PROMETHEUS®
Therapeutics & Diagnostics
For the person in every patient

PROMETHEUS® Anser ADA™
Cat. # 3170

Product Description

Serum concentrations of adalimumab (ADA) may vary among equally dosed patients which can ultimately affect patient outcomes. Suboptimal levels of ADA have been linked to lower response rates in IBD patients. Furthermore, some patients may develop immunogenicity to ADA by producing antibodies to adalimumab (ATA). The presence of ATA has also been associated with increased rates of infusion reactions and drug clearance leading to lower response rates. Therefore, the quantitative measurement of ADA and ATA levels in serum provides healthcare providers with valuable information to help them gain a better understanding of the factors that may be affecting a patient's loss of response.

The PROMETHEUS Anser ADA test is a next generation quantitative monitoring assay that allows healthcare providers to measure and monitor serum ADA and ATA levels at anytime during therapy. Incorporating therapeutic drug monitoring may clarify what factors are contributing to a patient's loss of response and help patient management by providing information to help decide an appropriate course of action.

- A quantitative monitoring analysis of ADA and ATA levels.
- PROMETHEUS Anser ADA is only offered at Prometheus.
- **Specimen Requirements** - Serum, 2.0 ml: SST or Red Top Tube.
- **Shipping and Handling** - Ambient or refrigerated.
- **Storage Conditions/Stability** -7 days Ambient or 9 days Refrigerated
- **Turn Around Time** - 3 business days from date of receipt.
- **Reference Range:**
    - Serum adalimumab (ADA) concentration: <1.6 ug/mL
    - Antibody to adalimumab (ATA) concentration: <1.7 U/mL

Facilities Description

- Prometheus is located in San Diego, CA. Tax ID# 33-0685754 NPI# 1073642641.
- Licensed in several states including New York and California.
- Prometheus Laboratories Inc. is CLIA certified and accredited by the College of American Pathologists. This test was developed and its performance characteristics determined by Prometheus Laboratories Inc. It has not been cleared or approved by the U.S. Food and Drug Administration. This test may be covered by one or more US pending or issued patents - see prometheuslabs.com for details.

CPT Codes

84999 (x1), Unlisted Chemistry Procedure (Quantitative assay that simultaneously measures serum adalimumab (ADA) and antibodies to adalimumab (ATA) concentrations).

Literature References

- Karmiris K., et al., Influence of Trough Serum Levels and Immunogenicity on Long-Term Outcome of Adalimumab Therapy in Crohn's Disease.Gastroenterology 2009;137:1628-1640.

- Wang S., et al., Influence of Trough Serum Drug Level and Immunogenicity on the Lack of Response to Adalimumab Therapy in IBD Patients. Am J Gastro 2012;107 (supplement 1): Abstract 1680.

Adalimumab Activity and Neutralizing Antibody

2011248

Supplemental Resources

ARUP Consult® Disease Topics

- Rheumatoid Arthritis - RA

Ordering Recommendation

Evaluate response failure to adalimumab therapy. Determine and adjust dosage or identify the need for change to another anti-TNF-α inhibitor.

Mnemonic

ADA NAB

Methodology

Cell Culture/Quantitative Chemiluminescent Immunoassay/ Semi-Quantitative Chemiluminescent Immunoassay

Performed

Mon,Wed,Thu,Sat

Reported

2-3 days

New York DOH Approval Status

This test is New York DOH approved.

Submit With Order

Specimen Required

Patient Preparation: Collect specimens before adalimumab treatment.

Collect: Serum separator tube.

Specimen Preparation: Separate serum from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.3 mL)

Storage/Transport Temperature: Refrigerated.

Unacceptable Conditions: Contaminated, hemolyzed, icteric, or lipemic specimens.

Remarks:

Stability: After separation from cells: Ambient: 48 hours; Refrigerated: 4 weeks; Frozen: 1 year (avoid repeated freeze/thaw cycles)

Reference Interval

Available Separately	Components	Reference Interval
No	Adalimumab Activity	Not Detected
No	Adalimumab Neutralizing Antibody	Not Detected

Interpretive Data

This test measures the capacity of adalimumab to neutralize TNF-activity. Additionally, adalimumab neutralizing antibodies (NAb) are titered (reporting the highest dilution of patient sera in which NAb activity is detected).

This test is used to evaluate secondary response failures to adalimumab therapy. Secondary response failure is defined as loss of clinical response after initial improvement of clinical signs and symptoms. Therapeutic decision should rest on both the clinical response and the knowledge of the fate of the drug including the emergence of immunogenicity in individual patients.

Circulating adalimumab levels have been shown to vary considerably between patients. These differences relate to route and frequency of administration and patient-related features such as age, gender, weight, drug metabolism, and concomitant medications such as methotrexate and other immunosuppressants.

IF Adalimumab Activity is....	AND Adalimumab Neutralizing Ab. Titer is....	THEN....
Not Detected	Not Detected	A higher dosage of adalimumab or shortening the dosing interval may be appropriate.
Not Detected	1:20 or greater	A change to another anti-TNF-α drug may be appropriate.
0 65 ug/mL or greater	Not Detected	A change to another type of therapy (not targeting TNF-α) may be appropriate.
0 65 ug/mL or greater	1:20 or greater	Repeat testing is suggested to rule out decreasing adalimumab activity and/or increasing adalimumab neutralizing antibodies.

Statement B: This test was developed and its performance characteristics determined by ARUP Laboratories. The U.S. Food and Drug Administration has not approved or cleared this test, however, FDA clearance or approval is not currently required for clinical use. The results are not intended to be used as the sole means for clinical diagnosis or patient management decisions.

Note

This test is performed pursuant to an agreement with Biomonitor.

CPT Code(s)

86352 x2

Components

Component Test Code*	Component Chart Name	LOINC
2011249	Adalimumab Activity	74117-3
2011250	Adalimumab Neutralizing Antibody	
2011251	EER Adalimumab	11526-1

** Component test codes cannot be used to order tests. The information provided here is not sufficient for interface builds; for a complete test mix, please view this test within the Laboratory Test Directory found at www.aruplab.com*

Aliases

- Humira