

if “瑩芳”幽門曲狀桿菌尿素酶快速測試組



產品型號：C0811

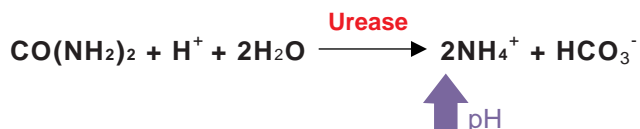
衛部醫器製壹字第 007818 號

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。



二、保存條件

需保存在 2~8°C，請勿冷凍！

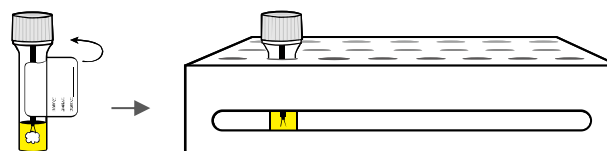
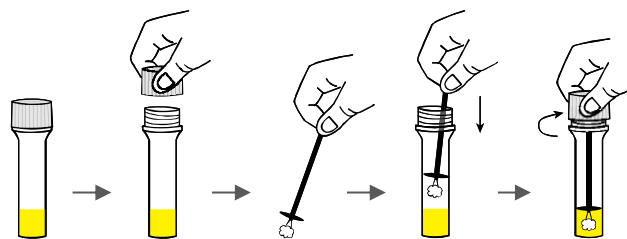
本試劑可穩定保存在 2~8°C 直到保存期限(如包裝標示)。

三、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。

四、操作流程

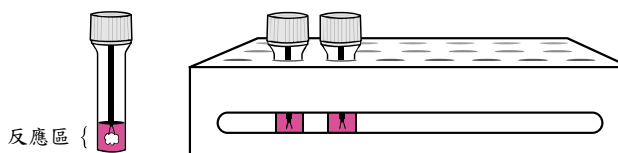
1. 檢查試劑在未使用前是黃色無破損，且試劑溶液之液面高度需高於反應區。
2. 使用前請將試劑回溫至室溫。
3. 打開上蓋，利用試劑盒內附的檢體採集棒將適當大小的組織放入試管內，如右圖。
4. 旋緊蓋子，特殊設計的採集棒會將多餘的試劑排出反應區，如右圖。
5. 將病人資訊及操作時間記錄於標籤上並黏貼於試管，注意黏貼位置需避開反應區，如右圖。
6. 將標示好的檢體置於試劑盒內所附的試管架上，如右圖。
7. 在室溫下反應 1 小時透過試管架上的判讀視窗進行判讀。
8. 請勿超過 24 小時後才判讀結果。



五、結果判讀

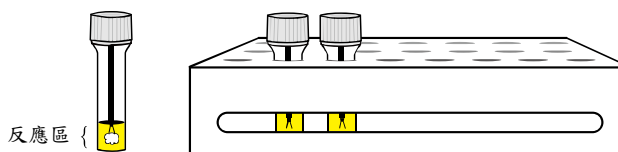
■ 陽性結果 (+)

若檢體含幽門曲狀桿菌，反應區之試劑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，反應區之試劑顏色仍會呈黃色。



六、結果判讀

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) 如檢體中含有含有血液，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，限由醫檢師或醫師使用。
2. 本試驗僅為定性分析。
3. 試劑應保存在攝氏 2-8°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。
9. 採檢棒前端較尖銳，須小心使用避免扎傷。

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.

■ 版次：第二版

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"IF" Rapid Helicobacter Test



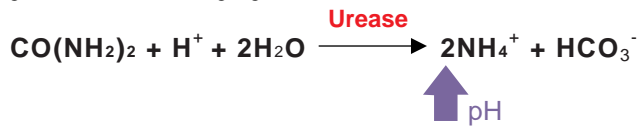
Article number: C0811

Intended Use:

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

1. Summary & Principle of The Test

The IF Rapid 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 will cause pH changes which is detected by a pH indicator present in the reagent. The IF Rapid Helicobacter Test is a liquid reagent containing urea, pH indicator, buffer and a bacteriostatic reagent preventing the growth of contaminating organisms in the tube.



2. Materials Supplied

The IF Rapid Helicobacter Test kit includes of 50 individual test tubes and 50 fork-like sample collectors.

3. Storage

Store at 2 to 8°C ,DO NOT FREEZE!

The IF Rapid Helicobacter test is stable at 2 to 8°C until the expiration date (indicated on the package label).

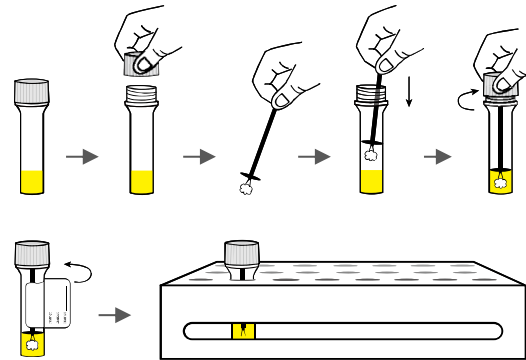
4. Specimen Collection & Preparation

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

5. Procedure

1. Make sure that the reagent slightly exceeds the reaction area and that its color is yellow.
2. The IF Rapid Helicobacter Test should be allowed to equilibrate to room temperature before using.
3. Use sample collector to collect appropriate size of tissue and put it into the test tube.
4. Screw the cap tightly, the specially designed collector will center the specimen in the reagent and also push out any excess liquid.

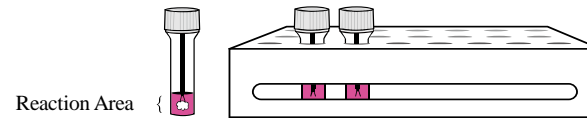
5. Record the patient name, date and time on the sticker. Put the sticker on the tube while avoiding to cover the reagent zone.
6. Put the labeled sample tube on the rack which is provided in the reagent kit.
7. Interpret the result after 1 hour of incubation at room temperature. For easier reading check the results through the window of the rack.



6. Interpretation of Results

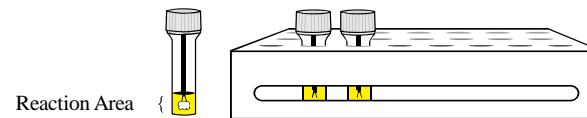
1. Positive Results

If H. pylori is present in the biopsy specimen, the yellow reagent would be changed to red or violet color 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 reagent would remain yellow after incubation and keep yellow up to 24 hours at room temperature. This constitutes 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 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 because 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.

⚠ Precautions / 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 to 8°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 kit reagents are handled.
6. If the reagent becomes pink BEFORE the specimen is added, the test should not be used.
7. DO NOT read the results more than 24 hours after the specimen was added to the reagent.
8. Disposal of medical wastes must be in accordance with all applicable federal, state, and local regulations.
9. In the most cases, positive results will already be seen at 5 and 30 minutes. All positive results are shown at 1 hour.

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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