Lab Dept: Serology

Test Name: ADALIMUMAB WITH REFLEX TO ANTI-ADALIMUMAB ANTIBODY

General Information

Lab Order Codes: AAAB

Synonyms: Humira®, Anti-TNF-α Drug

CPT Codes: 80299- Quantitation of therapeutic drug
82397- Chemiluminescent Assay (if appropriate)

Test Includes: Adalimumab drug level reported in mcg/mL. If the result is 5.0 mcg/mL or less, the adalimumab antibody test will be performed at an additional charge. Anti-Adalimumab Antibody is reported in AU/mL.

Logistics

Test Indications: To monitor anti-adalimumab therapy for individuals with Crohn's disease, inflammatory bowel disease, ulcerative colitis, rheumatoid arthritis or other autoimmune conditions. Detection and quantification of antibodies directed against adalimumab in human serum. Trough level quantitation for evaluation of patients with loss of response to adalimumab.

Lab Testing Sections: Chemistry- Sendouts

Referred to: Mayo Medical Laboratories (MML code: ADALX)

Phone Numbers: MIN Lab: 612-813-6280

STP Lab: 651-220-6550

Test Availability: Daily, 24 hours

Turnaround Time: 1 - 4 days, testing performed Tuesday and Friday

Special Instructions: N/A

Specimen Type: Blood

Container: SST (Gold, marble, or red)

Draw Volume: 1.5 mL (Minimum: 1.2 mL) blood

Processed Volume:	0.5 mL (Minimum: 0.4 mL) serum
Collection:	Routine venipuncture
Special Processing:	Lab Staff: Centrifuge specimen, aliquot serum into a plastic, screw-topped vial. Store and ship at refrigerated temperatures. Forward promptly.
Patient Preparation:	None
Sample Rejection:	Mislabeled or unlabeled specimen.

Interpretive

Reference Range:

Adalimumab Drug Level - Limit of quantitation is 0.8 mcg/mL. Optimal therapeutic ranges are disease specific.

Anti-Adalimumab Antibody- <14.0 AU/mL

Interpretation:
Currently, adalimumab quantitation is one of the most commonly tested monoclonal antibodies in routine practice; this testing is generally performed in conjunction with immunogenicity assessment for antibodies to adalimumab (ATA). Most often, this testing is ordered in inflammatory bowel disease (IBD) patients on adalimuab therapy who are experiencing loss of response, but the testing may be ordered on anyone on adalimumab. Results from adalimumab and aTA testing play an important role in patient management. When measured at trough, for patients who have undetectable or low concentrations of adalimumab, but no detectable ATA, the physician may choose to increase the dose of adalimumab in an attempt to increase the amount of drug in circulation. If the patient has low adalimumab in the presence of ATA, in many cases the physician may switch the patient to another tumor necrosis factor (TNF) inhibitor. In contrast, for patients with increased trough concentrations of adalimumab, whether or not an ATA is present, it may be necessary to switch the patient to a therapy with a different mechanism of action, such as the anti-alpha4-beta-7-integrin antibody vedolizumab or the IL12/IL23 antibody ustekinumab, in the setting of IDB.

Adalimumab quantitation will be interpreted in 2 different ways. When measured at trough, individuals may be considered to have adequate trough levels when drug concentrations are above 5 mcg/mL, and faster clearance of the drug, which may warrant a dosing adjustment or additional action if the adalimumab trough concentration is below or equal to 5 mcg/mL. Adalimuab quantitation may influence patient management decisions as to whether therapy should continue as is, dose escalation is necessary, or a switch to a new therapeutic regimen is needed.

Low trough concentrations may be correlated with loss of response to adalimumab. For adalimumab trough concentrations less than or equal to 5.0 mcg/mL, testing for antibodies to ATA is suggested.

For adalimumab trough concentrations above 5.0 mcg/mL, the presence of ATA is unlikely; patients experiencing loss of response to adalimumab may

benefit from an increased dose or more frequent dosing.

Adalimumab concentration results above 35 mcg/mL are suggestive of a blood draw at a time-point in treatment other than trough.

Limitations:

Laboratory testing of patients for quantitation of adalimumab and assessment of immunogenicity (development of autoantibodies against adalimumab) can help optimize therapy when partial response or loss of response to therapy are observed. As a side note, tumor necrosis factor (TNF) measurement is not the analyte of choice for monitoring therapy with TNF inhibitors (such as adaliumumab or infliximab), since it would not distinguish between free TNF and TNF bound to the monoclonal antibody, either in the estracellular or membrane-bound form of the cytokine.

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

Optimal therapeutic concentrations of adalimumab may vary according to the disease (eg, Crohn disease versus ulcerative colitis versus rheumatoid arthritis).

Methodology:

Enzyme-Linked immunoassay (ELISA)

References:

Mayo Medical Laboratories (September 2017)

Updates:

9/21/2017: Moved from forward to Esoterix to performed at MML.