INTENDED USE
The QuikPac II OneStep H. pylori Test is an immunochromatographic assay for qualitative determination of antibodies to Helicobacter pylori (H. pylori) in human serum or plasma.

SUMMARY AND EXPLANATION OF THE TEST
Helicobacter pylori (also known as Campylobacter pylori) are gram negative bacteria infecting gastric mucosa. H. pylori infection has been shown to be associated with the causative agent of type B active chronic gastritis, gastric lesions and some cases of duodenal ulcers. Current tests for diagnosing H. pylori infection involve histological staining and/or culture of antral biopsy methods. However, these techniques are invasive, and alternative, non-invasive methods such as the urea breath test and serological test are available. Various serological methods have been employed, including the complement fixation test, the bacterial agglutination test, the passive hemagglutination test, the hemagglutination assay, immunoblotting techniques, and enzyme-linked immunosassays. All of these techniques have demonstrated a correlation between the level of reactivities and the presence of H. pylori in the gastric antrum.

QuikPac II OneStep H. pylori test is a rapid immunochromatographic assay for qualitative determination of anti-H. pylori antibodies of all isotypes (IgG, IgM, IgA, etc.). It is a presumptive test intended for use as an aid in the diagnosis of H. pylori infection.

PRINCIPLE OF THE TEST
The immunochromatographic device contains dye-conjugated and immobilized H. pylori antigens which, in the presence of the antibody, combine to produce an antibody-antigen-dye conjugate sandwich, that appears as a distinctive visual pattern in the test zone of the device. The antibody in the test sample is detected in approximately ten minutes.

In the test procedure, serum specimen is allowed to migrate through the absorbent area of the device. If the antibody against H. pylori is present, labeled antigen-dye conjugate binds to it, forming an antibody-antigen-dye complex. The presence of the antibody is visually determined as a rose-pink color band when immobilized antigen in the Test Zone ("T") captures the complex forming an antigen-antibody-antigen-dye sandwich. Proper test performance is verified in the Control Zone ("C") by the appearance of a rose-pink band, produced by a parallel immunochromatographic reaction as an immobilized reagent captures dye conjugate regardless of the antibody in the test sample.

REAGENTS AND MATERIALS PROVIDED
1. Testing Device. Contains dye-conjugated and membrane-immobilized H. pylori antigens, in a protein matrix containing sodium azide. Cat. #21020
2. Sample Transfer Pipette Cat. # PIP-003
3. Positive Control, 1.0 ml/25 tests Inactivated serum containing antibody against H. pylori and preservative, in a dropper vial. Cat. # 21020P
4. Negative Control, 1.0 ml/25 tests Buffered solution containing serum proteins and preservative, in a dropper vial. Cat. # 21020N
5. Test Buffer, 5.0 ml/25 tests Cat. # 21020TB
6. Test Instructions Cat. # PI-21020

MATERIALS REQUIRED BUT NOT PROVIDED
1. Specimen collection container.
2. Watch or timer.

STORAGE AND STABILITY
Store the test kit between 2º-8ºC; do not freeze. Refer to the expiration date for stability. The Test Device may be stored at room temperature (15º-28ºC); however the controls must be refrigerated at 2º-8ºC.

WARNINGS AND PRECAUTIONS
1. Do not pipette by mouth.
2. Do not allow smoking or eating where the specimens are being handled.
3. Wear disposable gloves while handling kit reagents or specimens. Wash hands thoroughly afterwards.

SPECIMEN COLLECTION AND PREPARATION
The QuikPac II OneStep H. Pylori Test may be performed using human serum or plasma.

To obtain a serum specimen, collect blood aseptically by venipuncture into a clean tube without anticoagulants. Permit blood to clot for twenty to thirty minutes at room temperature. Centrifuge to obtain clear serum and transfer serum into a clean plastic or glass tube. Specimens containing precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying. Alternatively, plasma specimens may be used. If the specimens are not tested immediately they should be refrigerated at 2º-8ºC. For storage periods greater than three days, freezing is recommended. If specimens are to be shipped, they should be packed in compliance with federal regulations covering the transportation of etiologic agents.

ASSAY PROCEDURE

PROCEDURE NOTES
1. Bring all samples, controls and the test components to room temperature (15º-28ºC) prior to testing.
2. Do not remove the Test Device from its foil pouch until ready to perform the test.
3. Do not use commercial controls other than those provided with the kit as they may contain additives which interfere with test performance.

TESTPROCEDURE
1. Remove a Test Device and a Sample Transfer Pipette from the foil pouch by tearing along the “notch”. Place the Test Device on a level surface.
2. Using the Sample Transfer Pipette, carefully apply one drop of the test sample directly into the sample port (marked “S”) of the Test Device.
3. Using the dropper tip of the Extraction Buffer vial, add 3 drops of Extraction Buffer to sample port of the Test Device.
4. Read the test result at ten minutes.

Important: To avoid an incorrect reading or invalid result, do not interpret test result after more than 10 minutes.

INTERPRETATION OF RESULTS

1. Positive . Two rose-pink bands appear-- one in the Control Zone ("C") and one in the Test Zone ("T"). The sample should be considered positive for the presence of antibodies to H. pylori.
2. Negative . One rose-pink band appears in the Control Zone ("C") with no apparent band in the Test Zone ("T"). The sample should be considered negative for antibodies to H. pylori.
3. Invalid . If no rose-pink band appears in the Control Zone, or if a band appears the Test Zone, but not in the Control Zone, then the test is invalid. It is recommended that the specimen be retested using a new device.

Note: There is no meaning attributed to line color intensity or width.

QUALITY CONTROL
1. Internal Controls:
   The QuikPac II OneStep H. Pylori Test contains built-in quality control features. The development of a pink-rose line in the Control Zone ("C") indicates that the sample has been absorbed into the device, that capillary flow has occurred, and that antibody reactivity is still at a high level. If the test device is working properly, the background in the results window will clear, providing a distinct line.

FOR EXPORT ONLY - Not For Sale or Distribution In The U.S.
result.

2. **External Controls:**
   Good laboratory practice recommends the use of control materials to ensure proper kit performance. Positive and negative controls are included with the test kit. Use controls in the same manner as specimens by following the test procedure. The expected results should be obtained when using controls.

### LIMITATIONS OF THE TEST

1. The test is limited to the detection of antibody against *H. pylori* in human serum or plasma.
2. The test is for in vitro diagnostic use only.
3. Although the test is very accurate, a low incidence of false results can occur.
4. If negative or questionable results are obtained, the test should be repeated on a fresh serum specimen using a new device.
5. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.
6. The test detects anti-*H. pylori* antibody as a general indication of *H. pylori* infection. It does not differentiate between different types of infections (current, ongoing, etc.).

### PERFORMANCE CHARACTERISTICS

**SPECIFICITY AND SENSITIVITY**

A study was performed with 439 patient serum and plasma samples which included both symptomatic G.I. disorders and samples from non-symptomatic patients. The Syntron OneStep Immunochromatographic Assay and a traditional enzyme immunoassay were tested on all specimens. Of these, 173 were confirmed *H. pylori* positive and 266 were confirmed *H. pylori* negative using the traditional enzyme immunoassay. Fourteen samples tested negative with the Syntron OneStep Test and positive with the enzyme immunoassay. In addition, 9 samples tested negative with the enzyme immunoassay and positive with the Syntron product. The results of this comparison evaluation are shown in the table below.

<table>
<thead>
<tr>
<th>EIA TEST</th>
<th>Positive (173)</th>
<th>Negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>QuikPac II H. Pylori Test</td>
<td>159</td>
<td>14</td>
</tr>
<tr>
<td>Negative (266)</td>
<td>9</td>
<td>257</td>
</tr>
</tbody>
</table>

Compared with a conventional enzyme immunoassay for the detection of antibodies to *H. pylori* from serum specimens, QuikPac II OneStep H. Pylori Test demonstrated a relative sensitivity of 92% (159/173) and a relative specificity of 96.6% (257/266). The fourteen positive *H. pylori* antibody results which initially tested negative with the QuikPac II Immunochromatographic Assay were retested by enzyme immunoassay; the results were equivocal. The 9 negative *H. pylori* antibody results which initially tested positive with the QuikPac II OneStep Test were retested by enzyme immunoassay; 5 samples were weak positive.

### PRECISION

A. Intra-Assay Precision was determined by assaying the 11 replicates of confirmed negative, low and high positive patient samples.

<table>
<thead>
<tr>
<th>Number of determinations</th>
<th>Negative</th>
<th>Low</th>
<th>Positive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expected Results</td>
<td>-</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Observed Results</td>
<td>-</td>
<td>+</td>
<td>+</td>
</tr>
</tbody>
</table>

B. Inter-Assay Precision was determined by assaying the 11 replicates of confirmed negative, low and high positive patient samples at 3 independent test sites with 3 separate lots of reagent. Negative specimens tested negative after 10 minutes each time with all 3 reagent sets at all 3 test sites. Low and high antibody *H. pylori* patient samples tested positive within 10 minutes each time with all 3 lots at all 3 test sites. The QuikPac II OneStep H. Pylori test demonstrates excellent reproducibility.

### CROSS-REACTIVITY

To test the cross-reactivity of the *H. Pylori* Immunochromatographic Assay, the following organisms were harvested on blood agar plates:

- *Campylobacter jejuni*
- *Campylobacter fetus*
- *Campylobacter coli*
- *Escherichia coli*

The membranes were coated with the extract of these organisms. The assays were then performed simultaneously with membrane coated with the extract of *H. pylori* (i.e. QuikPac II OneStep H. Pylori Test). Forty serum samples were used for each experiment. All forty samples tested negative with the above listed organism coated membranes. Thirty of forty serum samples tested positive by the QuikPac II OneStep H. Pylori Test, and ten of forty serum samples tested negative. These results indicate that no cross-reactivity was observed.

A second set of cross-reactivity experiments was performed using 10μg of each of the extract organisms identified above to absorb the positive patient serum samples. The patient sera were then analyzed by the QuikPac II OneStep H. Pylori Test. Only the antigens from *H. pylori* absorbed out the antibodies observed.

### BIBLIOGRAPHY