

CoproStrip *H. pylori* Positive Control **Catalog no. 41221-10**

INTENDED USE

The CoproStrip *H. pylori* Positive Control (Cat#41221-10) is an external quality control for the CoproStrip *H. pylori* kit (Cat#41221).

PRINCIPLE

The CoproStrip *H. pylori* Positive Control consists of one bottle with *H. pylori* inactivated antigen.

PRECAUTIONS

- For in vitro diagnostic use only
- Do not use after the expiration date.
- To be used with the Savyon CoproStrip *H. pylori* kit (Cat#41221) only.
- The bottle should remain closed until use.
- Follow Good Laboratory Practices, wear protective clothing, use disposal gloves, do not eat, drink or smoke in the area.
- All the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The bottle should be discarded in a proper biohazard container after testing.

STORAGE AND STABILITY

Store the CoproStrip *H. pylori* Positive Control solution bottle at a refrigerated temperature (2- 8°C). The *H. pylori* Positive Control is stable until the expiration date printed on the box label.

Do not freeze.

MATERIALS PROVIDED

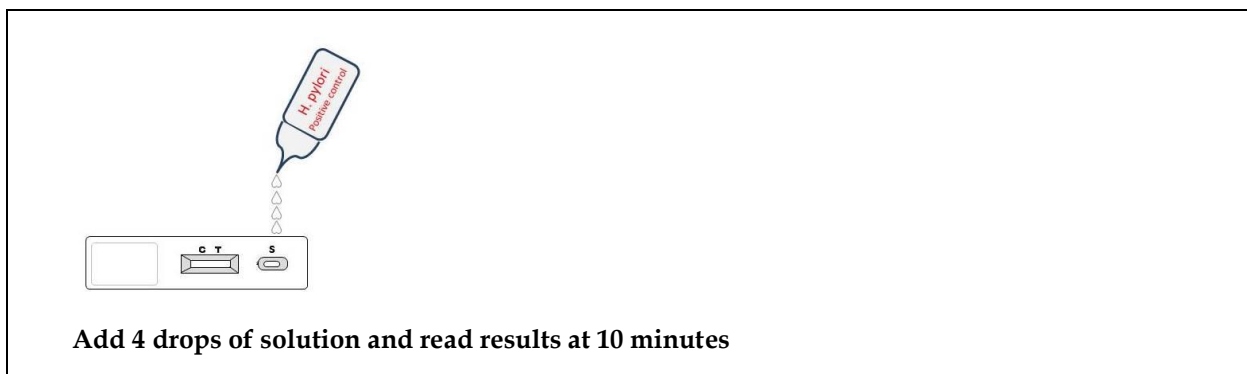
Savyon's CoproStrip *H. pylori* Positive Control contains: 3.2 mL solution of *H. pylori* antigen

PROCEDURE

Allow the positive control bottle to reach room temperature (15-30°C) prior to testing. Do not open the test pouch until ready to perform the assay.

Remove the CoproStrip *H. pylori* cassette from the pouch and place it on the work table. Shake the Positive control bottle for several seconds prior to testing. Add **4 drops** (≈160µl) of the CoproStrip *H. pylori* Positive Control solution into the testing hole (marked with S) carefully (see illustration 1). Ensure the normal flow of the liquids along the test. Read results at 10 minutes (see illustration 2).

Illustration 1



INTERPRETATION OF RESULTS

Illustration 2











POSITIVE CONTROL:

Two lines appear on the test strip. A **red** test line marked in the illustration with the letter T in the test zone and a **green** control line (marked in the illustration with the letter C in the control zone).
In case only a green line (CONTROL) appearing please contact your local distributor.

INVALID: A total absence of the green control line regardless the appearance or not of the red test line in each strip.

Note: Incorrect procedural techniques or deterioration of the reagents are the most likely reasons for control positive failure or variations. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit and contact your local distributor.

The intensity of the red /green lines can vary between different runs of the same test strip.

Symbols for IVD components and Reagents			
	Manufacturer		For <i>in vitro</i> diagnostic use only
	Authorized representative		Consult instructions for use
	Catalogue Code		Temperature limitation
	Lot Number		Use by



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