Techlab gets FDA clearance for *H. pylori* tests

Aug. 22, 2018—Techlab received FDA 510(k) clearance for its H. Pylori Quik Chek and H. Pylori Chek tests. The tests aim to offer quick and reliable detection of *Helicobacter pylori*–specific antigen in human fecal specimens. The H. Pylori Quik Chek test is a rapid diagnostic test that detects *H. pylori* in 30 minutes. The H. Pylori Chek test is a 96-well plate format diagnostic for laboratories testing large numbers of specimens and can be performed with or without automation in one hour. The company says both exhibit strong performance and offer flexible transport conditions including room temperature storage of specimens and the use of C&S and Cary Blair transport media.

“Our tests were compared against histology and urease testing performed on biopsies collected during endoscopy as both an initial diagnostic and a test of cure. Both assays provide excellent clinical performance,” Joel Herbein, PhD, vice president of scientific affairs at Techlab, said in a press release.

H. pylori infection is responsible for most duodenal and gastric ulcers and is associated with a two- to threefold increased risk of gastric cancer and mucosa-associated lymphoid type lymphoma.