

BIOCARD™ *Helicobacter pylori* UREASE

In vitro diagnostic test for the rapid detection of urease activity
in gastric or duodenal biopsy specimens
REF 3-018-945

KIT CONTENT

- * 45 tablets packed in hermetic pouches
- * 45 test tubes
- * 45 patient labels
- * 1 instruction for use

COMPOSITION OF THE TABLET

- * urea
- * phenol red

STORAGE

Store the kit in +2 ... +25°C. Do not freeze or expose to direct sunlight. Keep in a dry place.

TEST PROCEDURE

Figure 1. Place one (1) tablet into a test tube with a pair of tweezers.

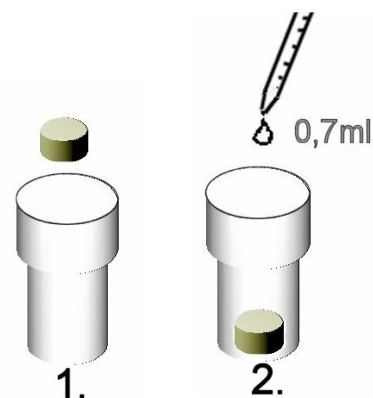


Figure 2. Add 0,7 ml of sterile distilled water.

Figure 3. Close the tube and shake well. A yellowish, slightly turbid solution is formed. The test is now ready for use. Use the solution during the same day

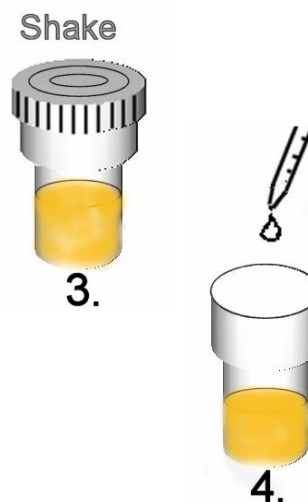


Figure 4. Apply a tissue specimen into the suspension and re-close the tube.

READING AND INTERPRETATION OF THE TEST RESULT

Figure 5. A **positive** result is indicated by colour change from yellow (can vary from bright to dark yellow) to red or red-violet. The speed of colour change depends on the density of the germs in the biopsy specimen. The colour change takes place with most patients with a *Helicobacter pylori* infection within 30 minutes.



Figure 6. A **negative** result is indicated by the absence of colour change within 24 hours of application of the specimen.



WARNINGS AND LIMITATIONS

The test is intended for the detection of urease activity in gastric or duodenal biopsy specimens only according to the instruction for use. If the instruction for use is not followed carefully, the outcome of the test may be false.

Handle all Specimens with utmost care.

Even a short contact of the test tablet with other substances, for example those found on the palms may lead to a false positive result.

If the test medium in some cases is red-violet or red before inoculation of the tissue specimen, the test is not to be used any longer.



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