

ADALIMUMAB QUANTITATIVE WITH REFLEX TO ANTIBODY, SERUM

Test ID: ADALX

USEFUL FOR:

- Trough level quantitation of adalimumab (Humira, AbbVie Pharmaceuticals) for evaluation of patients with loss of response to adalimumab.
- Detection and quantification of antibodies directed against adalimumab in human serum.

REFLEX TESTS:

Test ID	Reporting Name	Available Separately	Always Performed
ADLAB	Adalimumab Ab, S	No	No

TESTING ALGORITHM: If the result of the adalimumab quantitation is 5.0 mcg/mL or less, the adalimumab antibody test will be performed at an additional charge.

METHOD: Enzyme-Linked Immunosorbent Assay (ELISA)

REFERENCE VALUES:

Adalimumab Quantitative with Reflex to Antibody: Limit of quantitation is 0.8 mcg/mL.
Optimal therapeutic ranges are disease specific.

Adalimumab Antibody: <14.0 AU/mL

SPECIMEN REQUIREMENTS:**Container/Tube:**

Preferred: Serum gel

Acceptable: Red top

Specimen Volume: 0.5 mL

Minimum Volume: 0.35 mL

SPECIMEN STABILITY INFORMATION:

Specimen Type	Temperature	Time
Serum	Refrigerated (preferred)	7 days
	Ambient	72 hours
	Frozen	21 days

CAUTIONS:

- 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 adalimumab or infliximab), since it 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 adalimumab concentrations.
- Optimal therapeutic concentrations of adalimumab may vary according to the disease (eg, Crohn disease verses ulcerative colitis verses rheumatoid arthritis).

CPT CODE: 80299-ADALX
83520-ADLAB (if appropriate)

DAY(S) SET UP: Tuesday and Friday; 9 a.m.

ANALYTIC TIME: 1 day

NOTE: The following referral test code(s) will become obsolete.

Test Name	Test ID	Referral Lab Code	Referral Lab
Adalimumab Concentration and Anti-Adalimumab Antibody	FAAAB	803890	Esoterix Laboratory

QUESTIONS: Contact your Mayo Medical Laboratories' Regional Manager or
Dunisha Messmer, MML Laboratory Technologist Resource Coordinator
Telephone: 800-533-1710