

Children's Helicobacter pylori breath test approved

The first breath test for use in children three to 17 years to detect Helicobacter pylori (H. pylori) bacterial infections was approved by the United States Food and Drug Administration (FDA).

Helicobacter pylori (H. pylori) bacterial infections are responsible for chronic stomach inflammation (gastritis) and ulcers. The FDA first cleared the BreathTek UBT test for adults in 1996. The US Centers for Disease Control and Prevention (CDC) estimates that approximately two-thirds of the world's population is infected with H. pylori. Most people with this infection never have any symptoms but have a two- to six-fold increased risk of developing gastric cancer and mucosal-associated-lymphoid-type lymphoma compared with uninfected people. "Results from this test, when considered with a physician's assessment of the patient's history, other risk factors, and professional guidelines, can quickly indicate infection, which allows a physician to initiate appropriate health measures in a timely manner," said Alberto Gutierrez, PhD, director of the Office of In Vitro Diagnostic Device Evaluation and Safety in FDA's Center for Devices and Radiological Health. The FDA based its approval of the BreathTek UBT test for children on a multi-centre study of 176 patients, comparing its performance to a composite reference method and demonstrating 95.8 per cent sensitivity and 99.2 per cent specificity. An additional study was done at one to six months after therapy to support use for post-treatment monitoring of patients. The sensitivity was 83.3 per cent and the specificity was 100 per cent. BreathTek UBT is manufactured by Otsuka America Pharmaceutical based in Rockville, Md. Source: US Food and Drug Administration