Vstrip

Vstrip A+B 型流行性感冒快速檢驗試劑
說明書

REF IG01020S　IVD 20 TEST KIT　15°C 30°C　CE

體外診斷試劑 2016/11 V2.0
Vstrip Flu A&B Rapid Test
衛部醫器製壹字第 005923 號

Vstrip A+B 型流行性感冒快速檢驗試劑，用於檢測患者鼻腔分泌物是否具有 A 型或 B 型流行性感冒之抗原。

效能

Vstrip A+B 型流行性感冒快速檢驗試劑是一種體外快速定性檢測，針對具有流感症狀之患者，使用鼻咽拭子檢測 A 型流感及 B 型流感抗原。本產品在流感症狀產生初期即可偵測到流感病毒。本測試僅適用於實驗室及專業用途，旨在協助 A 型流感及 B 型流感之早期診斷，無法偵測 C 型流感。若本測試呈現陰性結果須以細胞培養方式進行確診。

闡釋

流感病毒是單鏈 RNA 病毒，包括 A 型，B 型和 C 型。其中 A 型病毒最典型也最普遍，且與嚴重的流感疫情密切相關。B 型病毒通常比 A 型溫和，而 C 型病毒則從未有引發重大疫情之紀錄[1]。 流感是一種具有高度傳染性的急性上呼吸道感染。流感病毒感染的典型症狀是發燒，頭痛，肌肉痠痛，全身乏力，乾咳，喉嚨痛和鼻炎。這種感染通常持續一周左右，大多數人可於一到兩週內恢復。若是發生在幼兒，老人和已罹患其他疾病的患者 (如肺部疾病，糖尿病，癌症，腎臟或心臟病)，流感將造成嚴重威脅，可能會導致嚴重的併發症、肺炎甚至死亡。
Vstrip A+B 型流行性感冒快速檢驗試劑是一種免疫層析試驗，使用單株抗體接合之乳膠粒子來檢測鼻腔分泌物中 A 型與 B 型病毒抗原。本測試不但容易執行且測試結果可在 10 分鐘內目視得出。

實驗原理

Vstrip A+B 型流行性感冒快速檢驗試劑是一種固相免疫層析。執行測試時，將試紙條放入含有萃取液及樣品的試管中。藉由毛細現象，樣品流經接合墊，內含藍色乳膠粒子 (已接合 A 型流感抗體) 及紅色乳膠粒子 (已接合 B 型流感抗體)。若樣品中含有 A 型流感或 B 型流感病毒抗原，抗原將結合到抗體上，形成抗原 - 抗體 - 乳膠粒子複合物。這些複合物在硝酸纖維素膜上以毛細作用持續向上移動，而此硝酸纖維素膜已於測試線區域預先植入相對應之抗體。當複合物到達測試線時，將與膜上之抗體結合，聚集成肉眼可見的一條線。
另一條獨立作用的紫色的控制線則永遠會出現以確保測試結果是正確的。如果抗原不存在或是低於本產品偵測極限，則只會出現一條紫色的控制線。如果紫色控制線沒有出現，則代表此測試失效。

提供的材料

1. Vstrip A+B 型流行性感冒快速檢驗試劑 (20)
   含 A 型流感單株抗體及 B 型流感單株抗體。
2. 檢體萃取液 (20)
3. 無菌鼻咽採檢拭子 (20)
4. A 型流行性感冒病毒陽性控制組 (1):
   拭子上塗佈無感染力之 A 型流行性感冒病毒抗原
5. B 型流行性感冒病毒陽性控制組 (1):
   拭子上塗佈無感染力之 B 型流行性感冒病毒抗原
6. Vstrip A+B 型流行性感冒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. 測試前仔細閱讀使用說明書。
3. 請勿使用超過有效期的試劑。
4. 請勿調換或混合使用不同組的流感檢驗試劑。
5. 請勿直接將試紙條放入病人之鼻咽或口腔等患處。
6. 陽性控制組須放入萃取液中與萃取液混合均勻後方可使用。
7. 超過指定時間 (10 分鐘) 之後的呈色結果不予採用。
8. 在收集檢體或處理、貯存、丟棄患者樣本及使用過之試劑耗材時須採用適當之預防措施。[2]
9. 處理患者檢體時請穿戴手套。[2]
10. 依照當地法規丟棄使用過之內容物。
11. 請勿重複使用本試劑。
12. 使用前確認試紙條包裝完整，若有損壞請勿使用。
13. 為了獲得正確的測試結果，請確實遵照說明書指示操作。
14. 不正確的採樣方式或檢體保存方式皆可能導致錯誤的檢測結果。
15. 若無收集檢體或實際操作檢驗試劑的相關經驗，請尋求具體的培訓或參閱相關操作指南。[3,4]

儲存方式

1. 本試劑組應貯存在 15-30°C，避免陽光直射。
2. 請勿將本試劑組儲存於冷凍或過熱的環境中。
3. 產品之有效期限標示於外包裝上。
4. 試紙條已密封於鋁箔袋中，使用前再開封，且一旦開封須立即使用。

樣本收集與準備

正確的採樣方式對本試驗有著關鍵性影響，不正確的方式可能導致錯誤的檢測結果。

採檢鼻腔拭子：
為了獲得最佳的測試效果，請使用試劑組所提供的拭子。為了盡可能取得較多的分泌物，須將無菌拭子插入可見較多分泌物的鼻孔中。輕柔旋轉拭子， 輕推至鼻甲骨處 (距離鼻孔小於 2.5 公分)，頂著鼻壁旋轉數次後取出。

採檢鼻咽拭子：
為了獲得最佳的測試效果，請使用試劑組所提供的拭子。為了盡可能取得較多的分泌物，須將無菌拭子插入可見較多分泌物的鼻孔中。將拭子沿著鼻腔膈膜輕推至後鼻咽部，旋轉數次後取出。

實驗步驟

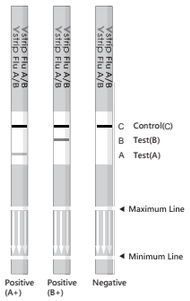
使用前所有臨床檢體必須要在室溫的狀態。使用前檢查每個測試包裝或外包裝盒的效期。請勿使用超過效期之試劑。
1. 取樣後，將拭子放入裝有萃取液的試管中，頂著管壁及管底轉動拭子**只需三次**，之後將拭子靜置於試管 1 分鐘。
2. 一邊轉動拭子頭部一邊沿著管壁慢慢移除拭子，用過之拭子請依照感染性廢棄物處理方式妥善處置。
3. 將試紙條插入試管中 (試紙條標示之箭頭朝下)。請勿移動試紙條，直到測試完成。
4. 於 10 分鐘時判讀結果，部分陽性結果可能更快出現，超過 10 分鐘請勿判讀。

結果判讀

陽性結果 (Positive)：
反應時間 10 分鐘時，於測試線出現任何藍色或紅色且控制線出現紫色，此即陽性結果，表示偵測到 A 型或 B 型流感抗原。
1. 若是在紫色控制線下方僅出現藍色測試線，表示偵測到 A 型流感抗原。
2. 若是在紫色控制線下方僅出現紅色測試線，表示偵測到 B 型流感抗原。
3. 若是在紫色控制線下方同時出現藍色及紅色測試線，表示同時偵測到 A 型及 B 型流感抗原。

陰性結果 (Negative)：
反應時間 10 分鐘時，僅出現紫色控制線，據以推斷為陰性結果，表示未偵測 到 A 型及 B 型流感抗原。

無效反應 (Invalid)：
反應時間 10 分鐘時，只要紫色控制線未出現，即使藍色或紅色測試線 (A 或 B) 出現，結果仍視為無效。如果測試是無效的，應使用新的樣品和新的試紙條重新進行測試。



陽性控制組

Vstrip A+B 型流行性感冒快速檢驗試劑包含另外的陽性控制組，以便用戶用來確認該試劑的品質。
1. 打開萃取液瓶蓋，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。陽性控制組的拭子以生物性廢棄物處理丟棄。
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 分鐘時讀取結果，超過 10 分鐘請勿判讀其結果。

產品限制

1. 該試劑的內容物將用於定性檢測從鼻腔和鼻咽拭子採檢的 A 型和 B 型流感抗原。
2. 陰性的結果有可能是因為檢體的抗原濃度低於本產品的偵測極限。
3. 未依照正常操作程序使用本產品或是錯誤的解讀結果會影響產品的表現以及產生無效的判讀結果。
4. 醫師須將測試結果配合其他臨床數據一起評估。
5. 陰性結果不能排除其他非流感病毒的感染。陰性結果必須要經過病毒培養來確定。
6. 陽性結果不能排除其他病毒共同感染的可能。
7. 陽性結果無法辨識 A 型流感或 B 型流感病毒的亞型。
8. 陽性與陰性的準確率與流感流行期間高度相關。偽陰性結果在流感流行期間可能比較高，偽陽性的結果在非流感季節可能會比較低。
9. 接種鼻腔劑型流感疫苗三天內請勿使用本產品 (可能會有偽陽性的結果)。
10. A 型流感病毒抗原決定位上的胺基酸改變後，單株抗體可能會無法偵測到或是靈敏度較差。
11. 如有需要分辨特定 A 型流感的病毒株或是亞型這些額外的測試，請洽相關機關。
12. 在 10 分鐘時，背景顏色可能未完全褪去，這個現象不會影響判讀結果。

產品性能

1. 偵測靈敏度 (偵測極限)：
取 17 種 A 型流感病毒株及 3 種 B 型流感病毒株進行測試。測試時每個病毒株皆以萃取液稀釋三重覆至沒有陽性訊號為止。
A 型流感病毒偵測靈敏度為 2.64×10^5 $TCID_{50}$/mL。
B 型流感病毒偵測靈敏度為 3.71×10^5 $TCID_{50}$/mL。
結果如下表：

Viral Strain	Type	Subtype	ATCC No.
Taiwan / 141 / 2002	A	H1N1	N/A
Taiwan / 2235 / 2009	A	H1N1	N/A
Taiwan / 2651 / 2010	A	H1N1	N/A
Taiwan / 12 / 2011	A	H1N1	N/A
Taiwan / 2030 / 2014	A	H1N1	N/A
NWS / 1933	A	H1N1	VR-219™
PR /8 / 1934	A	H1N1	VR-1469™
FM / 1 / 1947	A	H1N1	VR-97™
Taiwan / 3277 / 2011	A	H3N2	N/A
Taiwan / 2722 / 2012	A	H3N2	N/A
Taiwan / 2109 / 2013	A	H3N2	N/A
Taiwan / 2195 / 2014	A	H3N2	N/A
Taiwan / 534 / 2015	A	H3N2	N/A
Hong Kong / 8 / 1968	A	H3N2	VR-1679™
Taiwan / 1050 / 2014	B		N/A
Taiwan / 2578 / 2014	B		N/A
Taiwan / 3859 / 2014	B		N/A
New Caledonia / 20 /1999	A	H1N1	N/A
Anhui/1/2013	A	H7N9	N/A
Hong Kong / 486 / 1997	A	H5N1	N/A

$TCID_{50}$/mL = 50% tissue culture infectious dose

偵測特異性
本產品針對 A 型 / 或 B 型流行性感冒病毒之特異性 >99%

2. 交叉反應：
Vstrip A+B 型流行性感冒快速檢驗試劑以 15 種細菌，7 種病毒進行交叉反應測試。細菌之檢測濃度為 10^7 org/ml。病毒之檢測濃度落在 10^6 - 10^7 $TCID_{50}$/mL 之間。本實驗所用之細菌與病毒如下表，測試結果均無陽性反應。

Bacteria panel	Viral panel
Pseudomonas aeruginosa	Human respiratory syncytial virus
Serratia marcescens	Human rotavirus
Staphylococcus aureus	Adenovirus 7
Staphylococcus epidermidis	Adenovirus 40
Streptococcus Group A	human parainfluenza virus type 2
Streptococcus Group B	Echovirus type 11
Streptococcus Group C	herpes simplex virus type2
Streptococcus Group F	
Streptococcus Group G	
Streptococcus mutans	
Streptococcus pneumoniae	
Streptococcus sanguis	
Salmonella typhi	
Salmonella enteriditis	
Vibrio cholerae	

3. 干擾物測試：
以全血、市售鼻腔噴劑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)

Interference substances	
Whole Blood (4%)	Oxymetazoline HCl (10 mg/mL)
Aspirin/ Acetylsalicylic Acid (20 mg/mL)	Phenylephrine HCl (100 mg/mL)
Dextromethorphan (10 mg/mL)	Swinin nasal sprays (10%)
Diphenhydramine HCl (5 mg/mL)	

再現性

為了評估批次之間以及批次內 Vstrip A+B 型流行性感冒快速檢驗試劑的表現，使用高濃度與低濃度的 Flu A 抗原 (Texas 1/77 (H3N2)) 與 Flu B 抗原 (Hong Kong 5/72) 進行連續三天每次五重複的實驗，結果為批次之間以及批次內可 >99% 的重複再現性。

包裝形式

Vstrip Flu A&B Rapid Test.....20Tests/Kit

訂購資訊

產品型號 : IG01020S

參考資料

1. Murphy B.R. and Webster R.G., 1996, Orthomyxoviruses, pp. 1397–1445. In: Fields Virology, 3rd edition, B.N. Fields, D.M. Knipe, P.M.Howley, et al. (eds.), Lippincott-Raven, Philadelphia.
2. Biosafety in Microbiological and Biomedical Laboratories, 5th Edition. U.S. Department of Health and Human Services, CDC, NIH, Washington, DC (2007).
3. Henretig F.M. MD, King C. MD, Textbook of Pediatric Procedures, Chapter 123 – Obtaining Biologic Specimens Williams and Williams (April 1997).
4. The Clinical Virology Laboratory, Department of Laboratory Medicine at Yale: http://info.med.yale.edu/labmed/virology/booklet.html.

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

Vstrip

Vstrip Flu A&B Rapid Test
Package Insert

REF IG01020S IVD 20 TEST KIT 15°C 30°C CE

IVD Use 2016/11 V2.0
Vstrip Flu A&B Rapid Test
Registration Number:
MOHW-MD-(I)-No.005923

The Vstrip Flu A&B Rapid Test is for the detection of Influenza type A and type B viral antigens in the nasal secretions.

INTENDED USE

Vstrip Flu A&B Rapid Test is a rapid ***in vitro*** immunochromatographic assay for the qualitative detection of influenza type A and type B virus from the nasopharyngeal swab of symptomatic patients. The influenza A & B virus can be detected by this test in the very early stages of infection when symptoms have just initiated. The test is intended for professional and laboratory use as an aid in the rapid diagnosis of influenza type A and type B viral infections. The test doesn't detect Influenza type C and negative test results should be confirmed by cell culture.

SUMMARY AND EXPLANATION

Influenza viruses are single-strand RNA viruses and include type A, type B and type C. Type A viruses are classically more prevalent and are associated with the most serious influenza epidemics, while type B viruses are generally milder than type A. Type C viruses have not been previously associated with any serious epidemic diseases in history. Both types A and B viruses can prevalent simultaneously, but usually one type is dominant during a given season.[1] Influenza is a highly contagious, acute, viral infection of the upper respiratory tract. Typical symptoms of the influenza infection are an abrupt onset of fever, headache, myalgia, malaise, nonproductive cough, sore throat and rhinitis. The infection usually continues for about a week and most people recover within 1 to 2 weeks. If it occurs to the young, the elderly and people suffering from medical conditions such as lung diseases, diabetes, cancer, kidney or heart problems, influenza poses a serious threat. Under normal circumstances, the infection may lead to severe complications of underlying diseases, pneumonia and death.
Vstrip Flu A&B Rapid Test is an immunochromatographic test that using monoclonal antibody-coated latex to detect the presence of Influenza type A and type B viral antigens in the nasal secretions. The test is easy to perform and test results can be visually interpreted in 10 minutes.

PRINCIPLE OF THE TEST

Vstrip Flu A&B Rapid Test is a sandwich solid phase immunochromatographic assay. To perform the test, insert the test dipstick into the extraction buffer. The sample flows through a labeled pad containing anti-influenza A antibodies coupled to blue latex and anti-influenza B antibodies coupled to red latex. If the sample contains influenza A and/or influenza B viral antigens, the antigen will bind to the antibody to form antigen-antibody-latex complexes. These complexes move on the nitrocellulose membrane via capillary action toward the test line region in which influenza specific antibody is spotted. As the complexes reach the test line, they will bind to the antibody on the membrane in the form of a line. A purple control line will always appear in the result window to indicate that the test has been performed correctly and that the test device has functioned properly. If influenza antigen is not present, or is present at very low levels in the specimen, only the control line will be visible. If the control line does not develop, the test is invalid.

MATERIALS AND REAGENTS PROVIDED

1. Test Dipsticks (20):
   Mouse monoclonal anti-influenza A and anti-influenza B antibodies.
2. Extraction Buffer(20):
   Tube vials with detergent, protein and salt.
3. Nasopharyngeal Swabs (20)
4. Influenza A Positive Control Swab (1): Swab is coated with non-infectious recombinant influenza A antigen.
5. Influenza B Positive Control Swab (1): Swab is coated with non-infectious recombinant influenza B antigen
6. Package Insert (1)

MATERIALS NOT PROVIDED

1. Specimen containers
2. Timer or watch
3. Gloves

WARNINGS AND PRECAUTIONS

1. For ***in vitro*** diagnostic use.
2. Directions should be read and followed carefully.
3. Do not use the kit contents beyond the expiration date printed on the outside of the box.
4. Do not interchange or mix different lots of Vstrip Flu A&B Rapid Test.
5. Do not insert the test dipstick directly into the sampling area (month, nasal).
6. Positive control swab should be mixed in the extraction buffer gently before use.
7. Disregard test results beyond specified time (10 min).
8. Use appropriate precautions in the collection, handling, storage, and disposal of patient samples and used kit contents.[2]
9. Use of Nitrile or Latex gloves is recommended when handling patient samples.[2]
10. Dispose of containers and used contents in accordance with Local requirements.
11. Do not reuse kit components or test devices.
12. The test dipsticks must remain sealed in the protective foil pouch until use.
13. To obtain accurate results, you must follow the Package Insert.
14. Inadequate or inappropriate specimen collection, storage, and transport may yield false test results.
15. Seek specific training or guidance if you are not experienced with specimen collection and handling procedures.[3, 4]

STORAGE

1. The product should be stored at 15-30℃ , away from direct sunlight.
2. Kit contents are stable until the expiration date printed on the outer box.
3. The test dipsticks must be kept in the sealed pouch until use.
4. Do not freeze or overheat the test kit or kit reagents.

SPECIMEN COLLECTION AND HANDLING

Proper specimen collection, storage, and transport are critical to the performance of this test.

Nasal Swab Sample:
It is important to obtain as much secretion as possible. Therefore, to collect a nasal swab sample, insert the sterile swab into the nostril that presents the most secretion under visual inspection. Using gentle rotation, push the swab until resistance is met at the level of the turbinates (less than one inch into the nostril). Rotate the swab a few times against the nasal wall.

Nasopharyngeal Swab Sample:
For optimal test performance, use the swabs supplied in the kit.
It is important to obtain as much secretion as possible. Therefore, to collect a nasopharyngeal swab sample, carefully insert the sterile swab into the nostril that presents the most secretions under visual inspection. Keep the swab near the septum floor of the nose while gently pushing the swab into the posterior nasopharynx. Rotate the swab several times.

ASSAY PROCEDURE

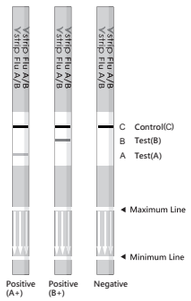
All clinical specimens must be at ***room temperature*** before beginning the assay.
Expiration date: Check the expiration date on each individual test package or outer box before use. Do not use any test beyond the expiration date on the label.

1. Place the swab with sample into the extraction buffer. Roll the swab ***ONLY*** three (3) times while pressing the head against the bottom and the side of the extraction buffer. Leave the swab in the extraction buffer for 1 minute.
2. Roll the swab head against the inside of the extraction buffer as you remove it. Dispose of the used swab in accordance with your biohazard waste disposal protocol.
3. Place the test dipstick into the extraction buffer with the arrows on the test dipstick pointing down. Do not handle or move the test dipstick until the test is complete and ready for interpretation.
4. Read result at 10 minutes. Some positive results may appear sooner. Do not read the result after 10 minutes.

INTERPRETATION OF RESULTS

Positive result
At 10 minutes, the appearance of ANY shade of a blue and/or red Test Line below the purple Control Line, and the appearance of a purple procedural Control Line indicates a positive result for the presence of influenza A and/or B viral antigen.

1. If only a ***BLUE*** line appears below the Control Line (C), the test result is positive for type A (A).
2. If only a ***RED*** line appears below the Control Line (C), the test result is positive for type B (B).
3. If both a ***BLUE*** and ***RED*** line appear below the Control Line (C), the test results are positive for both types A (A) and type B (B) .



Negative result
At 10 minutes, the appearance of ***ONLY*** the purple procedural Control Line indicates influenza A and B antigen were not detected. A negative result indicates that the sample is negative for antigen or the antigen level is below the detection limit.

Invalid
If at 10 minutes, the purple procedural Control Line does not appear, even if a Blue or Red Test Line (A or B) appears, the result is considered invalid. If the test is invalid, a new test should be performed with a new patient sample and a new test dipstick.

QUALITY CONTROL

The Vstrip Flu A&B Rapid Test contains external controls within the kit in order to allow users to confirm the integrity of the test dipstick.

Positive Control
1. Place the positive control swab into the extraction buffer.
2. Mix the solution by rotating the positive control swab forcefully against the side of the extraction buffer at least 1 minute. Extract as much liquid as possible from the swab, squeezing the sides of the extraction buffer as the swab is withdrawn. Discard the swab with biohazard waste disposal protocol.
3. Remove the test dipstick from its protective foil pouch before using it.
4. Put the test dipstick into the extraction buffer (the arrows pointing down).
5. Read the result within 10 minutes. Do not read the test result later than 10 minutes.

LIMITATIONS

1. The contents of this kit are to be used for the qualitative detection of influenza A and B antigen from the Nasal and Nasopharyngeal swab.
2. A negative test result may occur if the level of antigen in a sample is below the detection limit of the test.
3. Failure to follow the Test Procedure and interpretations of Test Results may adversely affect test performance and/or invalidate the Test Results.
4. Test Results must be evaluated in conjunction with other clinical data available to the physician.
5. Negative test results do not rule out other potential non-influenza viral infections. Negative results should be confirmed by cell culture.
6. Positive test results do not rule out co-infections with other pathogens.
7. Positive test results do not identify specific influenza A or B virus subtypes.
8. Positive and negative predictive values are highly dependent on prevalence. False negative test results are more likely during peak activity when the prevalence of disease is high. False positive test results are more likely during periods of low influenza activity when prevalence is moderate to low.
9. Individuals who received nasally administered influenza vaccine may have positive test results for up to three days after vaccination.
10. Monoclonal antibodies may fail to detect, or detect with less sensitivity, influenza viruses that have undergone minor amino acid changes in the target epitope region.
11. If differentiation of specific influenza A or B subtypes and strains is needed, additional testing, in consultation with the state or local public health department, is required.
12. Background does not affect the interpretation of the results.

PERFORMANCE CHARACTERISTICS

Analytical sensitivity (Limit of Detection)
The analytical sensitivity was evaluated using 20 influenza strains; 17 influenza A and 3 influenza B strains. Each strain was serially diluted in Vstrip extraction buffer. Strains were assayed in triplicate using the Vstrip Flu A&B Rapid Test until no positive signal could be observed. Results are summarized below:

The lowest $TCID_{50}$/mL obtained for Flu A was 2.64 x 10^5
The lowest $TCID_{50}$/mL obtained for Flu B was 3.71 x 10^5

Viral Strain	Type	Subtype	ATCC No.
Taiwan / 141 / 2002	A	H1N1	N/A
Taiwan / 2235 / 2009	A	H1N1	N/A
Taiwan / 2651 / 2010	A	H1N1	N/A
Taiwan / 12 / 2011	A	H1N1	N/A
Taiwan / 2030 / 2014	A	H1N1	N/A
NWS / 1933	A	H1N1	VR-219™
PR /8 / 1934	A	H1N1	VR-1469™
FM / 1 / 1947	A	H1N1	VR-97™
Taiwan / 3277 / 2011	A	H3N2	N/A
Taiwan / 2722 / 2012	A	H3N2	N/A
Taiwan / 2109 / 2013	A	H3N2	N/A
Taiwan / 2195 / 2014	A	H3N2	N/A
Taiwan / 534 / 2015	A	H3N2	N/A
Hong Kong / 8 / 1968	A	H3N2	VR-1679™
Taiwan / 1050 / 2014	B		N/A
Taiwan / 2578 / 2014	B		N/A
Taiwan / 3859 / 2014	B		N/A
New Caledonia / 20 /1999	A	H1N1	N/A
Anhui/1/2013	A	H7N9	N/A
Hong Kong / 486 / 1997	A	H5N1	N/A

$TCID_{50}$/mL = 50% tissue culture infectious dose

Detection Specificity
Vstrip Flu A&B Rapid Test detects the influenza A and/or influenza B virus at >99% specificity.

Cross reactivity study
The Vstrip Flu A&B Rapid Test was evaluated with a total of 15 bacteria, 7 viruses. Bacteria were evaluated at 10^7 org/ml. Viruses were evaluated at a concentration of at least 10^6–10^7 $TCID_{50}$ /mL. None of the microorganisms tested in the following table gave a positive result.

Bacteria panel	Viral panel
Pseudomonas aeruginosa	Human respiratory syncytial virus
Serratia marcescens	Human rotavirus
Staphylococcus aureus	Adenovirus 7
Staphylococcus epidermidis	Adenovirus 40
Streptococcus Group A	human parainfluenza virus type 2
Streptococcus Group B	Echovirus type 11
Streptococcus Group C	herpes simplex virus type2
Streptococcus Group F	
Streptococcus Group G	
Streptococcus mutans	
Streptococcus pneumoniae	
Streptococcus sanguis	
Salmonella typhi	
Salmonella enteriditis	
Vibrio cholerae	

INTERFERING SUBSTANCES

Whole blood, Swinin nasal spray products and common chemicals were evaluated and did not interfere with the Vstrip Flu A&B Rapid Test at the levels tested above:

Interference substances	
Whole Blood (4%)	Oxymetazoline HCl (10 mg/mL)
Aspirin/ Acetylsalicylic Acid (20 mg/mL)	Phenylephrine HCl (100 mg/mL)
Dextromethorphan (10 mg/mL)	Swinin nasal sprays (10%)
Diphenhydramine HCl (5 mg/mL)	

PRECISION STUDIES

The total, within-run, and between-run performance of the Vstrip Flu A&B Rapid Test was evaluated for precision. A panel consisting of two different levels of influenza A antigen (Texas 1/77(H3N2); weak positive and strong positive) and two different levels of influenza B antigen (Hong Kong 5/72; weak positive and strong positive) were repeated five times with a single lot of Vstrip Flu A&B Rapid Test on three different days. >99% accuracy was obtained from all specimens tested.

PACKAGING

Vstrip Flu A&B Rapid Test.....20 Tests/Kit

ORDERING INFORMATION

Product No. : IG01020S

REFERENCES

1. Murphy B.R. and Webster R.G., 1996, Orthomyxoviruses, pp. 1397–1445. In: Fields Virology, 3rd edition, B.N. Fields, D.M. Knipe, P.M.Howley, et al. (eds.), Lippincott-Raven, Philadelphia.
2. Biosafety in Microbiological and Biomedical Laboratories, 5th Edition. U.S. Department of Health and Human Services, CDC, NIH, Washington, DC (2007).
3. Henretig F.M. MD, King C. MD, Textbook of Pediatric Procedures, Chapter 123 – Obtaining Biologic Specimens Williams and Williams (April 1997).
4. The Clinical Virology Laboratory, Department of Laboratory Medicine at Yale: http://info.med.yale.edu/labmed/virology/booklet.html.

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
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