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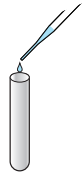
HpSA® Flex

REF 619096
IVD Rx Only

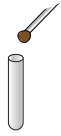
For the detection of *H. pylori* antigen in stool specimens. Please refer to current complete instructions for proper control testing and results interpretation.

TEST PROCEDURE
How to perform the test



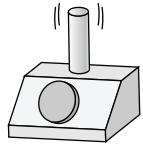
1. **Unpreserved stool specimens:** Add **500 µL** of Sample Diluent to a test tube.

   Preserved stool specimens: Add **100 µL** of Sample Diluent to a test tube.

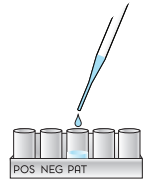


2. **Unpreserved, solid stool:** Using applicator stick, add small portion (**5 - 6 mm** diameter) of thoroughly mixed stool to tube and emulsify using the applicator stick.

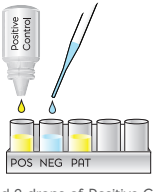
   Preserved stool or unpreserved, liquid stool: Using transfer pipette, add **100 µL** of stool to tube. Rinse pipette several times.



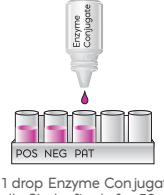
3. Vortex for 15 seconds.



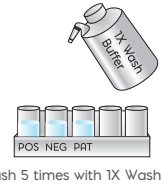
4. Using the transfer pipette, add 100 µL of diluted stool to a test well (PAT).



5. Add 2 drops of Positive Control and 100 µL of Negative Control (Sample Diluent) reagents to designated wells.

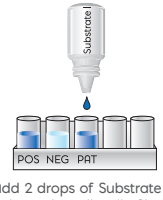


6. Add 1 drop Enzyme Conjugate to all wells. Shake firmly for 30 seconds. Seal the plate and incubate at 19-27 C for 1 hour.

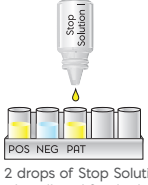


7. Wash 5 times with 1X Wash Buffer.

   *See package insert for proper wash procedure



8. Add 2 drops of Substrate Solution I to all wells. Shake firmly for 30 seconds and incubate for 10 minutes at 19-27 C.



9. Add 2 drops of Stop Solution I to each well and firmly shake for 30 seconds.

Interpretation of Results

Visual:
Negative: Colorless to Faint Yellow
Positive: Definite Yellow Color

A faint yellow color must be evaluated spectrophotometrically. If a spectrophotometer is not available, the cutoff must be determined by another method.

Spectrophotometric Single Wavelength (450 NM):
Positive Control= OD 450 ≥ 0.640
Negative Control= OD 450 < 0.140
Positive Test: OD 450 ≥ 0.140
Negative Test: OD 450 < 0.140

Spectrophotometric Dual Wavelength (450/630 NM):
Positive Control= OD 450/630 ≥ 0.600
Negative Control= OD 450/630 < 0.100
Positive Test: OD 450/630 ≥ 0.100
Negative Test: OD 450/630 < 0.100

NOTE: This chart does not contain complete instructions for use. For further information please thoroughly read the package insert.

This illustration is representative of the current and complete instructions for use at the time of publication. Please refer to the most current complete version of the assay instructions.
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