

**DIAGNOSTIC SETS****25 tests****Code: SO 331**

Information for Use

**ITEST HELICOBACTER****Purpose and Usage:**

HELICOBACTER set is designed for the rapid identification of *Helicobacter pylori* in samples of gastric mucous membrane biopsy by a biochemical method.

This set enables to differentiate peptic ulcer disease etiologically bound to helicobacter infection from cases which are *Helicobacter pylori* negative and developed by other specific causes (e.g. gastrinoma, Crohn disease etc.). The evidence of peptic ulcers due to *Helicobacter* infection enables early starting of antihelicobacter therapy.

**Principle:**

*Helicobacter pylori* produces urease, which is demonstrated by the change of pH at the development of ammonia.

**Technique:**

Add 2 drops of diluent into the detection tube with dehydrated substrate. Put the tested biopsy sample into the solution after complete dissolution of the substrate. Close the tube and incubate 3-4 hours at room temperature. In some sporadic cases you may incubate the tubes till the second day.

**Evaluation:**

Positive reaction (presence of *Helicobacter pylori*) demonstrates itself by pinkish violet to violet color of the substrate after incubation.

If the reaction is negative, the color of the substrate does not change, that means it stays yellow or yellow-orange.

**Warning:**

1. Helicobacter set is delivered in pack of 25 tests and is designed for the laboratory use only.
2. Keep the set in a dark place at 2 – 8°C and use by the expiration date stated on the packagin.
3. Dispose unused IVD device and empty packaging according to Act no 185/2001 Coll., on Waste, according to following categories: 15 01 01 – paper packaging, 15 01 02 – plastic packaging, 15 01 07 – glass packaging, aluminium – 17 04 02, chemicals containing dangerous substances – 18 01 06. Dispose residue and unused IVD preparation in category 18 01 09 – other unusable pharmaceuticals. Dispose the waste,requiring special requirements for collection and removal with respect to prevention of infection, in category 18 01 03.

