

**SAMPLE LETTER OF MEDICAL NECESSITY**  
**FOR PROMETHEUS<sup>®</sup> Serum Infliximab/HACA Measurement**

*(Please edit appropriately based on your patient's medical history and treatment experience.)*

<DATE>

John Smith, Medical Director  
Red Cross Red Shield  
P.O. Box 12345  
Los Angeles, CA 90060

Dear Dr. Smith:

I am writing to request full coverage or at least in-network benefit coverage for the diagnostic test PROMETHEUS<sup>®</sup> Serum Infliximab/HACA Measurement for my patient, Jane Doe. I am Ms. Doe's gastroenterologist practicing at Sunnyvale Community Hospital in San Diego, CA. I consider this test a medically necessary step in the treatment of my patient.

**PATIENT INFORMATION**

Patient: Jane Doe  
ID: XXX123456789  
Provider: Ulysses Grant, MD  
Date of service: July 4, 2005

My patient is receiving Infliximab infusions.

***(List information relevant to the patient's symptoms, treatment and test results if applicable)***

**TEST DESCRIPTION**

Serum infliximab concentrations may vary among equally dosed patients. PROMETHEUS<sup>®</sup> Serum Infliximab/HACA Measurement can aid physicians in determining the dose of infliximab and guide infusion intervals. The HACA portion of the test detects Human Anti-Chimeric Antibodies (antibodies against infliximab). Patients that develop HACA may experience infusion reactions and/or a reduced duration of efficacy of infliximab.

PROMETHEUS<sup>®</sup> Serum Infliximab/HACA Measurement is offered only at Prometheus Laboratories Inc., a clinical reference laboratory in San Diego, California. Prometheus is CLIA certified and CAP accredited. All laboratory tests have been validated in accordance with the guidelines established by these and other applicable agencies. Currently, Food and Drug Administration (FDA) approval is not required for testing performed by Prometheus.

**NETWORK PROVIDER SERVICES**

I chose Prometheus to perform PROMETHEUS<sup>®</sup> Serum Infliximab/HACA Measurement instead of alternative in-network laboratory testing because of the information provided on their comprehensive report. There is no in-network laboratory in my area willing to refer the test or able to provide comparable testing.

## **LABORATORY AND PHYSICIAN INFORMATION**

For additional information about PROMETHEUS® Serum Infliximab/HACA Measurement contact Prometheus Laboratories Inc. at 1-888-423-5227. If you require additional medical information, please feel free to contact me at XXX-XXX-XXXX

## **REFERENCE MATERIALS**

- St. Clair EW et al. The relationship of serum infliximab concentrations to clinical improvement in rheumatoid arthritis. *Arthritis and Rheumatism*. 2002;46(6):1451-1459.
- Baert F et al. Influence of immunogenicity on the long-term efficacy of infliximab in Crohn's disease. *The New England Journal of Medicine*. 2003;348:601-608.

Please approve full coverage for PROMETHEUS® Serum Infliximab/HACA Measurement or at least apply in-network benefit coverage for this test.

Thank you for your prompt attention. I look forward to receiving a written response from you within two weeks.

Sincerely,

Ulysses Grant, MD  
Sunnyvale Community Hospital  
12345 Sunnyvale Road  
San Diego, CA 92121  
XXX-XXX-XXXX