

BacterLab Division



Issue date: 02/01/2025

Version: 01.2025

**THE RAPID UREASE TEST FOR**  
***HELICOBACTER PYLORI***  
**BacterTest™ LABONE HP TEST**

Using the Rapid Test for determining the presence of *H.pylori* in the gastric mucosa.

**Code: EL0125**




## 1. INTENDED USE

**BacterTest™ LABONE HP TEST** is used in medical testing to detect and screen for *H. pylori* in the stomach based on the ability of this bacteria to produce the enzyme urease and hydrolyze urea.

## 2. PRINCIPLES

**BacterTest™ LABONE HP TEST** is based on the change in pH of the culture medium when bacteria. *H.pylori* have the ability to produce urease enzyme which quickly decomposes urea into ammonium hydroxide and alkalizes the medium and is identified by pH indicator.

## 3. TYPICAL COMPOSITION

	LABONE HP TEST	EL0125	Urea	7,2 mg
			Monopotassium Phosphate	0,018 mg
			Disodium Phosphate	0,018 mg
			Phenol red	3,0 µg
			Nước cất	0,3 mL

## 4. PREPARATION

- BacterTest™ LABONE HP TEST

## 5. INSTRUCTIONS FOR USE

- Before using, the LABONE HP TEST tubes should be removed from the refrigerator and allowed to stabilize at room temperature for 7-10 minutes.
- + Step 01: Use a pen to write the sample name on the tube, then open the BacterTest™ LABONE HP TEST tube cap
- + Step 02: Use forceps to pick up the sample and put it into the tube
- + Step 03: Tighten the cap to keep the tube at room temperature.
- + Step 04: Read the results within 30 minutes by observing the color change of the tube

## 6. RESULTS

- Observe the color change of the environment:
  - + Pink = Positive (bacteria capable of producing urease)
  - + No change color = Negative (bacteria that are unable to produce urease).

## 7. QUALITY CONTROL

**BacterLab** ensures the quality of each product batch by checking the positive time with urease solution according to concentration:

QUALITY INDICATORS	STANDARD	RESULT
100 UI/mL	5 – 20 seconds	passed
20 UI/mL	30 seconds – 2 minutes	passed
4 UI/mL	5 – 20 minutes	passed

## 8. STORAGE AND TRANSPORT CONDITIONS

- Storage: 2 – 8°C.
- Transportation: Ambient temperature.

## 9. PACKAGING

- Packaging: 50 tubes/ box or as per customer request.

## 10. SHELF LIFE

- Expiration Date: 12 months from the manufacturing date.

## 11. BIBLIOGRAPHY