Helicobacter Test

Article Number：C0311

■ INTENDED USE：

The Helicobacter Test is intended to detect the Helicobacter pylori urease activity in biopsy specimens.

■ SUMMARY & PRINCIPLE OF THE TEST

The Helicobacter Test is an in vitro diagnostic test for detecting Helicobacter pylori in gastric mucosal biopsies. Helicobacter pylori is a spiral shaped Gram-negative bacterium that colonizes the human stomach. Infection with H. pylori causes chronic inflammation and significantly increases the risk of developing duodenal and gastric ulcer disease and gastric cancer. Infection with H. pylori is the strongest known risk factor for gastric cancer. H. pylori produces large amount of urease. If H. pylori is present in the biopsy specimens, urea would be converted to ammonia and carbon dioxide by the action of urease. The ammonia would cause pH changes which would be detected by a pH indicator present in the gel.

The Helicobacter Test is a cartridge with a single well prefilled with a selective agar gel containing urea, pH indicator, buffer and a bacteriostatic reagent preventing the growth of contaminating organisms.

$$CO(NH_2)_2 + H^+ + 2H_2O \xrightarrow{\text{Urease}} 2NH_4^+ + HCO_3^-$$

(pH)

■ MATERIALS SUPPLIED

The Helicobacter Test kit consists of 50 individual test cartridges and a package insert.

■ STORAGE

Store at 2~8℃ ,DO NOT FREEZE!

The Helicobacter test is stable at 2~8℃ until the expiration date (indicated on the package label) and at 25℃ for 2 months.

■ SPECIMEN COLLECTION & PREPARATION

1. Wear disposable gloves when handling specimens and wash hands thoroughly afterwards. Collect specimens with biopsy forceps.
2. The usual area to biopsy is the sump of the antrum, along the greater curve.
3. The specimen size would be approximately 1-3mm. If the specimen appears to be very small, it may be worthwhile taking a second specimen.
4. Don't use the test after the expiration date.

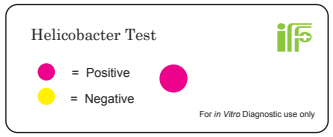
■ PROCEDURE

1. Check if the gel is present in the well and its color is yellow.
2. The Helicobacter Test should be allowed to equilibrate to room temperature before using.
3. Peel back the label sticker from the plastic slide until you could see the yellow gel. DO NOT remove the label.
4. With a sterile needle, take the biopsy specimen from the biopsy forceps and push it into the gel.
5. Reseal the label sticker on the plastic slide by pressing so that the gel is covered.
6. Record the patient name, date and time on the label.
7. Incubate the plastic slide at 37℃ for 2 hours for rapid results. Alternatively, incubate the test at room temperature for reading during 24 hours.
8. DO NOT read the results after 24 hours.

■ INTERPRETATION OF RESULTS

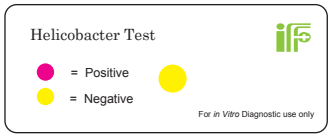
1. Positive Results

If H. pylori is present in the biopsy specimen, the yellow gel would be changed to the red or violet gel after incubation. The color change from yellow to red/violet indicates a positive result.



2. Negative Results

If H. pylori is absent in the biopsy specimen, the gel would remain yellow after incubation and keep yellow up to 24 hours at room temperature. This constitutes a negative result.



■ LIMITATION OF THE TEST

False Negative

The following conditions may lead to false negative results:

1. If patient has recently taken antibiotics, bismuth salts, proton pump inhibitors, or sucralfate which could inhibit the organism.
2. Very low numbers of H. pylori in the biopsy specimen.
3. Patchy H. pylori distribution so that the organism is not captured in the biopsy specimen.

False positive

The following conditions may lead to false positive results:

1. Patients with achlorhydria or pernicious anemia, previous gastric surgery or who recently has taken medicines (antacid, H2 receptor antagonist) may yield false positive results.
2. When acid is absent, commensal organisms such as Proteus spp., may grow in the stomach and produce urease. False positive results due to bacteria others than H. pylori would not react before two hours becuse they may produce urease much less than H. pylori.
3. If the specimen contains blood, it is usually seen as red edge around the specimen. This is not a positive result.

⚠ WARNING / NOTES

1. **All reagents of this kit are strictly intended for in vitro diagnostic and professional use only.**
2. **The test is a qualitative test to detect H. pylori in biopsy specimens.**
3. **The test should be stored at 2~8℃.**
4. **Wear disposable gloves when handling specimens and wash hands thoroughly afterwards.**
5. **Do not eat, drink, smoke or apply makeup in areas where specimens or kit reagents are handled.**
6. **If the gel becomes pink BEFORE the specimen is added, the test should not be used.**
7. **DO NOT read the results after 24 hours when the specimen is added to the gel.**
8. **Disposal of medical wastes must be in accordance with all applicable federal, state, and local regulations.**

■ REFERENCES

1. M. Castro Fernández Diagnosis of Helicobacter pylori infection using urease rapid test in patients with bleeding duodenal ulcer: influence of endoscopic signs and simultaneous corporal and antral biopsies. REV ESP ENFERM DIG 2004; 96(9): 599-605.
2. Lydia E. Wroblewski. Helicobacter pylori and Gastric Cancer: factors that modulate disease risk. CLINICAL MICROBIOLOGY REVIEWS. 2010;(4):713–739.

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螢芳 幽門曲狀桿菌尿素酶測試組

產品編號：C0311　　**衛署醫器製壹字第003440號**

■ 效能：
檢測胃組織檢體是否含有幽門曲狀桿菌所分泌的尿素分解酶。

■ 說明
本試劑用來檢測消化道黏膜的組織中是否含有幽門曲狀桿菌。幽門曲狀桿菌為存在人體胃內的曲狀革蘭氏陰性細菌。若感染可能會造成慢性胃部發炎和增加十二指腸、胃潰瘍及胃癌的風險，且幽門曲狀桿菌感染已被證實是引發胃癌的主因之一。其可以產生大量的尿素分解酶，若檢體含有此酵素則會將尿素分解，其分解物氨($NH4^+$)將會改變試劑中指示劑的顏色。
本試劑由尿素、指示劑和緩衝液所組成。

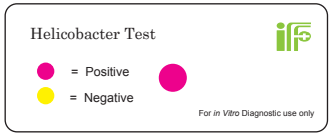
$$CO(NH_2)_2 + H^+ + 2H_2O \xrightarrow{\text{Urease}} 2NH_4^+ + HCO_3^-$$
(pH)

■ 保存條件
需保存在2～8℃，請勿冷凍!
本試劑可穩定保存在2～8℃直到保存期限(如包裝標示)，
如在25℃可存放2個月。

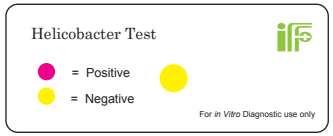
■ 檢體收集與準備
1. 檢體收集與準備時須戴上拋棄式手套。
2. 建議由胃組織的病灶部位採集1-3mm大小之檢體為佳。
3. 若試劑已超過保存期限，請勿使用。

■ 操作流程
1. 檢查試劑在未使用前是黃色且無破損。
2. 使用前請將試劑回溫至室溫。
3. 撕開貼紙直到可以看見黃色的培養基且勿將貼紙與塑膠盤分開。
4. 將檢體放入培養基中。
5. 重新貼回貼紙並將培養基蓋住。
6. 將病人資訊及操作時間記錄在標籤上。
7. 在37℃反應2小時做快速判讀；也可放置在室溫反應，24小時內判讀。
8. 請勿超過24小時後才判讀結果。

■ 結果判讀
1. 陽性結果
若檢體含幽門曲狀桿菌，培養基將會呈紅色或紫色。



2. 陰性結果
若檢體不含幽門曲狀桿菌，培養基仍會呈黃色。



■ 結果干擾
1. 偽陰性
(1) 病人服用抗生素或鉍鹽將會降低其靈敏度。
(2) 若菌落數過少，或採檢的位置未有幽門曲狀桿菌，都會造成偽陰性，建議可從胃竇及其黏膜各採樣一次。

2. 偽陽性
(1) 以下情形可能造成偽陽性，如胃酸缺乏症、貧血、胃部手術、服用制酸劑或氫離子接受位阻斷劑。
(2) 當胃酸缺乏時，在胃部常見的桿菌屬如Proteus spp.等，其也會產生尿素分解酶導致偽陽性。
(3) 如檢體中有含有血液，將可能使試劑變色，干擾判讀，但並非為陽性反應。

⚠ 注意事項
1. **本試驗為體外診斷試劑，限由醫師或醫檢師使用。**
2. **本試驗僅為定性分析。**
3. **試劑應保存在攝氏2-8℃。**
4. **操作時應戴上拋棄式手套，操作結束後應清洗雙手。**
5. **不可用口碰觸及吞食本試劑。**
6. **請勿在處理檢體時飲食、吸煙或化妝。**
7. **如試劑未使用前變色(非呈黃色)時，請勿使用。**
8. **請勿超過24小時後才判讀結果，延遲判讀可能會導致偽陽性。**

■ 參考資料

1. M. Castro Fernández. Diagnosis of Helicobacter pylori infection using urease rapid test in patients with bleeding duodenal ulcer: influence of endoscopic signs and simultaneous corporal and antral biopsies. REV ESP ENFERM DIG 2004; 96(9): 599-605.
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