Adalimumab and Antibodies to Adalimumab Quantitation

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Adalimumab is a chimeric immunoglobulin (IgG1 kappa) that targets tumor necrosis factor alpha (TNF-α) and is currently FDA-approved for the treatment of multiple inflammatory conditions.[1] The commercial reference product for adalimumab is Humira. FDA-approved adalimumab biosimilar products include Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Yuflyma, and Yusimry.[2]

This assay is specifically designed to quantify the concentrations of adalimumab and antibodies to adalimumab in human serum using an electrochemiluminescence immunoassay method on the MesoScale Discovery platform. The assay can also be used for all approved adalimumab biosimilar products.

Featured ARUP Testing

Adalimumab and Antibodies to Adalimumab Quantitation 3017043

Method: Quantitative Electrochemiluminescent Immunoassay (ECLIA) with Acid Dissociation

Use to monitor adalimumab or adalimumab biosimilar therapy.

Clinical Overview

Circulating levels of adalimumab have been found to vary significantly between patients. This variation is influenced by physiological characteristics such as age, sex, body mass index, and the presence of antibodies against adalimumab.[3] Antibodies to adalimumab can interfere with the binding of adalimumab to TNF-α or increase the clearance of the drug, resulting in a loss of drug efficacy.[4]

Patients treated with TNF-α antagonists, including adalimumab, can experience primary or secondary treatment failure. Primary treatment failure occurs early in the treatment course when the disease does not respond to initial induction therapy. Secondary treatment failure occurs when the disease initially responds to treatment but there is subsequent loss of therapeutic effect that leads to disease flares during the maintenance phase. In general, primary failure rates of TNF-α antagonists can be as high as 30-40%.[5,6] Up to 50% of patients who initially respond to therapy may experience a secondary loss of response within a year of treatment.[5,6]

Primary treatment failures can be attributed to pharmacokinetic issues, as well as poor adherence to the treatment regimen. Secondary treatment failures are primarily caused by the development of antibodies to the TNF-α antagonist. Because these scenarios cannot be discerned clinically, it is crucial to perform clinical laboratory monitoring to detect and quantify antidrug antibodies and concomitant drug levels.[7,8,9] This helps determine whether the patient will benefit from additional drug therapy or if switching to a different TNF-α antagonist or a drug from a different class would be beneficial.

Measurement of adalimumab and antibodies to adalimumab concentrations should be performed at trough (the time immediately prior to the next scheduled infusion).

For more information about laboratory testing for adalimumab and other monoclonal antibody drugs, refer to the ARUP Consult Laboratory Testing for Monoclonal Antibody Therapeutics topic.

Test Interpretation

Adalimumab and Antibodies to Adalimumab Quantitation: Results Interpretation

Test Component	LOQ	Results	Interpretation
Adalimumab quantitation	0.4 µg/mL	≥0.4 µg/mL	Adalimumab or adalimumab biosimilar detected Therapeutic level may vary depending on the disease being treated
		<0.4 µg/mL	Adalimumab or adalimumab biosimilar not detected

Test Component	LOQ	Results	Interpretation
Antibodies to adalimumab quantitation	20 ng/mL	≥20ng/mL	Antibodies against adalimumab or an adalimumab biosimilar detected Interpret in the context of adalimumab or adalimumab biosimilar trough concentration to determine clinical significance and impact on treatment efficacy
		<20 ng/mL	Antibodies against adalimumab or an adalimumab biosimilar not detected

LOQ, limit of quantitation

Limitations

- This test does not differentiate between adalimumab and the various adalimumab biosimilar products.
- This assay is subject to biotin (vitamin B7) interference:
  - Serum samples from patients who are taking biotin (eg, as a dietary supplement) may contain elevated concentrations of biotin.
  - Elevated serum biotin concentrations may affect the accuracy of adalimumab and anti-adalimumab antibody measurements.
- The presence of endogenous adalimumab in serum samples can interfere with most antibody assays:
  - To mitigate this interference, this assay includes an acid dissociation step that helps reduce the impact of endogenous adalimumab.
  - The actual tolerance for endogenous adalimumab may vary depending on the specific concentration of the antibody to adalimumab present in the sample.

References

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