Vstrip

Vstrip 輪狀病毒快速檢驗試劑
說明書

REF IG04020S　IVD 20 TEST KIT　15℃ 30℃　CE

體外診斷使用　2016/09 V1.0
輪狀病毒快速檢驗試劑
衛部醫器製壹字第 005974 號

Vstrip 輪狀病毒快速檢驗試劑用於檢測人類糞便中的輪狀病毒抗原。

效能

Vstrip 輪狀病毒快速檢驗試劑是一種體外快速定性檢測，針對人類糞便中的輪狀病毒抗原。本試劑僅適用於實驗室及專業用途，旨在於協助輪狀病毒感染之早期診斷。若檢測結果為不確定，而患者有明顯臨床症狀，須考慮以其他臨床診斷加以佐證。

闡釋

輪狀病毒是小兒急性腸胃炎的主要原因，特別是在年齡 6 至 24 個月的兒童[1,3]。平均潛伏期為 3 天。輪狀病毒感染初期症狀是發燒和嘔吐，隨後頻繁的水樣腹瀉，通常持續 3-9 天，嚴重脫水會導致死亡。受感染的兒童在症狀出現前 2 天至發病後 10 天，糞便中仍可發現大量輪狀病毒。因現有的組織培養方法不易分離輪狀病毒，一般檢測方式以電子顯微鏡檢驗為標準[3]。新穎的酵素免疫分析法和乳膠凝集試驗增加了靈敏度和專一性，是現在的首選方法[2,4]。然而，Vstrip 輪狀病毒快速檢驗試劑提供了一種更簡單、快速的方法為病人檢測輪狀病毒抗原。

實驗原理

Vstrip 輪狀病毒快速檢驗試劑是一種定性免疫層析。執行測試時，試紙放入含有樣品之稀釋液管中，藉由毛細現象，樣品稀釋液流經接合墊，內含紅色乳膠粒子 (抗輪狀病毒單株抗體)，若樣品稀釋液中含有輪狀病毒抗原，抗原將結合至抗體上，形成抗原 – 抗體 – 乳膠粒子複合物。當樣品稀釋液經硝酸纖維素膜以毛細作用持續向上移動，而此膜已於測試線區預先塗覆相對應之抗體。當複合物與膜上抗體結合聚集成肉眼可見之紅色線，則表示含有輪狀病毒抗原；若無輪狀病毒抗原或低於偵測水平則只有藍色控制線。添加樣品測試後應出現藍色控制線以表示有效結果。通過此法，可準確於 10 分鐘內偵測輪狀病毒。

提供的材料

1. Vstrip 輪狀病毒快速檢驗試劑 (20) – 試紙含輪狀病毒單株抗體
2. 含稀釋液糞便收集管 (20) – 稀釋液含 0.08% 防腐劑
3. 輪狀病毒陽性控制組 (1)
4. Vstrip 輪狀病毒快速檢驗試劑說明書 (1)

未提供的材料

1. 樣本收集容器
2. 計時器
3. 手套

注意事項

1. 限體外診斷使用。
2. 測試前請詳閱使用說明書。
3. 尚未進行測試前，請勿撕開檢驗試劑鋁袋。
4. 處理患者檢體時請穿戴手套[5]。
5. 取樣前須確保患者糞便檢體混合均勻，勿取已乾涸之糞便。
6. 使用前應輕柔地搖晃糞便收集管，以便稀釋液與糞便檢體徹底混合均勻。
7. 超過判讀時間之測試結果不予採用。
8. 請勿直接將試紙插入患者之糞便檢體中。
9. 含稀釋液糞便收集管為一次性使用，使用完畢後請丟棄，切不可重複使用。
10. 使用前確認試劑包裝完整，試劑包裝若有損壞請勿使用。
11. 請勿重複使用本試劑或其他配件。
12. 本試劑套組的溶液不可飲用。
13. 患者糞便檢體可能含有傳染性病原體，應作為潛在生物性廢棄物處理。
14. 請勿交換使用不同批號之檢驗試劑或其配件。
15. 請勿使用過期的檢驗試劑。
16. 本試劑盒內部分配件含有防腐劑，可能對皮膚具有刺激性，應避免接觸皮膚。
17. 將使用過檢驗試劑及配件存放於適當容器中作為潛在生物性廢棄物處置[5]。
18. 為了獲得正確的測試結果，請確實遵照說明書指示操作。

儲存說明

有效期限標示於外包裝上，本試劑套組應存放於 15-30℃，避免陽光直射。

樣本採集與保存

正確的樣本採集、儲存與運輸方式對本試劑有著關鍵性影響，不正確的方式可能導致錯誤或無效的檢測結果。

為獲得最佳結果，樣本應於症狀出現後立即採集。不可將樣本長時間放置於室溫。若含有高濃度血液之樣本可能會影響試劑流動，導致無效 / 偽陽性結果，此情況建議另取樣本進行測試。糞便樣本可以實驗室常規方法進行收集，檢體不需事先稀釋。

糞便檢體應收集在不包含培養基、防腐劑、動物血清、洗滌劑或任何會干擾輪狀病毒抗原檢測的添加劑的乾淨容器中。若從尿布上取得檢體也應存放於乾淨容器中。

糞便樣本在沒有與測試性能有所干擾的情況下可以保存於 2 ～ 8℃溫度環境 2 天。若要長期儲存，建議於 -20℃或更低溫條件儲存。不建議將樣本反覆冷凍解凍，可能導致錯誤的結果。也不可存放於自我解凍冷凍環境中。

樣本製備

糞便樣本：

1. 將內含稀釋液糞便收集管瓶蓋打開，使用採檢棒挖取少量糞便檢體 (直徑約 2-5 mm; 約 30-50 mg)，放入含稀釋液糞便收集管中。
2. 旋緊採樣瓶蓋並搖動收集管，使糞便檢體充分溶解於稀釋液中。
3. 標示與病患或其他相關信息於收集管上。

檢測程序

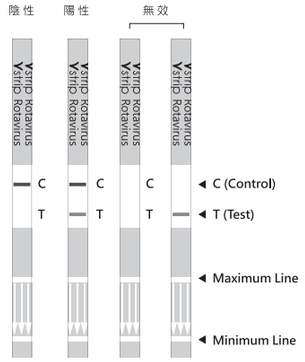
1. 從鋁箔袋中取出試紙條。
2. 旋開稀釋液糞便收集管瓶蓋後，將試紙條插入瓶中 (試紙條標示之箭頭朝下)。
3. 於 10 分鐘內讀取結果，超過 10 分鐘請勿判讀其結果。

結果判讀

陽性結果 (Positive)：
目視可觀察到控制區出現藍色線且測試區出現鮮明的紅色線。陽性結果表示輪狀病毒抗原的存在。

陰性結果 (Negative)：
目視可觀察到控制區顯示了一條明顯的藍色線但測試區無出現紅色線。陰性結果表示輪狀病毒抗原不存在或低於偵測極限。

無效結果 (Invalid)：
目視觀察控制區無出現藍色線，即使在測試區觀察到有紅色線仍判為無效結果。造成無效原因可能是過多的樣品量，不正確的操作程序或試劑變質。應確實審查操作過程並使用新的樣品與新的試劑重新測試。如果問題仍然存在，請停止使用檢測試劑，並聯繫當地經銷商。



結果判讀注意事項

試劑判讀區的紅色顯色度取決於樣品中抗原濃度而變化。但是定量數值或抗原增加比例皆無法通過此定性試驗確定。

品質控制

陽性控制組應於收到試劑時進行測試。此試劑包含內部品質控制，於控制區顯示出一條明顯的藍色線作為控制線，用以確保操作程序正確及樣本量足夠。陽性控制組目的為監測試劑是否失效而非保證其分析檢測之精準度。

品質控制測試程序

陽性控制組：

1. 打開內含稀釋液糞便收集管瓶蓋，並將陽性控制組的拭子插入管中。
2. 陽性控制組的拭子於稀釋液瓶中轉動至少 1 分鐘，取出拭子時盡量擠壓管壁確保稀釋液留在管內。
3. 從鋁箔袋中取出試紙條。
4. 將試紙條放入試管中 (試紙條標示之箭頭朝下)。
5. 於 10 分鐘內讀取結果，超過 10 分鐘請勿判讀其結果。
6. 結果：目視可觀察到判讀區有明顯的兩條線 (藍：控制線 / 紅：測試線)。

產品限制

1. Vstrip 輪狀病毒快速檢驗試劑針對輪狀病毒抗原檢測具有高度靈敏度及專一性。本試劑用於檢測人類輪狀病毒，而非區分病毒類型。如同其他所有的體外診斷試劑，其偵測結果應由醫師與其他臨床資訊一同評估。
2. 感染一週後的糞便中病毒量會減少而使反應減弱，應在出現症狀一週內收集糞便檢體。
3. 糞便樣品過量可能導致判讀錯誤 (出現褐色線)。
4. 陰性結果不排除患者感染輪狀病毒的可能性。造成偽陰性結果的原因可能是測試過程中輪狀病毒抗原濃度低於偵測極限、不正確或不適當的採樣或是糞便檢體處理不當。最終結果應由醫師確診評估。
5. 合併感染病原菌是有可能的。因此，應同時進行細菌化驗以排除細菌感染病因。

期望值

Vstrip 輪狀病毒快速檢驗試劑用於檢測糞便中存在的輪狀病毒抗原。輪狀病毒感染率取決於許多因素，如年齡、地理位置、糞便檢體收集、處理和運送等。測試健康個體應是沒有輪狀病毒。一些被感染的個體可能僅有輕微症狀，但這些患者可能檢測為陰性。

產品效能

使用 Vstrip 輪狀病毒快速檢驗試劑與市售檢驗試劑進行評估，比較所得結果如下：

■靈敏度
輪狀病毒檢測結果顯示具有 >99% 的靈敏度。

■專一性
輪狀病毒檢測結果顯示具有 >99% 的專一性。

■再現性
三批不同批次的 Vstrip 輪狀病毒快速檢驗試劑針對批次內、批次間、不同的時間點及操作者，分別以陰性緩衝液、弱陽性、中等陽性及強陽性抗原進行重複性測試，所有測試結果符合率 >99%。

■偵測極限
針對 Vstrip 輪狀病毒快速檢驗試劑之檢測極限。該研究使用自 ATCC 購得之人類輪狀病毒 (HRV)。偵測極限為 $1.58X10^3$ $TCID_{50}$ / mL 的濃度。

Rotavirus strain	Limit of detection ($TCID_{50}$/mL)
Hu/Australia/102510/77/L	$8.89X10^2$
HRV 89-12C2	$1.58X10^3$

交叉反應

本實驗所用之細菌與病毒如下表，測試結果均無陽性反應。

細菌：

Pseudomonas aeruginosa	Serratia marcescens
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
Salmonella typhi	Salmonella enteriditis
Vibrio cholera	

病毒：

Adenovirus type 7	Adenovirus type 41
Echovirus Type 11	

干擾物測試

以抗腹瀉藥及一般常用藥物進行測試，結果顯示以下藥物並不會干擾本試劑之測試結果。(測試項目與使用劑量如下表)

干擾物 / 濃度

Aspirin/ 20mg/ml	Metronidazole/ 0.25 mg/ml
Barium sulfate/ 0.25 mg/ml	Voren Supp./ 12.5mg/ml
Bilirubin/ 0.25 mg/ml	PECOLIN/ 5%
Hemoglobin/ 0.25 mg/ml	

包裝

Vstrip 輪狀病毒快速檢驗試劑 20 組 / 盒

訂購資訊

產品型號 : IG04020S

參考資料

1. Burke, B. and U. Desselberger. 1996. Minireview: Rotavirus Pathogenicity. Virol.218: 299-305.
2. Christensen, M.L. 1989. Human viral gastroenteritis. Clin. Microbiol. Rev. 2: 51-89.
3. Truant, A.L. and T. Chonmaitree. 1982. Incidence of rotavirus infection in different age groups of pediatric patients with gastroenteritis. J. Clin. Microbiol. 16: 568-569.
4. Mathewson, J., Winsor, D. Jr., Dupont, H.L., and Secor, S. L. (1989). Evaluation of assay systems for the detection of Rotavirus in stool specimens. Diag. Microbiol. Infect. Diseases. 12:139-141.
5. Biosafety in Microbiological and Biomedical Laboratories, 5th Edition. U.S. Department of Health and Human Services, CDC, NIH, Washington, DC (2007).

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		製造商	EC REP	歐盟的授權代表

07/16

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.t
www.pbf.com.tw
www.vstriptech.com

Vstrip

Vstrip Rotavirus Rapid Test
Package Insert

REF IG04020S IVD 20 TEST KIT 15°C 30°C CE

IVD Use 2016/09 V1.0
Vstrip Rotavirus Rapid Test
Registration Number:
MOHW-MD-(I)-No.005974

Vstrip Rotavirus Rapid Test for the Detection of Rotavirus Antigen in Human Stool Specimen

INTENDED USE
Vstrip Rotavirus Rapid Test is an in vitro qualitative immunochromatographic assay for the detection of Rotavirus antigens in human stool specimen. Test results are intended to aid in the early diagnosis of Rotavirus infection or early confirmation of infection. This test is for professional use only. If the check result is uncertain, and patients with significant clinical symptoms, a further determination should be carried out with other clinical diagnostics.

SUMMARY AND EXPLANATION
Rotavirus is the major cause of children with acute gastroenteritis, especially in children 6 to 24 months in age[1,3]. The average incubation period for the Rotavirus infection is 3 days. Initial symptoms of Rotavirus infection are fever and vomiting, followed by frequent watery diarrhea, and diarrhea usually lasts 3-9 days. Severe dehydration can cause death. 2 days before symptoms appear to 10 days after finding a large number of Rotavirus in feces. The gold standard for detecting Human Rotavirus depends on electron microscopy since existing tissue culture methods are unreliable[3]. However, newly introduced enzyme immunoassays and latex agglutination assays with increased sensitivities and specificities are now the methods of choice[2,4]. Vstrip Rotavirus Rapid Test offers a simple, rapid method for detecting Rotavirus antigen in patient stool.

PRINCIPLE OF THE TEST
Vstrip Rotavirus Rapid Test is a qualitative immunochromatographic assay for the determination of Rotavirus in stool samples. The membrane is pre-coated with monoclonal antibodies, on the test band region, against viral antigens. During testing, the sample is allowed to react with the colored conjugate (anti-Rotavirus monoclonal antibodies) which was pre-dried on the test strip. The mixture then moves upward on the membrane by capillary action.
An extract is first prepared by suspension of the specimen in the provided diluent buffer solution. If the sample extract contains Rotavirus antigens, these will form an antigen-antibody complex with the colored particles and a visible Test band will appear as a Red line. If Rotavirus antigen is not present, or is present at very low level in the specimen, only the control line will be visible. The C band (Blue color) should always appear after a sample is applied, indicating a valid result. By this means, the device can accurately indicate the presence of Rotavirus in 10 minutes.

MATERIALS AND REAGENTS PROVIDED
1. Test dipsticks (20)
   Each strip contains Rotavirus specific monoclonal antibodies.
2. Stool collection tubes with diluent (20)
   The buffer contains 0.08% sodium azide.
3. Rotavirus Positive control swab (1)
4. Package Insert (1)

MATERIALS NOT PROVIDED
1. Specimen collection container
2. Timer
3. Disposable gloves

WARNINGS AND PRECAUTIONS
1. For in vitro diagnostic use.
2. Read the entire procedure carefully prior to testing.
3. Do not open the test pouches until ready to perform the assay.
4. Use of Nitrile or Latex gloves is recommended when handling patient samples[5].
5. Stool must be mixed thoroughly to insure a representative sample prior to pipetting. Do not use stools that have dried out.
6. Patient specimens should be mixed in the stool collection tubes with diluent gently and thoroughly before use.
7. Disregard test results beyond specified time (10 min).
8. Do not insert the test strip directly into patient stool specimens.
9. Use only one sample diluent vial. Discard after use. Do not attempt to reuse.
10. Do not use the test if the foil pouch is damaged.
11. Do not reuse kit components or test devices.
12. Do not mouth pipette samples or reagents.
13. Patient specimens may contain infectious agents and should be handled and disposed of as potential biohazards.
14. Do not interchange or mix different lots of Vstrip Rotavirus Rapid Test.
15. Do not use the kit components beyond the expiration date, printed on the outside of the box.
16. Some reagents in this kit contain sodium azide, which is a skin irritant. Avoid skin contact with reagents.
17. Dispose all used materials in the appropriate container. Treat as potentially biohazard[5].
18. To obtain accurate results, you must follow the Package Insert.

SHELF LIFE AND STORAGE INSTRUCTION
The expiration date is indicated on the package label. Store kit reagents at 15-30°C, away from direct sunlight.

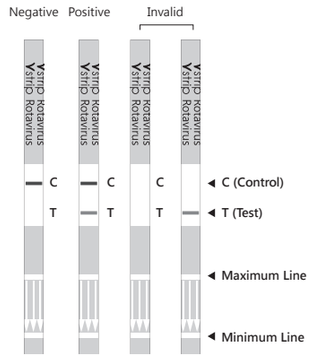
SPECIMEN COLLECTION AND STORAGE
Proper specimen collection, storage, and transport are critical to the performance of this test.
For the best results, specimens should be collected after onset of symptoms. Do not leave specimens at room temperature for prolonged periods. Specimens containing high levels of blood may fail to flow in the Vstrip Rotavirus device, resulting in an invalid / false positive test result. Testing of an additional specimen is recommended under such circumstances. Stool specimens may be collected by the method routinely utilized by the laboratory, providing no dilution of the specimen occurs.
Stool specimens should be collected in clean containers that do not contain media, preservatives, animal serum, or detergents as any of these additives may interfere with the Rotavirus antigen test or obtained from a diaper.
Specimens may be stored at 2~8°C for 2 days without interfering with the test performance. For long-term storage of specimens, -20°C or colder is recommended. Repeated freezing and thawing of specimens is not recommended and may cause erroneous results.
Do not store specimens in self-defrosting freezers.

SPECIMEN PREPARATION
Stool specimen:
1. Unscrew the sample diluent vial cap, use the spoon attached to the cap to transfer small piece of stool (2-5 mm in diameter; approximately 30-50 mg) into the vial containing sample diluent buffer.
2. Close the vial and tighten securely. Shake the stool collection tube in order to assure good sample dispersion.
3. Label the sample diluent vial with a patient or other control information.

ASSAY PROCEDURE
1. Remove a test strip from its sealed bag.
2. Unscrew the sample diluent vial cap then place the test strip into the stool collection tube (the arrows pointing down).
3. Read the result at 10 minutes. Some strong positive results may appear sooner. Do not read result after 10 minutes.

INTERPRETATION OF RESULTS
Positive Result:
Visually detectable in addition to the blue colored line on the control region, a distinct red colored line also appears in test region. A positive result indicates the presence of Rotavirus antigen.

Negative Result:
Visually detectable no line appears in the test region. A distinct blue line shows on the control region. A negative result indicates that Rotavirus antigen is absent or below the level of detection.



Invalid:
No visually detectable the blue colored line in the control region, with or without a visually detectable red colored line on the test region. Insufficient specimen volume, incorrect procedural techniques or deterioration of the reagents are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit and contact your local distributor.

Notes on the Interpretation of Results
The intensity of the red colored band in the result will vary depending on the concentration of antigens in the specimen. However, neither the quantitative value, nor the rate of increase in antigens can be determined by this qualitative test.

QUALITY CONTROL
The Positive Controls should be assayed once upon receipt of the kit. Internal procedural controls are included in the test. A blue line appearing in the control region is an internal control. It confirms sufficient specimen volume and correct procedural technique. The positive controls are intended to monitor for reagent failure, but will not ensure precision at the analytical assay cutoff.

QUALITY CONTROL TESTING PROCEDURE
Positive Control:
1. Unscrew the sample diluent vial cap and immediately introduce the positive control swab into the stool collection tube.
2. Mix the solution by rotating the positive control swab forcefully against the side of the stool collection tube at least 1 minute. Extract as much liquid as possible from the swab, squeezing the sides of the stool collection tube as the swab is withdrawn.
3. Remove the test strip from its sealed bag before using it.
4. The test strip put into the stool collection tube (the arrows pointing down).
5. Read the result within 10 minutes. Do not read the test result later than 10 minutes.
6. Result: The Positive Control should yield visually detectable two lines (Blue: control line/Red: test line).

LIMITATIONS OF THE PROCEDURE
1. Vstrip Rotavirus Rapid Test is highly sensitive and specific for Rotavirus antigen. The monoclonal antibody in this test will detect human Rotaviruses, but cannot be used to differentiate types. As with all in vitro diagnostic procedures, test results should be interpreted by a physician in conjunction with other clinical information.
2. After one week of infection, the number of viruses in feces is decreasing, making the sample less reactive. Stool samples should be collected within one week of the onset of symptoms.
3. An excess of stool sample could cause wrong results (brown bands appear).
4. A negative result does not exclude the possibility of Rotavirus infection in the patient. False negative results may occur due to low concentration levels of the Rotavirus antigen below the sensitivity level of the test, improper or inadequate sampling, or improper handling of the specimen. Test results should be interpreted by a physician
5. Co-infection with bacterial pathogens is possible. Therefore, bacteriological tests should be performed in parallel with this test to rule out bacteriological etiology.

EXPECTED VALUES
Vstrip Rotavirus Rapid Test detects the presence of Rotavirus antigen in stool. Expected values for a given population should be determined for each laboratory. The prevalence of Rotavirus infection will vary based on many factors such as age, geographic location, method of sample collection, sample handling and transportation, and the general health environment of the patient population under study. Healthy individuals tested should be negative for Rotavirus. Some infected individuals may show symptoms or only minor symptoms, and these patients may test negative.

PERFORMANCE CHARACTERISTICS
The evaluation was conducted comparing the results obtained using Vstrip Rotavirus Rapid Test to another commercially available Rotavirus Rapid Test .

■ **Sensitivity**
The detection of Rotavirus showed >99% of concordance in sensitivity.

■ **Specificity**
The detection of Rotavirus showed > 99% of concordance in specificity.

■ **Reproducibility**
Three different lots of the Vstrip Rotavirus Rapid Test was tested in multiple replicates using negative, low positive, medium positive and high positive samples. Reproducibility was tested within each lot, between lots, and on different days. In each case, all tests yielded >99% reproducibility.

■ **Limit of Detection**
To determine the limits of detection of the Vstrip Rotavirus Rapid Test. The study used human Rotavirus (HRV) as following table which were obtained from ATCC. The limit of detection of the test is a concentration of $1.58x10^3$ $TCID_{50}$/mL.

Rotavirus strain	Limit of detection ($TCID_{50}$/mL)
Hu/Australia/102510/77/L	$8.89X10^2$
HRV 89-12C2	$1.58X10^3$

Cross Reactivity
The cross reactivity of the Vstrip Rotavirus Rapid Test was assessed by testing the following organisms and viruses. None of the microorganisms tested in the following table gave a positive result in the Vstrip Rotavirus Rapid Test.

Microorganisms

Pseudomonas aeruginosa
Staphylococcus aureus
Streptococcus Group A
Streptococcus Group C
Streptococcus Group G
Streptococcus pneumoniae
Salmonella typhi
Vibrio cholera
Serratia marcescens
Staphylococcus epidermidis
Streptococcus Group B
Streptococcus Group F
Streptococcus mutans
Streptococcus sanguis
Salmonella enteriditis

Viruses
Adenovirus type 7
Adenovirus type 41
Echovirus Type 11

Interfering Substances
Common the-counter medication, anti-diarrhea drug and substances occasionally present in feces were tested with the Vstrip Rotavirus Test in order to verify that they did not interfere with the test. The following substances showed no interference:

Interference substances/ Concentration

Aspirin/ 20mg/ml
Barium sulfate/ 0.25 mg/ml
Bilirubin/ 0.25 mg/ml
Hemoglobin/ 0.25 mg/ml
Metronidazole/ 0.25 mg/ml
Voren Supp./ 12.5mg/ml
PECOLIN/ 5%

PACKAGING
Vstrip Rotavirus.....20 Tests/Kit

ORDERING INFORMATION
Product No. : IG04020S

REFERENCE
1. Burke, B. and U. Desselberger. 1996. Minireview: Rotavirus Pathogenicity. Virol.218: 299-305.
2. Christensen, M.L. 1989. Human viral gastroenteritis. Clin. Microbiol. Rev. 2: 51-89.
3. Truant, A.L. and T. Chonmaitree. 1982. Incidence of Rotavirus infection in different age groups of pediatric patients with gastroenteritis. J. Clin. Microbiol. 16: 568-569.
4. Mathewson, J., Winsor, D. Jr., Dupont, H.L., and Secor, S. L. (1989). Evaluation of assay systems for the detection of Rotavirus in stool specimens. Diag. Microbiol. Infect. Diseases. 12:139-141.
5. Biosafety in Microbiological and Biomedical Laboratories, 5th Edition. U.S. Department of Health and Human Services, CDC, NIH, Washington, DC (2007).

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

07/16

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

Panion & BF Biotech Inc.

16F., No.3, Park St., Nangang Dist., Taipei City 115, Taiwan
Manufactured by: Panion & BF Biotech Inc. at Xizhi
Manufacturer Address:
6F.-3, No.306, Sec. 1, Datong Rd., Xizhi Dist., New Taipei City 22146 Taiwan
Technical Support: +886-2-2691-9895
Email: xizhi@pbf.com.tw
www.pbf.com.tw
www.vstriptech.com