MAYO CLINIC LABORATORIES

NEW TEST

Notification Date: December 5, 2023
Effective Date: December 19, 2023

Infliximab Quantitation with Antibodies to Infliximab, Serum

Test ID: INFXP

Useful for:

Trough level quantitation for evaluation of patients undergoing therapy with infliximab for proactive or reactive therapeutic drug monitoring

Profile Information:

Test ID	Reporting Name	Available Separately	Always Performed
INFX	Infliximab, S	Yes (INFXR)	Yes
INXAB	Infliximab Ab, S	No	Yes

Methods:

INFX: Selective Reaction Monitoring Liquid Chromatography Tandem Mass Spectrometry (LC-MS/MS)
INXAB: Electrochemiluminescent Bridging Immunoassay with Acid Dissociation

Reference Values:

INFLIXIMAB QUANTITATION:
Limit of quantitation is 1.0 mcg/mL. Therapeutic ranges are disease specific.

Pediatric reference ranges are not established.

INFLIXIMAB ANTIBODIES
Absence of antibodies to infliximab (ATI) is defined as <50 U/mL
Presence of ATI is reported as positive when concentrations are > or =50 U/mL

Specimen Requirements:

	1. Draw blood immediately before next scheduled dose (trough specimen).
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.
Collection Container/Tube:	Red top (serum gel/SST are **not acceptable**)
Submission Container/Tube:	Plastic vial
Specimen Volume:	1.2 mL

Collection Instructions: Centrifuge and aliquot serum into plastic vial within 2 hours of collection.

Minimum Volume: 0.5 mL

Specimen Stability Information:

Specimen Type	Temperature	Time
Serum Red	Refrigerated (preferred)	28 days
	Frozen	28 days

Cautions:

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.(3)

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

The American Gastroenterology Association established thresholds associated with positive outcomes for adults with active inflammatory bowel disease based on several clinical studies.(8)

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 our 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.

CPT Code:

INFX - 80230
INXAB - 82397

Day(s) Performed:

INFX: Monday, Wednesday, Thursday
INXAB: Monday, Wednesday, Friday

Report Available:

3 to 6 days

Questions

Contact Amy Ennis, Laboratory Resource Coordinator at 800-533-1710.