SAMPLE PATIENT APPEAL LETTER FOR PROMETHEUS® TPMT Genetics

(Please edit appropriately based upon your own information and medical history)

Note to Patient: If coverage was denied by your Medical Group rather than your Insurance Carrier, this letter should be addressed to the Medical Director at the Medical Group with a copy to your Insurance Carrier.

<DATE>

Red Cross Red Shield P.O. Box 12345 Los Angeles, CA 90060

Dear Medical Appeals Reviewer:

I am writing to appeal your decision about medical coverage for the PROMETHEUS® TPMT Genetics diagnostic test that my gastroenterologist, Dr. Ulysses Grant at Sunnyvale Hospital in San Diego, CA ordered. Dr. Grant and I felt that this test was a medically necessary step in the treatment of my inflammatory bowel disease.

PATIENT INFORMATION

I am 20 years old, and because of my inflammatory bowel disease, my doctor ordered PROMETHEUS TPMT Genetics test to evaluate my genetic profile concerning my individual risk and likely response for thiopurine immunosuppressant therapy.

(List information relevant to your symptoms and treatment)

Name: Jane Doe

Date of Birth: November 12, 1985 Insurance ID: XXX123456789 Policy Holder: Mr. John Doe

Claim #: 111111

Date of service: July 4, 2005 Original Claim: \$395.00

Date of EOB: December 31, 2005 Explanation of Benefits (EOB):

- 1. Laboratory testing considered experimental
- 2. Out-of-network deductibles/rate applied
- 3. Laboratory services available through a capitated laboratory
- 4. Laboratory testing not considered medically necessary

(List information provided on the insurance EOB)

I would like to address these coverage issues hoping that you will reconsider your decision given the new information listed below.

TEST DESCRIPTION

PROMETHEUS TPMT Genetics classifies patients as one of three genotypes: homozygous normal (wild type), heterozygous or homozygous mutant. Because each patient metabolizes thiopurines differently, the efficacy and toxicity of thiopurines can vary widely from patient to patient. Knowledge of the TPMT genotype may: reduce time to response, allow physicians to individualize dosing, identify patients in whom thiopurine therapy should be avoided and help reduce the risk of leukopenia.

PROMETHEUS TPMT Genetics is performed 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

Doctor Grant and I chose Prometheus to perform PROMETHEUS[®] TPMT Genetics testing instead of alternative in-network laboratory testing because Prometheus is one of only two laboratories that can provide this test and because of the information provided on their comprehensive report.

>AND/OR<

My in-network physician ordered the testing and directed me to an in-network laboratory which does not offer PROMETHEUS TPMT Genetics testing. I have made a good-faith attempt to follow insurance guidelines and was unaware of the referral to an out-of-network provider.

LABORATORY AND PHYSICIAN INFORMATION

For additional information about the PROMETHEUS TPMT Genetics test contact Prometheus Laboratories Inc. at

1-888-423-5227. If you require additional medical information, please contact Dr. Grant at XXX-XXX-XXXX.

REFERENCE MATERIALS

- Black A, et al. Thiopurine methyltransferase genotype predicts therapy-limiting severe toxicity from azathioprine. *Annals of Internal Medicine* 1998;129(9) 716-18
- Stolk J, et al. Reduced thiopurine methyltransferase activity and development of side effects of azathioprine treatment in patients with rheumatoid arthritis.
 Arthritis and Rheumatism. 1998;41(10)1858-1866
- Colombel JF, et al. Genotypic analysis of thiopurine s-methyltransferase in patients with Crohn's disease and severe myelosuppression during azathioprine therapy. Gastroenterology. 2000:118(6):1025-30
- Seidman E, Clinical use and practical application of TPMT enzyme and 6-mercaptopurine metabolite monitoring in IBD. Gastroterol Disord. 2003;3 Suppl 1:S30-8
- Dubinsky M, et al. A Cost-Effective Analysis of Alternative Disease Management Strategies in Patients with Crohn's Disease Treated with Azathioprine or 6-Mercaptopurine. *American Jf Gastroenterol*. 2005 Oct;100(10):2239-2247

Please approve full coverage for PROMETHEUS TPMT Genetics 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,

Jane Doe 1234 Main Ave. Los Angeles, CA 90210 XXX-XXX-XXXX

cc: Dr. Ulysses Grant

cc: [YOUR STATE DEPARTMENT OF INSURANCE OR EQUIVALENT] DX06384 11/06