

<b>Procedure:</b> Pyloriset™ Dry
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Prepared by	Date Adopted	Supersedes Procedure #

Review Date	Revision Date	Signature

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**PRINCIPLE:**

The Pyloriset Dry Latex Reagent containing latex particles sensitized with partially purified *H. pylori* antigens, is dried on the test card as dry spots. *H. pylori* antibodies present in serum specimens will react with the sensitized latex particles, resulting in visually detectable agglutination. Sera containing antibodies reactive to *H. pylori*, and sera free of antibodies to *H. pylori*, are included in the kit as positive and negative controls respectively.

**SPECIMEN:****Type:**

Serum

**Handling Conditions:**

A normal venous blood sample should be taken and the serum separated. If serum is not immediately analyzed, the serum sample can be stored at 2-8°C for seven (7) days or at -20°C or lower temperature for several months. (Do not store in self-defrosting refrigerators).

**EQUIPMENT AND MATERIALS:****Materials:**

The Pyloriset Dry Test Kit contains material sufficient for 24 tests.

## Materials provided:

Pyloriset Dry test cards	4 packs of 2 cards
Positive Control	1 vial
Negative Control	1 vial
Dilution Buffer	1 bottle
Mixing Sticks	30 pcs
Plastic storage pouch	

Materials not provided:

Micropipette - 40 µl, 50 µl, 150 µl (see Dilution Method A)  
Micropipette - 10 µl or 30 µl (see Dilution Method B)  
Test tubes if using Dilution Method A

**Storage Requirements:**

2-8°C

**QUALITY CONTROL:**

To check the performance of the kit reagents use the provided Positive and Negative Control instead of the patient sample. The controls should be performed each day the Pyloriset Dry test is used. Follow the procedure as described in "Procedure - Stepwise".

To check the performance of the Dilution Buffer follow the procedure as described in the "Procedure - Stepwise" section replacing the diluted sample with 40 µl of Dilution buffer.

The inability of the Positive Control to yield an agglutination within three minutes, or any evidence of a nonspecific agglutination with either the Negative Control or the Dilution Buffer is regarded as evidence of reagent deterioration. Such reagents must not be used for patient samples. The controls should not be used if they are contaminated.

**PROCEDURE - STEPWISE:**

Remove the reagents from the refrigerator and allow them to reach room temperature (18-25°C) before use.

For proper performance of the test, dilute patient samples with Dilution Buffer prior to testing (Positive and Negative Control reagents are used directly in the test without dilution).

The dilution step can take place either separately in a glass or plastic test tube (Dilution Method A) or directly on the test card (Dilution Method B). Both Dilution Methods give equivalent test results.

**Dilution Method A (Dilution in a Test Tube):**

1. Dilute the serum specimen 1:4 with Dilution Buffer in a test tube (e.g. 50 µl specimen + 150 µl buffer).
2. Pipette 40 µl of diluted serum sample onto a circle of the test card next to the latex reagent. Proceed as described in "Use of dry latex cards".

**Dilution Method B (Dilution on the Test card):**

1. Using a micropipette, dispense 30 µl of Dilution Buffer next to the latex reagent onto one circle of the test card for each sample to be tested.
2. Dispense 10 µl of patient serum sample to be tested onto the Dilution Buffer drop. Mix thoroughly by pulling the solution back and forth into the pipette at least five (5) times. Proceed as described in "Use of dry latex cards".

**Use of Dry Latex Test Cards**

1. When testing either the negative or the positive kit control, dispense one drop from the respective dropper vial onto a clean circle of the test card. Note: The control reagents are already diluted and are used as dispensed.
2. Using the clean end of a mixing stick for each circle, carefully mix the samples or controls with the latex reagent on the card. Use the sample to cover the entire circle. Discard each stick after use.
3. Tilt and rotate the test card, moving the reagents in a circular motion within the circle. Observe the latex particles for evidence of agglutination occurring within three (3) minutes.

**REPORTING RESULTS:**

### Reference Ranges:

The test result is reactive, i.e. the serum sample contains detectable levels of antibodies to *H. pylori*, when agglutination is detected in the test circle within three (3) minutes. The agglutination may be complete (red granules on a white background) or partial (granules can be detected but the background remains opaque). The test result is nonreactive and the sample does not contain detectable level of antibodies to *H. pylori* when no agglutination is detected in the circle within three (3) minutes.

If controls do not behave as expected, assay results are invalid.

### PROCEDURE NOTES:

1. Do not use the reagents beyond the indicated expiration date. Microbiological contamination of reagents must be avoided as this may reduce the life of the product and cause erroneous results.
2. Allow all reagents to come to room temperature (18-25°C) before use. Return reagents to 2-8°C for storage as appropriate, immediately after use.
3. Do not mix reagents from different lots of Pyloriset Dry.
4. Do not touch the reaction areas on the cards.
5. Do not freeze the kit.
6. A sticky dry spot is evidence that the reagent has been exposed to moisture or excessive heat and should not be used.

### LIMITATIONS OF THE PROCEDURE:

1. The test results should be weighed along with the patient's clinical symptomology in determining its significance. .
2. A negative test result indicates that the patient does not have detectable levels of antibodies to *H. pylori*. This may occur when testing a patient at too early stage in the development of disease, before an immune response is mounted.
3. A positive test result does not distinguish between the presence of active or passive disease or colonization in the patient.
4. A positive test result does not necessarily indicate a gastrointestinal disorder.
5. The Pyloriset Dry test should be carried out only for patients symptomatic for gastrointestinal disorders and is not intended for use with asymptomatic patients.

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