

**NEW TEST**

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**Adalimumab and Antibodies to Adalimumab Quantitation**

3017043, ADA PAN

**Specimen Requirements:**

**Patient Preparation:** Collect specimens before next scheduled dose of adalimumab or adalimumab biosimilar (trough specimen). Avoid exposure to biotin (vitamin B7) for 12 hours prior to specimen collection.

**Collect:** Serum separator tube.

**Specimen Preparation:** Separate serum from cells ASAP. Transfer 1 mL serum to an ARUP standard transport tube. (Min 0.1 mL)

**Transport Temperature:** Refrigerated.

**Unacceptable Conditions:** Grossly hemolyzed, icteric, or lipemic specimens.

**Remarks:**

**Stability:** After separation from cells: Ambient: 2 days; Refrigerated: 2 weeks; Frozen: 1 month (avoid repeated freeze/thaw cycles).

**Methodology:** Quantitative Electrochemiluminescent Immunoassay (ECLIA) with Acid Dissociation

**Performed:** Sun-Sat

**Reported:** 3-7 days

**Note:**

**CPT Codes:** 80145; 82397

**New York DOH Approval Status:** Specimens from New York clients will be sent out to a New York DOH approved laboratory, if possible.

**Interpretive Data:**

**Adalimumab Quantitation:**

Results of 0.4 ug/mL or higher indicate the detection of adalimumab or an adalimumab biosimilar. Therapeutic level may vary depending on the disease being treated.

**Antibodies to Adalimumab Quantitation:**

Results of 20 ng/mL or higher indicate the detection of antibodies against adalimumab or an adalimumab biosimilar. Interpret in the context of adalimumab or adalimumab biosimilar trough

concentration to determine clinical significance and impact on treatment efficacy.

Reference Interval:

Test Number	Components	Reference Interval
	Adalimumab Quantitation	0.4 ug/mL or greater
	Antibodies to Adalimumab Quantitation	19 ng/mL or less

**HOTLINE NOTE: Refer to the Hotline Test Mix for interface build information.**