

BreathTek™ UBT

Cat. # 1202

Product Description

BreathTek™ UBT is a 95% sensitive and specific, non-radioactive, Carbon¹³-labeled breath analysis. Unlike blood testing designed to detect antibodies associated with bacterial exposure, the breath test is designed to detect active *Helicobacter pylori* bacterial infection which is associated with peptic ulcer disease and stomach cancer. BreathTek™ UBT has been FDA cleared for both detection and for post-treatment monitoring of *H. pylori*.

- A ΔV analysis of C¹³ breath levels to detect the presence or verify eradication of *H. pylori*.
- Limited customer access to FDA approved test kits.
- FDA cleared to confirm cure.
- **Specimen Requirements** - Breath.
- **Shipping and Handling** - Special kit required: Follow kit instructions.
- **Storage Conditions/Stability** - 7 days ambient.
- **Turn Around Time** - 2 business days from date of receipt.
- **Reference Range:**
 - Adults: <2.4 Units
 - Pediatric: The performance characteristics of this test have not been established for persons under the age of 18. Positive criteria for 2.4 Units was established for adults. A formula from a published literature report¹ using the patient's age, sex, height, weight and C¹³ enrichment is applied to the result when applicable.

Facilities Description

- Prometheus is located in San Diego, CA. **Tax ID#** 33-0685754 **NPI#** 1073642641.
- Licensed in several states including New York and California.
- Prometheus Laboratories Inc. is CLIA certified and accredited by the College of American Pathologists. 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.

CPT Codes (as applied by Prometheus)

- **83013**, *H. pylori* breath test analysis

Literature References

- Graham KS, Graham DY. *Contemporary Diagnosis and Management of H. pylori-Associated Gastrointestinal Disease*. Newtown, PA: Handbooks in Health Care Co; 2002.
- Fox JG, Wang TC. Helicobacter pylori-not a good bug after all! *N Engl J Med*. 2001;345:829-832.
- Correa P. Is gastric carcinoma an infectious disease? *N Engl J Med*. 1991;325:1170-1171.

1. Klein PD, Malaty HM, Czinn SJ, et al, Normalizing Results of ¹³C-Urea Breath Testing for CO₂ Production Rates in Children, *J Pediatr Gastroenterol Nutr*. 1999;29:297-301