Vstrip®

飛確幽門桿菌抗原快速檢驗試劑 (未滅菌)
體外診斷使用

REF IG06020C 20 TEST KIT 15°C~30°C IVD Rx Only CE

體外診斷使用 2019/07 V07
飛確幽門桿菌抗原快速檢驗試劑
衛部醫器製壹字第 006503 號

飛確幽門桿菌抗原快速檢驗試劑是一種免疫層析法，可快速偵測糞便檢體中幽門桿菌抗原的存在。

用途
飛確 幽門桿菌抗原快速檢驗試劑為單次使用的定性體外診斷產品，透過免疫層析法偵測人類糞便中的幽門桿菌抗原，旨在輔助幽門桿菌感染的診斷及治療。本產品應配合患者病史與臨床症狀進行綜合評估。

總論
幽門桿菌為螺旋狀的革蘭氏陰性菌，是最常發現於人類之傳染性微生物，感染至少全球一半的人口。[1] 幽門桿菌感染為導致消化不良疾病、消化性潰瘍 (胃潰瘍、十二指腸潰瘍) 、胃癌和黏膜相關淋巴組織淋巴瘤的重要病因。[2-4]
幽門桿菌的診斷測試可分為侵入式和非侵入式。[5-7] 侵入性診斷需要使用內視鏡，及快速尿素酶試驗、組織檢查或培養確認幽門桿菌的存在。尿素酶呼氣試驗 (UBT) 及糞便抗原檢驗 (SAT) 可以鑑定幽門桿菌活性表現，為臨床建議使用之非侵入性測試。血清學檢測是另一種非侵入性測試，但由於無法區分現行和過往感染，故不適用於治療效果的評估。[8]
幽門桿菌糞便抗原檢驗旨用於幽門桿菌感染的診斷。

檢驗原理
飛確幽門桿菌抗原快速檢驗試劑是一種快速免疫層析法，利用一組幽門桿菌特異單株抗體去檢測糞便檢體，當幽門桿菌抗原存在時呈現出粉紅至紅色線。測試時，將檢體處理管中已備妥的稀釋糞便檢體加入測試匣。若樣品中存在幽門桿菌，在長方形 " 結果窗 " T 字體旁的測試線將呈現一條肉眼可見的粉紅至紅色測試線，並且在 C 字體旁另一條藍色控制線亦同時呈現。當幽門桿菌抗原不存在或存在非常低的水平時，只會出現藍色控制線。任何時刻只要藍色控制線未能在 10 分鐘內顯現，則測試結果是無效的。

提供的材料
所有提供之材料應儲存及操作於 15-30℃。
1. 測試匣 (20 匣) ─ 每一個測試匣嵌有一張含幽門桿菌特異單株抗體之試紙條，並單獨包裝於鋁箔袋中。
2. 檢體處理管 (20 管) ─ 檢體處理管管蓋上附有採檢棒用於糞便取樣，管內的 檢體稀釋液含 0.09% 疊氮化鈉 (sodium azide) 做為防腐劑。
3. 陽性控制試劑 (1 瓶) ─ 陽性控制試劑的主要組成為去活性幽門桿菌。
4. 飛確幽門桿菌抗原快速檢驗試劑說明書

未提供的材料
1. 樣本收集容器
2. 計時器
3. 手套

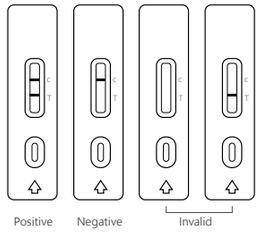
注意事項
測試前請詳閱使用說明書並確實遵循說明指示以取得正確結果。
1. 患者檢體及使用過之檢驗試劑材料應視同潛在傳染性物質，在收集、處理、貯存及處置時採取適當的預防措施。[9]
2. 不足或不當的檢體採集、儲存和運輸可能產生偽陽性或偽陰性的測試結果。[9]
3. 測試前應徹底混合均勻檢體稀釋液與糞便樣品。
4. 檢查每一檢驗試劑組合材料的效期，請勿使用過期的試劑材料。
5. 不要使用混濁的檢體稀釋液或陽性控制試劑。它們可能被微生物汙染。
6. 避免接觸含疊氮化鈉 (sodium azide) 之檢體稀釋液，可能對皮膚具有刺激性。
7. 未進行測試前，請勿撕開測試匣鋁袋。
8. 使用前確認測試匣鋁袋包裝完整，鋁袋包裝若有損壞請勿使用。
9. 只使用同組盒的材料進行檢測，請勿交換使用試劑組件。
10. 請勿重複使用本試劑或其他配件。
11. 超過 30 分鐘判讀時間之測試結果不予採用。
12. 如果對樣本採集和處理程序並不清楚時，請尋求相關的訓練或指導。
13. 操作樣本或試劑組件時，請勿吸煙或飲食。

檢體收集和準備
注意：本產品僅適用於固態與半固態的糞便檢體。
適當的檢體收集、儲存及運送是決定檢驗性能的重要因素。糞便檢體必須收集於不含培養液、防腐劑、動物血清、或清潔劑的乾淨容器中，因為任何這些附加物都會影響結果。檢體應該盡早測試，不要將檢體長時間放置於室溫。檢體可短暫儲存於 2-8℃ 七日；長期儲存則建議在 -20℃或更低的溫度且不超過 20 天。建議重複冰凍或解凍檢體最多三次。

實驗步驟
所有測試檢體及實驗流程必須在室溫下、平坦表面上操作。
1. 檢查每個組件材料包裝或外包裝盒上之有效日期。請勿使用任何過期的檢驗試劑材料。
2. 標示檢體相關訊息於藍色檢體處理管上。
3. 打開檢體處理管瓶蓋，將附於蓋上之採檢棒插入糞便檢體以取得少量糞便 (約 30-50mg 或 3-5mm)。避免取量過多，以免造成無效結果或帶狀棕色線的出現。 不要採樣乾涸之糞便。
4. 將採檢棒放回管中，旋緊瓶蓋。反轉、搖動或震盪檢體處理管至少 1 分鐘，使稀釋液與糞便檢體徹底混合均勻。
5. 將測試匣從鋁箔袋中取出放置於平坦表面上。
6. 在測試匣上標示檢體資料識別資訊。
7. 折斷或切下藍色檢體處理管蓋之最頂端部位，並滴 3 滴糞便稀釋液至測試匣箭頭上方的圓形 " 檢體窗 "。過程中避免將檢體處理管頂端處碰觸到測試匣。
8. 於 10 分鐘時判讀結果。

結果判讀
陽性結果 (Positive)：
在長方形 " 結果窗 " T 字體處的測試線出現粉紅至紅色線，且 C 字體處的控制線出現藍色線。陽性結果表示幽門桿菌抗原的存在。
陰性結果 (Negative)：
在長方型 " 結果窗 " T 字體處的測試線沒有顯現粉紅至紅色線，但 C 字體處的控制線出現明顯的藍色線 。陰性結果表示幽門桿菌抗原不存在或低於偵測極限。
無效結果 (Invalid)：
無論在長方型 " 結果窗 " 之測試線是否呈現粉紅至紅色線，當 C 字體處之控制線 未出現藍色線，仍視為無效結果。試劑變質可能導致無效結果，但多數造成無效結果的主因為過量的糞便檢體及不正確的操作。出現無效結果時應確實審查操作過程，並重複測試同檢體。若再次失敗則測試新的檢體。當問題仍然存在，請停止使用此檢測試劑，並聯繫當地經銷商。

品質控管
本試劑使用內部控管及陽性 / 陰性控制組作為品質控管機制。
內部控管：
1. 在 " 結果窗 " 顯現一條明顯的藍色控制線是為內部控管，用以確保正確的操作程序及試劑有效性。
2. 乾淨的背景是為內部陰性控管。背景顏色應該為白色，且不可干擾結果的判讀。若背景顏色影響判讀，應再次測試。



陽性 / 陰性控制組：
收到試劑組時應進行陽性和陰性控制組試劑的測試，陽性和陰性控制組是用以 監測試劑組是否可正常測出預期結果。陽性控制組測試結果應在 " 結果窗 " T 字體處及 C 字體處各自出現鮮明的紅色線及藍色線。陰性控制組測試結果應在 " 結果窗 " T 字體處出現鮮明的藍色線。當控制組無法提供正確的測試結果時， 請勿使用該組試劑。

品質控管測試程序
陽性控制組：
1. 從鋁箔袋中取出測試匣，放置於平坦表面上。
2. 滴 3 滴陽性控制試劑至測試匣之圓形 " 檢體窗 "。避免將陽性控制試劑的管頂端處碰觸到測試匣。
3. 於 10 分鐘時判讀結果。

陰性控制組：
1. 從鋁箔袋中取出測試匣，放置於平坦表面上。
2. 取出檢體處理管並折斷或切下藍色檢體處理管蓋之最頂端部位。
3. 滴 3 滴稀釋液至測試匣箭頭上方的圓形 " 檢體窗 "。過程中避免將檢體處理管頂端處碰觸到測試匣。
4. 於 10 分鐘時判讀結果。

期望值
全球至少一半的人口感染幽門桿菌，是世界上最廣泛的感染。實際感染率因區域和年齡而異。多數幽門桿菌感染者不會出現臨床症狀，但約有 10-20%的慢性胃炎患者會引發胃潰瘍和十二指腸潰瘍，1%導致額外胃併發症。[10] 世界衛生組織建議所有國家考慮篩查幽門桿菌以預防胃癌。[11]

產品限制
1. 如果檢體中抗原的濃度低於試劑的檢測極限，可能會出現陰性的測試結果。測試結果必須結合其他醫師的臨床數據進行評估。
2. 採樣不當或不足或不當檢體處理可能會造成偽陰性。
3. 檢體為含少量或沒有固體的腹瀉性水便可能會造成偽陰性。
4. 陰性檢測結果不能完全排除感染的可能性，本試劑無法保證偵測所有幽門桿菌菌株。
5. 糞便檢體取量過多可能造成無效結果或帶狀棕色線的出現。
6. 檢體若出現高濃度干擾物質或本試劑未測試過之干擾物質，可能影響測試結果。
7. 除了下表所列出的微生物之外，其他微生物尚未評估交叉反應。
8. 陽性檢測結果不排除合併感染其他病原體或病毒之可能性。
9. 陽性檢測結果僅表示檢體含有幽門桿菌抗原存在，並不代表罹患腸胃道疾病。
10. 抗生素，氫離子幫浦阻斷劑 (PPI) 與鉍化合物為已知會抑制幽門桿菌的藥物。在藥物治療的 14 天內收集檢體，可能導致偽陰性結果；正確的收集方式應於藥物治療前或是停止藥物治療 14 天後收集糞便檢體。

產品效能
飛確 幽門桿菌抗原快速檢驗試劑與美國 FDA 許可上市產品 (ELISA) 比較結果，此上市產品已被證實靈敏度與專一性皆大於 95%，信賴區間 (95%CI) 大於 89%。

		市售競品	
		+	-
飛確	+	58	5
	-	2	268

靈敏度 : 96.67% (58/60= 96.67%)
(95% Two-Sided CI: 88.6-99.1%)
專一性 : 98.17% (268/273= 98.17%)
(95% Two-Sided CI: 95.8-99.2%)

再現性
透過 5 組冷凍糞便檢體 (每組共 12 個檢體，分別含有中度陽性，低度陽性，高度陰性和陰性四種濃度隨機組合)，由不同地點的測試人員在 5 天內完成 5 組檢體測試。試驗結果，在中度陽性檢體為 97.8% (88/90)，低度陽性檢體為 97.8% (88/90)，高度陰性檢體為 98.9% (89/90)，陰性檢體為 100% (90/90)。結果說明本試劑可由不同操作人員不同地點輕鬆重現。

分析靈敏度 (偵測極限)
幽門桿菌菌株 (ATCC 43504) 偵測極限為 8.5 X10^5 CFU/ mL 於糞便。

交叉反應
本實驗交叉反應所用之微生物 (濃度 : 細菌 ≥1x10^7 CFU/mL; 病毒 ≥1x10^5 $TCID_{50}$/mL) 如下表，測試結果在糞便檢體中均無陽性反應。

病毒
Adenovirus type 7, Adenovirus type 41*, Coxsackie type B2, Coxsackie type B6, Echovirus Type 11, Rotavirus (VR-2104), Rotavirus (VR-2272)
細菌
Aeromonas hydrophila, Bacillus sp., Borrelia burgdorferi, Campylobacter jejuni, Candida albicans, Citrobacter freundii, Clostridium difficile, Clostridium perfringens, Enterobacter cloacae, Escherichia coli, Haemophilus influenza, Klebsiella pneumoniae, Proteus vulgaris, Pseudomonas aeruginosa, Salmonella enteriditis 16, Salmonella typhi 17, Serratia marcescens18, Shigella boydii, Shigella dysenteriae, Shigella flexneri, Shigella sonnei, Staphylococcus aureus, Staphylococcus epidermidis, Streptococcus Group A, Streptococcus Group B, Streptococcus Group C, Streptococcus Group F, Streptococcus Group G, Streptococcus mutans, Streptococcus pneumoniae, Streptococcus sanguis, Vibrio cholera, Yersinia enterocolitica, Listeria innocua, Salmonella Hilversum, Salmonella paratyphi, Salmonella typhimurium

*Adenovirus type 41 測試濃度為 1x10^3 $TCID_{50}$/mL

干擾物測試
下表物質在所列濃度下經測試，並不會干擾本試劑之測試結果。

Interference substances	Concentration	Interference substances	Concentration
Aspirin	3 mg/ml	Omeprazole	5 mg/ml
Barium sulfate	2% (w/v)	Palmitic acid	4% (w/v)
Bilirubin	0.25 mg/ml	Pepto-Bismol®	5% (w/v)
Cimetidine	5 mg/ml	Stearic acid	4% (w/v)
Hemoglobin	12.5% (w/v)	Tums®Antacid	5 mg/ml
Leukocytes	50% (w/v)	Whole blood	40% (w/v)
Metronidazole	0.25 mg/ml	Mucin	3.4 % (w/v)
Mylanta	5% (w/v)		

儲存
本試劑組有效期限標示於外包裝上，應存放於 15-30℃並避免陽光直射。測試匣必須保持在密封鋁袋中，直到使用前拆開。不要冷凍或加熱本檢驗試劑組或內附試劑。

包裝
飛確幽門桿菌抗原快速檢驗試劑.....20 組 / 盒

訂購資訊
產品型號 : IG06020C

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符號列表

REF	型號	LOT	批號	Σ	可進行的試驗總數
IVD	體外診斷醫療器材	CONTROL+	陽性控制組		不可重複使用
	仿單		保存期限	CE	CE 標示
	溫度界線		製造廠	EC REP	歐盟的授權代表
Rx Only	處方器材				

CE EC REP HiSS Diagnostics GmbH, Tullastraße 70
D-79108 Freiburg

PIC/S GMP 藥廠
PBF

寶齡富錦生技股份有限公司
台北市南港區園區街 3 號 16 樓
製造廠 : 寶齡富錦生技股份有限公司汐止廠
製造廠址 : 新北市汐止區大同路一段 306 號 6F 之 3
消費者諮詢專線 :+886-2-2691-9895
Email: xizhi@pbf.com.tw
www.pbf.com.tw
www.vstriptech.com

Vstrip®

Vstrip H. pylori Antigen Rapid Test
For *in vitro* diagnostic use

REF IG06020C 20 TEST KIT 15℃/30℃ IVD Rx Only CE

IVD USE 2019/07 V07
Vstrip H. pylori
Antigen Rapid Test

Vstrip Antigen Rapid Test is an immunochromatographic assay for the rapid detection of H. pylori antigen in human stool specimens.

INTENDED USE

Vstrip H. pylori Antigen Rapid Test is a single use immunochromatographic assay for the qualitative detection of *H. pylori* antigen in unpreserved human stool specimens. Test results are intended to aid in the initial diagnosis and treatment of *H. pylori* infection. Test results should be taken into consideration by the physician in conjunction with the patient history and symptoms.

SUMMARY

Helicobacter pylori (*H. pylori*) is a spiral-shaped gram negative bacteria, the most common infectious microorganism found in humans, and infects approximately 50% of the world's populations.[1] *H. pylori* infection has been recognized as an important factor in the cause of dyspepsia disease, peptic ulcer (gastric ulcer, duodenal ulcer), stomach cancer, and MALT (mucous-associated lymphoid tissue) lymphoma .[2-4]
H. pylori infection can be diagnosed using invasive or noninvasive methods.[5-7]
Invasive methods require the use of endoscopy and rapid urease testing, histology, culture for confirmation. The clinical recommended noninvasive testing methods include urea breath test (UBT) and stool antigen test (SAT), from which the active presentation of *H. pylori* is indicated. Another noninvasive method, serology testing, is not recommended for evaluating treatment effectiveness as it is unable to distinguish between active infection and previous exposure to *H. pylori*.[8]
H. pylori stool antigen testing is indicated in the diagnosis of *H. pylori* infection.

PRINCIPLE OF THE TEST

Vstrip H. pylori Antigen Rapid Test is a rapid immunochromatographic assay that utilizes a pair of *H. pylori* specific monoclonal antibodies to detect the presence of fecal *H. pylori* antigens indicated by a pink-red color line. To perform the test, a diluted stool sample which is first prepared by a sample preparation tube is added to the Test Cassette. If the sample contains *H. pylori* antigen, a pink-red test line (next to the letter T) along with a blue control line (next to the letter C) will be visible in the rectangle "Result Window". If *H. pylori* antigen is not present or is present at very low levels in the stool sample, only a blue control line will be visible. Whenever the blue control line does not develop within 10 minutes, the test is considered invalid.

MATERIALS PROVIDED

All provided materials should be stored and handled at 15-30℃ .

1. Test cassette (20 cassettes): Each test cassette houses a strip incorporated with a pair of *H. pylori* specific monoclonal antibodies and packed in individual foil pouch.
2. Sample preparation tubes (20 tubes): Each tube composes a "Sampler" attached to the tube cap and sample diluent buffer for the specimen sampling and dilution. 0.09% sodium azide is used as the preservative for the diluent buffer.
3. Positive control reagent (1 vial): Inactivated *H. pylori* is the main component of the positive control reagent.
4. Package Insert.

MATERIALS NOT PROVIDED

1. Specimen collection container
2. Timer
3. Disposable gloves

PRECAUTIONS

Read the package insert carefully prior to testing the kit and follow the instruction to obtain accurate results.

1. Manage patient samples and kit materials as potential infectious agents and take appropriate precautions in collection, handling, storage, and disposal.[9]
2. Inadequate or inappropriate specimen collection, storage, and transport may yield false or negative test results.[9]
3. Patient specimens should be mixed in the sample preparation tube with diluent thoroughly before use.
4. Check the expiration date printed outside of each material package, and do not use the kit components beyond the expiration date.
5. Do not use sample diluent buffer or positive control reagent with turbidity. The reagent may be contaminated with microorganism.
6. Avoid skin contact with the sample diluent buffer, which contains sodium azide (may be a skin irritant).
7. Do not open the test cassette pouches until ready to perform the assay.
8. Do not use the test cassette if the foil pouch is damaged.
9. Perform the test with materials only from the same kit. Do not interchange materials from different kits for test performance.
10. Do not reuse kit components or test devices.
11. Disregard test results beyond specified time (30 min).
12. Seek specific training or guidance if you are not experienced with specimen collection and handling procedures.
13. Do not smoke, eat or drink in areas where specimens or kit components are handled.

SPECIMEN COLLECTION AND PREPARATION

Note: Only solid, formed, or semisolid stool samples are recommended for this test.

Proper specimen collection, storage, and transport are critical to the performance of this test. Stool specimens should be collected in a clean container that do not contain media, preservatives, animal serum, or detergents as any of these additives may interfere the results. The specimen should be tested as soon as possible. Do not leave specimen at room temperature for prolonged periods. Specimens can temporarily stored at 2-8℃ for 7 days. For long-term storage of specimens, specimens can be stored at -20℃ for up to 20 days. Repeated freezing and thawing of specimens may undergo up to no more than 3 cycles.

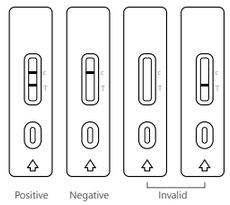
ASSAY PROCEDURE

All stool specimens and assay procedures must be handled at room temperature and on a flat surface.

1. Check the expiration date on each component's package or outer box before use. Do not use any test material beyond the labelled expiration date.
2. Label information of studied specimens on the blue color sample preparation tube.
3. Unscrew the sample preparation tube cap. Stick the "Sampler" into the stool specimen to collect a small portion of stool (approximately 30-50mg or 3-5 mm). An excess of stool sample could cause invalid result or may cause the appearance of brown bands. Do not use stools that have dried out.
4. Put the "Sampler" back to the sample preparation tube and tighten the tube securely. Mix thoroughly by inversion, shaking or vortex the tube for at least 1 min in order to assure good sample dispersion.
5. Remove a test cassette from its foil pouch and place it on a flat surface.
6. Label the cassette with the samples' ID information.
7. Break off (or cut) the blue tip on the top of the sample preparation tube and dispense 3 drops of diluted stool sample into the round "Sample Window" above the arrow mark on the test cassette. Do not let the tip of the tube touch the test cassette during the process.
8. Read the result at 10 minutes.

INTERPRETATION OF RESULTS

Positive result:
A visible PINK-RED colored line (Test line) appears next to the letter T, and a BLUE line (Control line) appears next to the letter C in the rectangle "Result Window" of the cassette.
A positive result indicates that the *H. pylori* antigen is in the stool specimen.
Negative result:
No PINK-RED line appears in the rectangle "Result Window" of the cassette next to the letter T, but a distinct BLUE line shows next to the letter C.
A negative result indicates that the *H. pylori* antigen is absent or below the level of detection.
Invalid result:
No visible BLUE line in the rectangle "Result Window" of the cassette next to the letter C, with or without a visually detectable PINK-RED line. Invalid result may occur with the deteriorated materials, but an excess of stool sample and incorrect procedure is mostly the main reason for control line failure. Review the procedure, re-test the same specimen when invalid result appears. Repeat the test with different specimens, if the test fails again. When the problem persists, discontinue using the test kit and contact your local distributor.



QUALITY CONTROL

Vstrip H. pylori Antigen Rapid Test utilizes the Internal Controls, Positive and Negative Control as the mechanism for quality control.
Internal Controls

1. A blue line appearing in the "Result Window" (next to the letter C) is an internal control. It confirms correct assay procedure and active kit components. If not, the test result is invalid.
2. A clear background is served as the internal negative control. The background color should be white and should not interfere with the reading of the test result. If the background color interfere the reading, it is recommended to repeat the test.

Positive /Negative Control
It is recommended that testing for positive and negative control reagent of *H. pylori* antigen should be performed when a new shipment of product is received. The positive and negative control are intended to monitor whether the whole package kit is functional to produce the expected results. The positive control result should show two distinct colored line (red and blue) appear in the "Result Window" of the cassette next to the letter T and C. The negative control result should show one distinguished colored line (a blue line) in the "Result window" of the device next to letter C. The kit should not be used if tests using these controls fail to deliver the correct test results.

POSITIVE CONTROL TESTING PROCEDURE

1. Remove a test cassette from its foil pouch and place it on a flat surface.
2. Add 3 drops of positive control reagent into the "Sample Window" on the test cassette. Do not let the tip of the tube touch the test cassette.
3. Read the result at 10 minutes.

NEGATIVE CONTROL TESTING PROCEDURE

1. Remove a test cassette from its foil pouch and place it on a flat surface.
2. Remove the sample preparation tube and break off (or cut) the blue tip on the top of the sample preparation tube.
3. Dispense 3 drops of diluted buffer into the round "Sample Window" above the arrow mark on the test cassette. Do not let the tip of the tube touch the test cassette during the process.
4. Read the result at 10 minutes.

EXPECTED VALUES

At least half the world's population is infected by *H. pylori*, making it the most widespread infection in the world. The actual infection rates vary from geography and age. Although most infected people will never experience clinical symptoms despite colonized by *H. pylori*. Approximately 10-20% of the infected group having chronic gastritis will ultimately develops gastric and duodenal ulcers and 1% will develop additional gastric complications.[10] The World Health Organization recommends all countries consider screening for *H. pylori* to prevent gastric cancer.[11]

LIMITATIONS OF THE PROCEDURE

1. A negative test result may occur if the level of antigen in a stool sample is below the detection limit of the test. Test results must be evaluated in conjunction with other clinical data available to the physician.
2. An excess of stool sample could cause an invalid result or may cause the appearance of brown bands.
3. A false negative result may be found in specimens with watery diarrheal stools that compose little or no solid matter.
4. A negative test result does not rule out the possibility of *H. pylori* infection for not all *H. pylori* strains can be detected by the kit.
5. False negative results may occur due to improper or inadequate sampling, or improper handling of the specimen.
6. Higher concentration of the tested interfering substances or substances other than what have been examined may exist in the stool specimen and interfere the test result.
7. Cross reactivity has not been evaluated for microorganisms other than what have been described below.
8. A positive test result does not rule out co-infections with other pathogens.
9. A positive test result only indicates the presence of *H. pylori* antigen and does not necessarily indicate that gastrointestinal disease is present.
10. Antimicrobials, proton pump inhibitors (PPIs) and bismuth compounds are known to suppress *H. pylori* and may give a false negative result if ingested in the 14 days prior to sample collection. In these cases, a new stool sample should be collected and tested 14 days after treatment has stopped. Positive results from patients that have used antibiotics, PPIs, or bismuth compounds in the 14 days prior to stool sample collection are still considered accurate.

PERFORMANCE CHARACTERISTICS

The evaluation was conducted comparing the results obtained using Vstrip H. pylori Antigen Rapid Test to an FDA-cleared ELISA that was previously evaluated relative to the endoscopy biopsy composite reference method (i.e., culture, histology, and RUT) for initial *H. pylori* diagnosis with a demonstrated sensitivity and specificity greater than or equal to 95% and a lower bound of the two-sided 95% confidence interval (CI) greater than 89%.

		FDA-cleared ELISA	
		+	-
Vstrip	+	58	5
	-	2	268

Percent Positive Agreement: 96.67% (58/60= 96.67%)
(95% Two-Sided CI: 88.6-99.1%)
Percent Negative Agreement: 98.17% (268/273= 98.17%)
(95% Two-Sided CI: 95.8-99.2%)

REPRODUCIBILITY

Five (5) panels of 12 frozen fecal samples each with random distributions of medium positive, low positive, high negative and negative samples were analyzed using the Vstrip H.pylori Antigen Rapid Test by each operator at each site over five (5) days. Across all sites and operators, agreement with the expected result was 97.8% (88/90) for the moderate positive panel member, 97.8% (88/90) for the low positive panel member, 98.9% (89/90) for the high negative panel member, and 100% (90/90) for the true negative panel member. The reproducibility study analyses demonstrated that results of the Vstrip H.pylori Antigen Rapid Test are reproducible by different operators in multiple locations.

ANALYTICAL SENSITIVITY (DETECTION LIMIT)

The test showed the limit of detection level was around 8.5 X10^5 CFU/mL for *H. pylori* strain (ATCC 43504) in stool.

CROSS REACTIVITY

The cross reactivity of the Vstrip H. pylori Antigen Rapid Test was assessed by testing the following microorganisms (bacteria spiked at ≥1x10^7 CFU/mL, viruses spiked at ≥1x10^5 $TCID_{50}$/mL). None of the microorganisms tested in the following table gave a positive result in the Vstrip H. pylori Antigen Rapid Test.

Viral Panel
Adenovirus type 7, Adenovirus type 41*, Coxsackie type B2, Coxsackie type B6, Echovirus Type 11, Rotavirus (VR-2104), Rotavirus (VR-2272)
Bacterial Panel
Aeromonas hydrophila, Bacillus sp., Borrelia burgdorferi, Campylobacter jejuni, Candida albicans, Citrobacter freundii, Clostridium difficile, Clostridium perfringens, Enterobacter cloacae, Escherichia coli, Haemophilus influenza, Klebsiella pneumoniae, Proteus vulgaris, Pseudomonas aeruginosa, Salmonella enteriditis 16, Salmonella typhi 17, Serratia marcescens18, Shigella boydii, Shigella dysenteriae, Shigella flexneri, Shigella sonnei, Staphylococcus aureus, Staphylococcus epidermidis, Streptococcus Group A, Streptococcus Group B, Streptococcus Group C, Streptococcus Group F, Streptococcus Group G, Streptococcus mutans, Streptococcus pneumoniae, Streptococcus sanguis, Vibrio cholera, Yersinia enterocolitica, Listeria innocua, Salmonella Hilversum, Salmonella paratyphi, Salmonella typhimurium

*Adenovirus type 41 is tested at 1x10^3 $TCID_{50}$/mL

Interfering Substances

The following substances were found to have no effect on results when present in stool at the concentrations indicated.

Interference substances	Concentration	Interference substances	Concentration
Aspirin	3 mg/ml	Omeprazole	5 mg/ml
Barium sulfate	2% (w/v)	Palmitic acid	4% (w/v)
Bilirubin	0.25 mg/ml	Pepto-Bismol®	5% (w/v)
Cimetidine	5 mg/ml	Stearic acid	4% (w/v)
Hemoglobin	12.5% (w/v)	Tums®Antacid	5 mg/ml
Leukocytes	50% (w/v)	Whole blood	40% (w/v)
Metronidazole	0.25 mg/ml	Mucin	3.4 % (w/v)
Mylanta	5% (w/v)		

STORAGE INSTRUCTION

The expiration date is indicated on the package label. Store the kit at 15-30℃ , and keep them away from direct sunlight. The test cassette must be kept in the sealed pouch until use. Do not freeze or overheat the test kit or kit reagents.

PACKAGING

Vstrip H. pylori Antigen Rapid Test.....20 Tests/Kit

ORDERING INFORMATION

Product No. : IG06020C

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SYMBOL LEGEND

REF	Catalog Number	LOT	Batch Code	Σ	Contains sufficient for < n > tests
IVD	In vitro diagnostic medical device	CONTROL+	Positive Control		Do not reuse
	Consult instructions for use		Use-by date	CE	CE Marking
	Temperature Limit		Manufacturer	EC REP	Authorized Representative in the European Community
Rx Only	Prescription Devices				

CE EC REP HiSS Diagnostics GmbH, Tullastraße 70
D-79108 Freiburg

Panion & BF Biotech Inc.

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