



“瑩芳”幽門曲狀桿菌尿素酶快速檢測試紙(未滅菌)



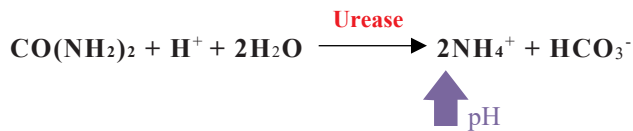
衛部醫器製壹字第 009848 號

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。

一、原理

本試紙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⁺)將會改變試紙中指示劑的顏色。



二、型號規格

型號	C0914	C0911	C0926
包裝規格	幽門曲狀桿菌尿素酶快速檢測試紙		
	35 T	50 T	70 T

三、保存條件

本試紙可穩定保存在 2~30°C 直到保存期限(如包裝標示)。

四、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. 若試紙已超過保存期限，請勿使用。

五、操作流程

1. 檢查試紙在未使用前是黃色無破損。
2. 使用前請將試紙回溫至室溫。
3. 撕開貼紙直到可以看見黃色的反應區且勿將貼紙與塑膠盤分開。
4. 將檢體放入試紙上，並確實讓組織與試紙接觸。
5. 將貼紙重新貼回，以手指按壓試紙上的壓扣，並將檢體內之組織液擠出。
6. 將病人資訊及操作時間記錄在標籤上。
7. 放置在室溫反應，於 1 小時內判讀。
8. 請勿超過 2 小時後才判讀結果。

六、結果判讀

- 陽性結果 (+)
若檢體含幽門曲狀桿菌，反應區之試紙顏色將會呈紅色或紫色。
- 陰性結果 (-)
若檢體不含幽門曲狀桿菌，反應區之試紙顏色仍會呈黃色。

七、限制

1. 偽陰性
 - (1) 病人服用抗生素或鋁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) 以下情況可能造成偽陽性：患有胃酸缺乏症或惡性貧血、近期接受胃部手術，或短期內服用制酸劑或氫離子受體阻斷劑。
 - (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) 如檢體中含有血液，將可能使試紙變色，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，限由醫檢師或醫師使用。
2. 本試驗僅為定性分析。
3. 試紙應保存在攝氏 2-30°C。
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紙。
6. 如試紙未使用前變色(非呈黃色)時，請勿使用。
7. 請勿超過 2 小時後才判讀結果，延遲判讀可能會導致偽陽性。
8. 在大多數情況下，陽性反應會在 5 到 30 分鐘內呈現，所有的陽性結果會在 1 小時反應完成。

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.
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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"IF" Rapid Helicobacter Disc Test (Non-Sterile)

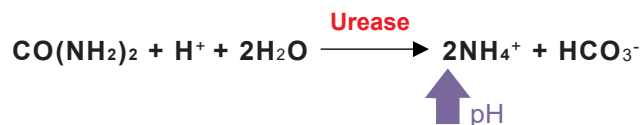


Intended Use:

The "IF" Rapid Helicobacter Disc Test (RHD Test) is intended to detect the Helicobacter pylori urease activity in biopsy specimens.

1. Summary & Principle of The Test

The "IF" RHD 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 associated with 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 RHD Test.



2. Specification

Product number	C0914	C0911	C0926
specification	Rapid Helicobacter Disc Test		
	35 T	50T	70 T

3. Storage

Store at 2 to 30°C, DO NOT FREEZE!

The RHD Test is stable at 2 to 30°C until the expiration date (indicated on the package label).

4. 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 should be approximately 1-3mm. If the specimen appears to be very small, a second specimen is highly recommended.
4. Do not use the test after the expiration date.

5. Procedure

1. Check if the test disc is intact in the well and its color is yellow.
2. The RHD Test should be allowed to equilibrate to room temperature before use.
3. Peel back the label sticker from the plastic slide until you could see the yellow test disc in the well. Do NOT remove the plastic disc from the sticker.
4. Put the specimen into the well and make sure that the specimen and the test disc are fully contact.
5. Reseal the label sticker and press the plastic disc to squeeze out the tissue fluid of the specimen.
6. Record the patient name, date and time on the label.
7. Interpret the result after 1 hour of incubation at room temperature.
8. DO NOT read the results after 2 hours.

6. Interpretation of Results

1. Positive Results

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

2. Negative Results

If H. pylori is absent in the biopsy specimen, the test disc would remain yellow after incubation and keep yellow up to 2 hours at room temperature. This indicates a negative result.

7. 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 number of H. pylori organism 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 other than H. pylori may produce urease. But the amount of urease produced by these bacteria are much lower than H. pylori and will not cause a yellow to red/violet color change within two hours.
3. If the specimen contains blood, it is usually seem as red edge around the specimen. This is not a positive result.

⚠ Precautions / Notes

1. All tests 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 to 30°C.
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 tests are handled.
6. If the test disc becomes pink BEFORE the specimen is added, the test should not be used.
7. DO NOT read the results more than 2 hours after the specimen was added to the test disc.
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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