Microorganism and virus tested:

Adenovirus type II	Salmonella(Group B)
Campylobacter coli	Salmonella dublin
Campylobacter fetus Campylobacter jejuni	Salmonella hilversum(Group N)
Campylobacter lari	*Salmonella typhimurium*
Candida albicans	*Salmonella minnesota*
Citrobacter freundii	*Shigella boydii*
Clostridium difficile	*Shigella dysenteriae*
Clostridium perfringens	*Shigella flexneri*
Enterococcus feacalis	*Shigella sonnei*
Enterobacter cloacae	*Serratia liquefaciens*
Escherichia coli	*Staphylococcus aureus*
Escherichia fergusonii	*Staphylococcus aureus (Cowan)*
Escherichia hermanii	*Staphylococcus faecalis*
Helicobacter cinaedi	*Staphylococcus galactiae Staphylococcus epidermidis*
Helicobacter mustelae	*Yersinia enterocolitica*
Klebsiella pnumoniae	Salmonella(Group B)
Mycobacterium smegmatis	Salmonella dublin
Providencia stuartii	Salmonella hilversum(Group N)
Nocardia asteroids	*Salmonella typhimurium*
Proteus vulgaris	*Salmonella minnesota*
Pseudomonas fluorescen	*Shigella dysenteriae*
Rotavirus	*Shigella flexneri*

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Form No. 1032
Rev. April 2009

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Helicobacter Pylori Antigen Card Test

INTENDED USE

Pulse H. pylori Antigen Card Test (Pulse HP Antigen Card Test) is a qualitative immunochromatographic assay for the rapid detection of Helicobacter pylori antigens in human stool specimen. The test results are intended to aid in the diagnosis of H. pylori infection, to monitor the effectiveness of therapeutic treatment of H. pylori in peptic ulcer patients. This product is intended for Laboratory use only. This product is not intended for use in emergency rooms or point of care facilities.[1]

SUMMARY

Helicobacter pylori is a corkscrew-shaped, gram-negative rod that lives in the mucous layer of the stomach. H. pylori infection is now accepted as the most common cause of gastritis, and is etiologically involved in gastric ulcer, duodenal ulcer, gastric adenocarcinoma and primary gastric *B*-cell lymphoma.[1,2]

The organism is common and infects at least half of the world's population with infection typically acquired in childhood. The acquired infection persists chronically, probably continuing in the stomach throughout life. The damage to gastric structure and function of stomach is constant and direct. Approximately one in six of H. pylori infection develops peptic ulcer disease and a small portion of H. pylori infection leads to gastric cancer.[3]

The diagnostic tests for H. pylori can be classified into two categories: Invasive and Noninvasive tests. Direct detection by invasive test procedures requires an endoscopy and biopsy specimens from antrum and stomach body.[4] The presence of active H. pylori infection is then confirmed by direct culture, histological examination or rapid urease test. The procedure is specific with high positive predictive value. It is expensive and causes discomfort to the patients. Serology Test is the widely available noninvasive test. It detects H. pylori specific IgG antibody in patient serum with current or prior infection.[5,6] It is a simple, convenient test with relative high sensitivity; with main limitation as the inability to distinguish current and past infections. Antibody may be present in the patient's serum long after eradication of the organism.[6] The urease breath test (UBT) with ^{14}C or ^{13}C labeled urea, is a noninvasive test based on the urease activity of the organism. UBT detects active H. pylori infection and is highly sensitive and specific. The UBT requires a high density and active bacteria and should not be performed until 4 weeks after therapy to allow residual bacterial to increase to a sufficient number for detection.[7]

PRINCIPLES

Pulse HP Antigen Card Test is an immunochromatographic assay that uses antibody- coated colloidal gold to detect the presence of *H. pylori* antigens in stool specimens. The test detects directly antigens in specimens for an active infection. The test is simple and easy to perform and the test results can be visually interpreted within 15 minutes.

[1] This Statement is made to comply with Health Canada Regulation regarding the Intended Use for Class II Medical Device.

To perform the test, an aliquot of diluted stool sample is added to the sample well of the test cassette. The sample flows through a label pad containing H. pylori antibody coupled to red-colored colloidal gold. If the sample contains H. pylori antigens, the antigen will bind to the antibody coated on the colloidal gold particles to form antigen-antibody-gold complexes. These complexes move on the nitrocellulose membrane by capillary action toward the test line region on which H. pylori specific antibodies are immobilized. As the complexes reach the test line, they will bind to the antibody on the membrane in the form of a line. A second red control line will always appear in the result window to indicate that the test has been correctly performed and the test device functions properly. If H. pylori antigen is not present or lower than the detection limit of the test, only the control line will be visible. If the control line dose not developed, the test is invalid.

MATERIALS SUPPLIED

1. H. Pylori Antigen card test
   Each cassette contains a test strip with H. pylori specific antibody on the test region of the membrane and colored H. pylori antibody-gold conjugate pad.
2. Sample bottle
   Each sample bottle contains 1 ml of stool specimen collection buffer. Store at 4-30 degree C.

Materials required but not provided

1. Specimen collection container.
2. Timer or clock.

STORAGE & STABILITY

The test device and the Sample Collection Tubes (without introducing the sample) can be stored at 4-30 degree C and will be effective until the expiration date stated on the package. The product is humidity-sensitive and should be used immediately after being open. Any improperly sealed product should be discarded.

PRECAUTIONS

1. For in vitro diagnostic use in Laboratory only.
2. This product is not intended for use in emergency rooms or point of care facilities.[1]
3. Do not use the product beyond the expiration date.
4. Humidity sensitive product, do not open foil pouch until it is ready to be tested.
5. Wear protective gloves while handling kit components and test specimens.
6. Patient specimens and inactivated Positive Control may contain infectious agents and should be handled and disposed of as potential biohazards. Dispose all used materials in appropriate container.

SPECIMEN COLLECTION

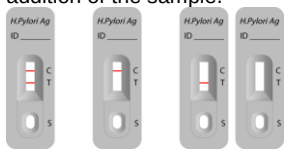
Stool specimens should be collected in containers that do not contain media, preservatives, animal serum or detergents as any of these additives may interfere with the Pulse HP Antigen Card Test.
Specimens may be stored at 2-8 degree C for 3 days without interfering with the assay performance. For long-term storage of specimens, -20 degree C or colder is recommended. Repeated freezing and thawing of specimens is not recommended and may cause erroneous results. Do not store specimens in self-defrosting freezers.
Note: Watery or diarrhea specimens are inappropriate for testing.

PROCEDURE

1. Bring all materials and specimens to room temperature.
2. Remove the test card from the sealed foil pouch.
3. Hold the sample bottle upright with the tip point towards the direction away from the test performer, snap off the tip.
4. Hold the bottle in a vertical position over the sample well of the test card, deliver 3 drops (120 -150 µL) of diluted stool sample to the sample well.
5. Read the result within 10 - 15 minutes. A strong positive sample may show result earlier.
   Test results after 15 minutes may not be accurate.

RESULTS

Positive result: A distinct pink colored band appears on test line regions, in addition to a pink line on the control line region.
Negative result: No line appears in the test line region. A distinct pink line shows on the control line region.
Invalid: The control line next to the test line does not become visible within 10 minutes after the addition of the sample.



POSITIVE NEGATIVE INVALID

QUALITY CONTROL

1. The control band is an internal reagent and procedural control. It will appear if the test has been performed correctly and the reagentsare reactive.
2. Good Laboratory Practice recommends the daily use of control materials to validate the reliability of the device. Control materials which is not provided with this test kit may be commercially available.

EXPECTED VALUES

Helicobacter pylori infects more than half the people in the world.[9] The prevalence of the infection varies among countries and among different groups within the same country.[10] The prevalence rate in the United State suggests an incidence of infection of 2%. The lifetime prevalence of peptic ulcer disease is about 12% in men and 9% in women.[11] Studies have found that more than 90% of patients with duodenal ulcer and 80% of patients with gastric ulcer are infected with H. pylori.[12,13]
Pulse HP Antigen Card Test detect the presence of H. pylori antigens in stool specimens. Expected values for any given population should be determined for each laboratory. The positivity rate of any given laboratory may vary depending on geographic location, ethnic group, and living environment.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

Pulse HP Antigen Card Test was evaluated on 170 adults. The test results were compared to diagnosis of H. pylori infection by reference tests, urease breath test and histology tests. Patients were considered positive if both rapid urease and histology tests were positive. Patients with both negative urease breath test and histology tests were considered negative. Among fifty (50) positive samples and one hundred and twenty (120) negative samples, Pulse HP Antigen Card Test showed 94.0% clinical sensitivity and 96.7% specificity. The accuracy is 97.5%.

	Reference Test		
Pulse HP Antigen Card Test		Positive	Negative
	Positive	47	4
	Negative	3	116

Sensitivity = 94.0% (47/50)
Specificity = 96.7% (116/120)
Positive Predictive Value = 92.2% (47/51)
Negative Predictive Value = 97.5% (116/119)
Accuracy = 95.9% (163/170)

Reproducibility

Reproducibility of Pulse HP Antigen Card Test was determined using negative, low positive, and high positive samples along with negative and positive controls. These samples were tested in replicates of 8 in a blind study by 5 operators working independently in the same laboratory. The agreement of the expected result was 100%.

Assay Specificity

Following bacterial and viral strains were used to test the specificity of Pulse HP Antigen Test. Positive and negative stools were spiked with $>1x10^8$ organism/ml and tested by Pulse HP Antigen Card Test H. pylori positive stool remained positive with the spiked organisms. Negative stool remained negative with the spiked organisms.