

Test Discontinuation: Helicobacter pylori (H. pylori) Serology Testing

Offering our clients state-of-the-art testing is part of CPL's ongoing commitment to excellence.

Effective December 10, 2018, Clinical Pathology Laboratories (CPL) will no longer offer *Helicobacter pylori (H. pylori)* serology testing in support of the current diagnostic guidelines for H. pylori.

The **<u>discontinued</u>** tests are as follow:

Order Code	Test Name
4565	H. pylori IgG, Qualitative
4496	H. pylori Antibody Reflex Quantitative
4611	H. pylori IgA Antibody
4672	H. pylori IgG Antibody
4607	H. pylori IgM Antibody
4449	H. pylori IgG/IgA Antibodies
4609	H. pylori IgG, IgM, IgA Quantitative

CPL recommends the following alternative assays:

Order Code	Test Name
4499	H. pylori Antigen, Stool
5591	H. pylori (Breath)
5653	H. pylori (Breath), Pediatric

To better support high quality patient care, CPL will inactivate the serology test codes for H. pylori listed above and recommend active infection assays. These changes are consistent with the current diagnostic guidelines of the American College of Gastroenterology (ACG) and the American Gastroenterology Association (AGA) that recommend either the urea breath test or the stool antigen test as preferred testing modalities for active H. pylori infection. These alternative noninvasive testing methods demonstrate higher clinical utility, sensitivity and specificity.¹

Serologic evaluation of patients to determine the presence or absence of H. pylori infection is no longer considered clinically useful. As a result, many insurance providers are no longer providing coverage to patients for serologic testing. Antibody tests cannot distinguish between active and past infection with adequate sensitivity and specificity. Despite older literature suggesting that IgG serology can be used as a test of cure after 18 months, this has shown to be inaccurate. Both the urea breath test and stool antigen test are FDA cleared for use as a test of eradication.

Please contact your CPL Account Representative should you have any questions regarding this change.

References

¹ Choosing Wisely: Fifteen Things Physicians and Patients Should Question, 2016; American Society for Clinical Pathology (ASCP).

Thank you for supporting Clinical Pathology Laboratories