PROMETHEUS®
Therapeutics & Diagnostics
For the person in every patient

PROMETHEUS® Anser™ IFX

Cat. # 3150

Product Description

Serum concentrations of IFX may vary among equally dosed patients which can ultimately affect patient outcomes. Suboptimal levels of IFX have been linked to lower response rates in IBD patients. Furthermore, some patients may develop immunogenicity to IFX by producing antibodies to Infliximab (ATI). The presence of ATI has also been associated with increased rates of infusion reactions and drug clearance leading to lower response rates. Therefore, the quantitative measurement of IFX and ATI 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 IFX test is a new generation and more sensitive quantitative infliximab monitoring assay that allows healthcare providers to measure and monitor serum IFX and ATI levels anytime during therapy. Incorporating drug monitoring may clarify what factors are contributing to a patient's loss of response and help guide treatment decisions by providing information to help determine an appropriate course of action.

- A quantitative monitoring assay of IFX and ATI levels.
- PROMETHEUS Anser IFX 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 & Refrigerated.
- **Turn Around Time** - 3 business days from date of receipt.
- **Reference Range:**
    - Serum infliximab (IFX) concentration: <1.0 ug/mL
    - Antibody to infliximab (ATI) concentration: <3.1 U/mL

Facilities Description

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. Prometheus Laboratories Inc. is a CAP-accredited CLIA laboratory.

CPT Codes (as applied by Prometheus)

- **84999 (x1), Unlisted Chemistry Procedure** (Quantitative assay that simultaneously measures serum Infliximab (IFX) and antibodies to Infliximab (ATI) concentrations).

Literature References

- Ternant D., et al. Infliximab Pharmacokinetics in Inflammatory Bowel Disease Patients. Ther Drug Monit 2008;30:523-529.
- Baert F., et al. Influence of Immunogenicity on the Long Term Efficacy of Infliximab in Crohn's Disease. N Engl J Med 2003;348:601-608.
- Feagan B., et al. Novel Infliximab (IFX) & Antibody-to-Infliximab (ATI) Assays are Predictive of Disease Activity in Patients with Crohn's Disease. Gastroenterology 2012; 142(5), Supplement 1, Abstract 565.
- Afif W., et al. Clinical Utility of Measuring Infliximab and Human anti-Chimeric Antibodies Concentrations in Patients with Inflammatory Bowel Disease. Am J Gastroenterology 2010;105:1133-1139.

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Infliximab Activity and Neutralizing Antibody

2008320

Supplemental Resources

ARUP Consult® Disease Topics

- Rheumatoid Arthritis - RA
- Inflammatory Bowel Disease - IBD

Ordering Recommendation

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

Mnemonic

IFX 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 infliximab 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	Infliximab Activity	Not Detected
No	Infliximab Neutralizing Antibody Titer	Not Detected

Interpretive Data

This test measures the capacity of infliximab to neutralize TNF-activity. Additionally, infliximab 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 infliximab 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 infliximab 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 Infliximab Activity is....	AND Infliximab Neutralizing Ab. Titer is....	THEN....
Not Detected	Not Detected	A higher dosage of infliximab 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 infliximab activity and/or increasing infliximab 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)

86352x2

Components

Component Test Code*	Component Chart Name	LOINC
2008321	Infliximab Activity	39803-2
2008322	Infliximab Neutralizing Antibody Titer	72623-2
2008323	EER Infliximab	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

- Anti-TNF-alpha Drug
- Human Anti-Chimeric Antibody
- IFD
- Infliximab/HACA measurement
- Remicade
- TNFa antibody