PROMETHEUS®
Therapeutics & Diagnostics
9410 Carroll Park Drive
San Diego, CA 92121
Phone: (888) 423-5227
www.prometheuslabs.com

PROMETHEUS® Anser® IFX

SAMPLE REPORT

Patient & Order Information

Order ID	**3048079**		
Patient	**Patient, Test**		
DOB	**05/05/1955**		
SSN	**XXX-XX-0000**	Sex	**F**
Institution ID	**A01294262**	Prometheus ID	**1193090**
Ordered	12/10/2014	Completed	03/11/2016
Ordered By	Ordering Physician M.D.		

Report Recipient

Example Medcenter
AAA Medical Laboratory
5678 South Main Street
Attn: Laboratory Box 17, Core Lab, Level D
San Diego, CA 92121

555/555-3456 Phone 555/555-6789 Fax

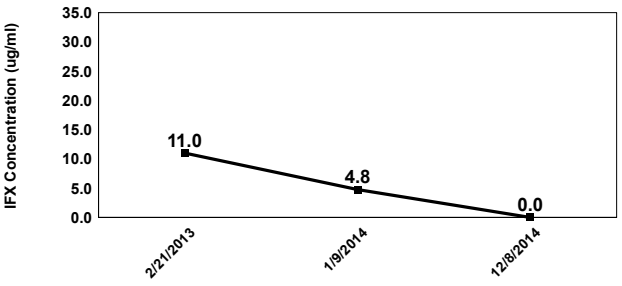
Sample ID: SQ12100423 Collection Date: 12/08/2014 (Serum) Institution Sample ID: PLI_00423

Results:

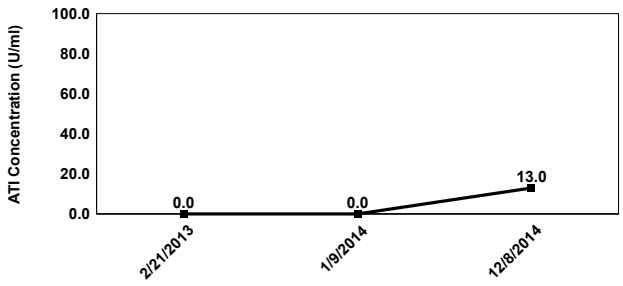
Undetectable Serum Infliximab
Detectable Antibodies to Infliximab

Assay	Result	Lower Limit of Quantification
Serum Infliximab (IFX) concentration	< 1.0 ug/ml	< 1.0 ug/ml
Antibodies to Infliximab (ATI) concentration	13.0 U/ml	< 3.1 U/ml

Serum Infliximab Concentration*



Antibodies to Infliximab Concentration*



Collection Date	IFX	ATI	Current Drug	Last Infusion	Current Dose	Current Interval
02/21/2013	11.0 ug/ml	< 3.1 U/ml	Not Provided	Not Provided	Not Provided	Not Provided
01/09/2014	4.8 ug/ml	< 3.1 U/ml	Not Provided	Not Provided	Not Provided	Not Provided
12/08/2014	< 1.0 ug/ml	13.0 U/ml	Biosimilar	12/10/2014	5 mg/kg	Every 4 weeks

*Note - Values reported as exceeding the upper limit of quantification for the assay are plotted on the chart with the limit of quantification value

- The presence of detectable antibodies to infliximab (ATI) is associated with a 34% shorter half-life and 2.7 fold increased clearance.[1]
- The presence of detectable ATI is independently associated with a shorter duration of response.[2]
- A serum infliximab concentration ≥3 ug/ml at trough is associated with a mean CRP level that is 52% less than in samples having an infliximab concentration <3 ug/ml.[3]
- Measuring both serum infliximab level and ATI concentration can provide clinically useful information to aid in the management of patients on infliximab therapy.[4]
- Anser IFX has been validated for use in patients treated with infliximab biosimilars.[5]

The test results are determined by using a size exclusion chromatography based on mobility shift assay on a High-Performance Liquid Chromatography (HPLC) system.

References:

1. Ternant D., et al., Infliximab Pharmacokinetics in Inflammatory Bowel Disease Patients. Ther Drug Monit 2008;30:523-529.
2. 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.
3. Feagan B., et al., Novel Infliximab (IFX) and Antibody-to-Infliximab (ATI) Assays are Predictive of Disease Activity in Patients with Crohn's Disease. Gastroenterology 2012; 142(5), Supplement 1, Abstract 565.
4. Afif W., et al., Clinical Utility of Measuring Infliximab and Human anti-Chimeric Antibodies Concentrations in Patients with Inflammatory Bowel Disease. Am J Gastroenterol 2010;105:1133-1139.
5. Data on file. Prometheus Laboratories Inc. DOF16-002, 02/2016.