

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.