric and adult reference ranges were validated, and the presence of an ATI is established as greater than or equal to 50 U/mL by the bridging electrochemiluminescent/acid dissociation method.

The presence of endogenous infliximab is a recognized interference in most ATI methods. This assay includes an acid dissociation step which partially mitigates this interference. Tolerance up to 12.5 mcg/mL infliximab has been documented, although this is also determined by the titer of the ATI present in the patient sample.

Methodology:

Infliximab level: Selective Reaction Monitoring Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS)

Infliximab Antibody: Electrochemiluminescent Bridging Immunoassay with Acid Dissociation

References:

Mayo Clinic Laboratories (December 2023)

Updates:

8/3/2016: Updated tube SST.
8/23/2021: Moved from Esoterix to Mayo.
12/12/2023: Changed preferred transport temperature. Updated turnaround time, Children's Minnesota test code. Added specimen stability.