

**SAMPLE LETTER OF MEDICAL NECESSITY
FOR PROMETHEUS® Celiac Genetics**

(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® Celiac Genetics 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 diagnosis and treatment of my patient.

PATIENT INFORMATION

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

My patient has a history of diarrhea, GI bleeding, and bloating.
(List information relevant to the patient's symptoms, treatment and test results if applicable)

TEST DESCRIPTION

PROMETHEUS Celiac Genetics analyzes a patient's genetic profile for genes specifically associated with celiac disease. The result can predict with a greater than 95% to 100% chance that the patient does not have celiac disease. It could also show that the patient is very unlikely ever to develop the disease. Alternatively, the results may show that a patient does have genes associated with celiac disease and that they are at increased risk of developing symptoms, even if your serology (antibody) levels are low.

PROMETHEUS Celiac Genetics 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 Celiac Genetics instead of alternative in-network laboratory testing because Prometheus is the only laboratory looking for HLA-DQ2, HLA-DQ8

and the celiac-associated allele DQA1*0201 that together can exclude celiac disease with >99% certainty.

>AND/OR<

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 Celiac Genetics 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

- Fasano A. et al.: Prevalence of celiac disease in at-risk and not-at-risk groups in the United States. *Archives of Internal Medicine*. Feb. 9, 2003;163:286-292
- Kaukinen A, et al.: HLA-DQ typing in the diagnosis of celiac disease. *The American Journal of Gastroenterology*. 2002;97(3):695-699
- Green PHR, Jabri B: Coeliac disease. *The Lancet*. 2003;362(9381): 383-391

Please approve full coverage for PROMETHEUS Celiac 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,

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