
Lab Dept: Serology

Test Name: ADALIMUMAB & ANTI-ADALIMUMAB ANTIBODY

General Information

Lab Order Codes: AAAB

Synonyms: Humira®, Anti-TNF- α Drug

CPT Codes: 82397- Chemiluminescent Assay
80299- Quantitation of therapeutic drug

Test Includes: Adalimumab drug level reported in ug/mL.
Anti-Adalimumab Antibody reported in ng/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.

Lab Testing Sections: Chemistry- Sendouts

Referred to: Mayo Medical Laboratories (MML test FAAAB) (Mayo forward to Esoterix Endocrinology)

Phone Numbers: MIN Lab: 612-813-6280

STP Lab: 651-220-6550

Test Availability: Daily, 24 hours

Turnaround Time: 5 - 11 days, testing performed on Monday and Wednesday

Special Instructions: N/A

Specimen Type: Blood

Container: SST (Gold, marble, or red)

Draw Volume: 6 mL (Minimum: 3 mL) blood

Processed Volume: 2 mL (Minimum: 1 mL) serum

Collection:	Routine venipuncture
Special Processing:	Lab Staff: Centrifuge specimen, aliquot serum into a plastic, screw-topped vial. Store and ship at frozen temperatures. Forward promptly.
Patient Preparation:	None
Sample Rejection:	Mislabeled or unlabeled specimen.

Interpretive

Reference Range:	<p>Adalimumab Drug Level- results of 0.6 or higher indicates detection of adalimumab.</p> <p>In the presence of anti-adalimumab antibodies, the adalimumab drug level reflects the antibody-unbound fraction of adalimumab concentration in serum.</p> <p>Anti-Adalimumab Antibody- results of 25 or higher indicates detection of anti-adalimumab antibodies.</p> <p>All positive antibody results are verified by confirmatory test.</p> <p><100 ng/mL Low antibody titer, no significant impact on free drug level</p> <p>101 - 300 ng/mL Intermediate antibody titer, variable impact on free drug level</p> <p>>301 ng/mL High antibody titer, significant impact on free drug level</p>
Limitations:	<p>Adalimumab Drug Level Quantitation limit <0.6 ug/mL</p> <p>Anti-Adalimumab Antibody Quantitation limit <25 ng/mL</p>
Methodology:	Electrochemiluminescence immunoassay (ECLIA)
References:	Mayo Medical Laboratories (May 2017)