MAYO CLINIC LABORATORIES

NEW TEST

Notification Date: October 17, 2023
Effective Date: October 24, 2023

Adalimumab Quantitative with Antibody, Serum

Test ID: ADALP

Highlights:

Adalimumab (brand names Amjevita and Humira) is a fully human therapeutic monoclonal antibody targeting tumor necrosis factor alpha, a proinflammatory cytokine that is upregulated in several autoimmune inflammatory states.

Adalimumab is US Food and Drug Administration or Food and Drug Administration-approved for treatment of rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, pediatric and adult Crohn disease, ulcerative colitis, plaque psoriasis, hidradenitis suppurativa and uveitis. Adalimumab is a subcutaneous injection, usually self-administered every other week at a fixed dose of 40 mg in adults, although dosing can vary.

Testing for adalimumab concentration and presence of anti-adalimumab antibodies is helpful to adjust therapeutic strategies for patients starting therapy (proactive monitoring), and to adjust dosing or treatment strategy when partial response or loss of response to therapy is observed, manifested as recurrence of symptoms.

Useful for:

Therapeutic drug monitoring of adalimumab concentration and antibody levels

Profile Information:

Test ID	Reporting Name	Available Separately	Always Performed
QNADL	Adalimumab QN, S	Yes (ADALX)	Yes
ABADL	Adalimumab Ab, S	No	Yes
INTAD	Adalimumab Interpretation	No	Yes

Methods:

Adalimumab Quantitation:
The adalimumab enzyme-linked immunosorbent assay (ELISA) is designed to determine the quantity of free adalimumab (therapeutic antibody against tumor necrosis factor-alpha: TNF-alpha) in serum samples. In a first incubation step, the free adalimumab from the sample is bound to the specific monoclonal anti-adalimumab antibody coated on the plate. To remove all unbound substances, a washing step is carried out. In a further incubation step, peroxidase-labeled antibody is added. Tetramethylbenzidine (TMB) is used as a substrate for peroxidase. Finally, an acidic stop solution is added to terminate the reaction. The color changes from blue to

yellow. The intensity of the yellow color is directly proportional to the concentration of free adalimumab in the sample. A dose response curve of the absorbance unit (optical density: OD) verses concentration is generated, using the values obtained from standard. The concentrations of free adalimumab in the samples are determined directly from this curve.(Package insert: Adalimumab Drug Level ELISA reagent. Immun Diagnostik; 10/2020)

Antibodies to Adalimumab:
An ELISA is used to determine the presence of antibodies against TNF-alpha blocker adalimumab (Amjevita and Humira). During sample preparation, the antibodies-to-adalimumab (ATA) are separated from the therapeutic antibody adalimumab using an acid dissociation to acquire free ATA. By adding the peroxidase conjugate (POD-therapeutic antibody adalimumab) and the tracer (biotinylated therapeutic antibody adalimumab), the unlabeled therapeutic antibodies are replaced, and the labeled antibodies can form a complex with the ATA. This complex binds via biotin to the streptavidin-coated microtiter plate. It is detected via the peroxidase conjugate with the peroxidase converting the substrate, TMB, to a blue product. The enzymatic reaction is stopped by adding an acidic solution. The samples convert from blue to yellow. The color change is measured in a photometer at 450 nm. The interpretation is made using the cut-off control.(Package insert: Adalimumab Total ADA ELISA reagent. Immun Diagnostik; 02/2021)

Reference Values:

ADALIMUMAB QUANTITATIVE:
Limit of quantitation is 0.8 mcg/mL. Optimal therapeutic ranges are disease specific.

ADALIMUMAB ANTIBODY:
<14.0 AU/mL

Specimen Requirements:

Patient Preparation:	For 12 hours before specimen collection, it is recommended that the patient not take multivitamins or dietary supplements containing biotin (vitamin B7), which is commonly found in hair, skin, and nail supplements and multivitamins.
Container/Tube:	
Preferred:	Serum gel
Acceptable:	Red top
Specimen Volume:	1.0 mL
Collection Instructions:	Centrifuge and aliquot serum into a plastic vial
Minimum Volume:	0.35 mL

Specimen Stability Information:

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

Cautions:

Tumor necrosis factor (TNF) measurement is not the analyte of choice for monitoring therapy with TNF inhibitors (such as adalimumab or infliximab), since TNF testing would not distinguish between free TNF and TNF bound to the monoclonal antibody, either in the extracellular or membrane-bound form of the cytokine.

Toxicity effects other than acute hypersensitivity infusion reactions have not been described nor correlated with high adalimumab concentrations.

Optimal therapeutic concentrations of adalimumab may vary according to the disease.(11-13) For adults with active inflammatory bowel disease, a concentration of 7.5 mcg/mL or greater is considered therapeutic.(5)

For patients taking biotin supplements, it is recommended to wait at least 12 hours after the last ingestion of biotin to collect a blood sample for this test.

CPT Code:

80145
83520

Day(s) Performed: Monday, Wednesday, Friday **Report Available:** 2 to 4 days

Questions

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