Vstrip

Vstrip 呼吸道融合細胞病毒快速檢驗試劑
說明書

REF IG02020C　IVD 20 TEST KIT　15°C 30°C　CE

體外診斷使用 2017/04 V01
呼吸道融合細胞病毒快速檢驗試劑
衛部醫器製壹字第 005975 號

Vstrip 呼吸道融合細胞病毒快速檢驗試劑用於檢測患者使用鼻咽拭子及鼻咽沖洗 / 吸取液檢體中的呼吸道融合細胞病毒抗原。

效能

Vstrip 呼吸道融合細胞病毒快速檢驗試劑是一種體外快速定性檢測試劑，針對具有 RSV 症狀之患者，檢測其鼻咽拭子及鼻咽沖洗 / 吸取液中 RSV 抗原。本測試僅適用於實驗室及專業用途，旨在協助診斷患者是否感染呼吸道融合細胞病毒。若本測試呈現陰性結果須以細胞培養或以直接螢光抗體試驗 (DFA) 進行確診。

闡釋

呼吸道融合細胞病毒 (Respiratory Syncytial Virus, RSV)，是引起嬰兒細支氣管炎和肺炎最常見原因[1,2]。RSV 的初次感染常發生在 6 周至 2 歲的小孩。造成 RSV 細支氣管炎及肺炎的年齡，則是在 2 個月至 6 個月。高危險群如早產、先天性心臟病、支氣管肺葉發育不全、慢性肺病、神經肌肉病變等的嬰兒更要特別注意，RSV 可能會造成嚴重肺部感染，可能會因此需要住院治療。RSV 也會引起老年人嚴重的呼吸道感染及免疫力低下。[3,4]
RSV 感染初期可能會造成的症狀包括發燒、流鼻水。當病毒擴散到肺部，症狀會惡化，包括咳嗽、呼吸困難、呼吸快速、氣喘 (有喘鳴聲)。由於早期症狀類似一般感冒，一般無法由病徵確診為 RSV 感染，使用呼吸道融合細胞病毒快速檢驗試劑可以協助醫師早期辨識並正確投藥，防止不必要的抗生素及其他處理。[5] Vstrip 呼吸道融合細胞病毒快速檢驗試劑是一種免疫層析試驗，使用單株抗體接合之膠體金粒子來檢測鼻咽拭子及鼻咽沖洗 / 吸取液中 RSV 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 呼吸道融合細胞病毒快速檢驗試劑是一種複合式固相免疫層析。執行測試時，將含有萃取液及樣品的混合液加入檢驗試劑匣中。樣品將流經一個內含膠體金粒子 (接合 RSV 抗體) 之接合墊。若樣品中含有 RSV 抗原，抗原將結合到抗體上，形成抗原 - 抗體 - 膠體金粒子複合物。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紫紅色的線。另一條獨立作用的紫紅色的控制線則永遠會出現以確保測試結果是正確的。如果 RSV 抗原不存在或是低於本產品偵測極限，則只會出現一條紫紅色的控制線。如果紫紅色控制線沒有出現，則代表此測試失效。

提供的材料

1. Vstrip 呼吸道融合細胞病毒快速檢驗試劑 (20) – 內含 RSV 單株抗體。
2. 檢體萃取液 (20) – 萃取液成分包括介面活性劑、蛋白質、鹽類。
3. 拋棄式滴管 (20)
4. 無菌鼻咽採檢拭子 (20)
5. 呼吸道融合細胞病毒陽性控制組 (1)- 含無感染性 RSV 抗原、介面活性劑、蛋白質、鹽類。
6. 呼吸道融合細胞病毒陰性控制組 (1)- 含介面活性劑、蛋白質、鹽類。
7. Vstrip 呼吸道融合細胞病毒快速檢驗試劑說明書 (1)

未提供的材料

1. 檢本收集容器
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. 不要使用超過有效期限的試劑。
4. 不要調換或混合使用不同組的檢驗試劑。
5. 檢體萃取液或陽性 / 陰性控制組於滴入試劑匣時，請勿超過指定滴數 (3 滴)。
6. 超過指定時間 (10 分鐘) 之後的呈色結果不予採用。
7. 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。[6]
8. 處理患者檢體時請穿戴手套。[6]
9. 依照當地法規丟棄容器及使用過之內容物。
10. 請勿重複使用本試劑。
11. 使用前確認試劑包裝完整，若有損壞請勿使用。
12. 為了獲得正確的測試結果，請確實遵照說明書指示操作。
13. 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。
14. 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。[7]

儲存說明

1. 本試劑組應貯存於 15-30℃，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. 試劑匣已密封於鋁箔袋中，使用前再開封，且一旦開封須立即使用。

樣本採集與保存

請參考建議指南[7]或依所在機構之標準操作程序正確採集鼻咽拭子及鼻咽沖洗 / 吸取液樣本。其中鼻咽沖洗 / 吸取液樣本請使用您的操作程序中所允許之最小體積量操作，因為體積過大將降低樣本中 RSV 抗原濃度。
正確的採樣方式及運輸、保存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。

檢測程序

所有臨床樣品必須在**室溫**下開始測定。
有效日期：使用前檢查每個測試包裝或外包裝盒的有效日期。請勿使用任何過期的檢驗試劑。

鼻咽拭子測試步驟：
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至少五次，之後將拭子置於試管 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. 以拋棄式滴管自試管吸取檢體萃取液，滴 3 滴至試劑匣之樣本區。
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。

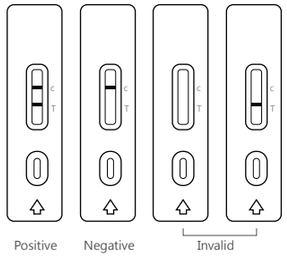
鼻咽沖洗 / 吸取液測試步驟：
1. 使用拋棄式滴管吸取 0.5 ml 之鼻咽沖洗 / 吸取液，置於裝有萃取液的試管中。
2. 將試管蓋旋緊，輕搖使溶液混合，等待 1 分鐘使反應完全。
3. 以拋棄式滴管 (步驟 1 所使用之同一支滴管) 自試管吸取檢體萃取液，並滴 3 滴至試劑匣之樣本區。
4. 於 10 分鐘時判讀結果。(部分陽性結果可能更快出現。) 超過 10 分鐘請勿判讀。

結果判讀

陽性結果 (Positive)：
反應時間 10 分鐘時，於試劑匣 T 處出現紫紅色測試線，同時於試劑匣 C 處出現紫紅色控制線，此即陽性結果，表示偵測到 RSV 抗原。

陰性結果 (Negative)：
反應時間 10 分鐘時，僅於試劑匣 C 處出現紫紅色控制線，未於 T 處出現紫紅色測試線，據以推斷為陰性結果，表示未偵測到 RSV 抗原或 RSV 抗原量小於偵測極限。

無效反應 (Invalid)：
反應時間 10 分鐘時，只要試劑匣 C 處未出現紫紅色控制線，即使 T 處出現紫紅色測試線，結果仍視為無效。若在 10 分鐘時，背景顏色尚未褪去，且干擾到判讀，結果視為無效。如果測試是無效的，應使用新的樣本和新的試劑匣重新進行測試。



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紫紅色線作為控制線，用以確保操作程序正確及樣本量足夠。
陽性控制組應於測試區顯示出一條明顯的紫紅色線作為測試線，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 / 陰性控制組：
1. 取陽性或陰性控制組滴眼瓶直接滴 3 滴於試劑匣之樣本區。
2. 於 10 分鐘時判讀結果。

產品限制

1. 該試劑的內容物將用於定性檢測鼻咽拭子及鼻咽沖洗 / 吸取液中採檢的 RSV 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 RSV 病毒的感染。陰性結果必須要經過細胞培養來確定。
6. 陽性結果不能排除其他病原體共同感染的可能。
7. RSV 病毒抗原辨識位上的胺基酸經過些微改變後，單株抗體可能會無法偵測到或是靈敏度較差。

產品效能

偵測靈敏度 (偵測極限)
取 2 種 RSV 病毒株進行測試。測試時每個病毒株皆以 Vstrip 檢體萃取液稀釋至沒有陽性訊號為止。(測試結果如下表)

Subgroup	RSV strain	$TCID_{50}$/ mL
A	A2 (ATCC VR-1540)	1.12×10^3
B	18537 (ATCC VR-1580)	8.89×10^3

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

交叉反應

Vstrip 呼吸道融合細胞病毒快速檢驗試劑以 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 CFU/mL。病毒之檢測濃度落在 10^6 -10^8 $TCID_{50}$/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。

細菌：

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

病毒：

Adenovirus type 7
Echovirus type 11
Influenza A virus H1N1
Influenza B virus
Human parainfluenza virus type 2
Herpes simplex virus type2
Influenza A virus H3N2

干擾物測試

以血紅素、一般常用藥物及市售鼻腔噴劑進行測試，結果顯示以下藥物並不會干擾本試劑之測試結果。

Interference substances/ Concentration

Hemoglobin (2%)
Aspirin/ Acetylsalicylic Acid (20 mg/mL)
Dextromethorphan (10 mg/mL)
Diphenhydramine HCl (5 mg/mL)
Oxymetazoline HCl (10 mg/mL)
Phenylephrine HCl (100 mg/mL)
Swinin nasal sprays (10%)

包裝

Vstrip 呼吸道融合細胞病毒快速檢驗試劑 .....20 組 / 盒

訂購資訊

產品型號 : IG02020C

參考資料

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6. Biosafety in Microbiological and Biomedical Laboratories, 5th Edition. U.S. Department of Health and Human Services, CDC, NIH, Washington, DC (2007).
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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+ / CONTROL−	陽性控制組 / 陰性控制組		不可重複使用
i	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

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 RSV Rapid Test
Package Insert

REF IG02020C IVD 20 TEST KIT 15℃ 30℃ CE

IVD Use 2017/04 V01
Vstrip RSV Rapid Test
Registration Number:
MOHW-MD-(I)-No.005975

Vstrip RSV Rapid Test is for the detection of respiratory syncytial virus (RSV) antigen in patient's specimen by using nasopharyngeal (NP) swab and nasopharyngeal (NP) wash/ aspirate.

INTENDED USE

The Vstrip RSV Rapid Test is an immunochromatographic test for rapid, qualitative detection of RSV from NP swab and NP wash / aspirate specimen. This test is intended for in vitro diagnostic use to aid in the diagnosis of RSV infections in patients. It is recommended that negative test results be confirmed by cell culture or DFA.

SUMMARY AND EXPLANATION

Respiratory syncytial virus (RSV) is the most frequent cause of infantile bronchiolitis and pneumonia.[1,2] Initial RSV infection often occurs in 6 weeks to 2 years old child, and the age of bronchiolitis and pneumonia caused by RSV infection is about 2 months to 6 months. Babies who are premature, congenital heart disease, bronchial lung hypoplasia, chronic lung disease, neuromuscular diseases, are considered as the high risk groups and requires more attention. RSV has also been implicated in severe respiratory infections in the elderly and immunocompromised.[3,4] Since RSV infection may lead to serious or even fatal lung infection, therefore hospitalization is required for high-risk patients. Early symptoms of RSV infection may show symptoms such as fever and runny nose. When the virus spreads to the lungs, the symptoms will aggravated which can be coughing, difficulty breathing, rapid breathing, wheezing. Since the early symptoms are similar to a common cold, it is hard to confirm the patient is RSV infected by these symptoms, therefore the use of Rapid Test can help physicians have early identification of the virus, give the correct dosage to patients, and prevent unnecessary antibiotics or other treatments being used. [5]
The Vstrip RSV Rapid Test is an immunochromatographic test that uses antibody-coated colloidal gold to detect the presence of RSV antigen in NP swab and NP wash / aspirate from symptomatic patients. The test is easy to perform and test results can be visually interpreted in 10 minutes.

PRINCIPLE OF THE TEST

The Vstrip RSV Rapid Test is a lateral flow immunochromatographic assay for the direct visual detection of RSV antigen in extracted specimen. When extracted specimen is added to the sample well, RSV antigen bind to the antibody coupled immunogold in the strip to form an antigen-antibody complex. This complex migrates across the test strip membrane and is captured by the line of RSV monoclonal antibody to form an antibody-antigen-antibody sandwiches and a reddish-purple line is observed in the test region. An independent 2nd functional control line in the control region will always appear which indicates that the test has been performed correctly. If RSV antigen is not present, or is present at very low level 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 cassettes (20) – Mouse monoclonal anti-RSV antibodies.
2. Extraction buffer vial (20) – with detergent, protein and salt.
3. Disposable droppers (20)
4. Sterile nasopharyngeal swabs (20)
5. Positive control reagent (1): With non-infectious RSV antigen, detergents, protein and salt.
6. Negative control reagent (1): With detergents, protein and salt.
7. 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. 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 reagents.
5. Do not add more than specified volume (3 drops) of sample extract buffer or positive/negative control to cassette.
6. Disregard test results beyond specified time (10 min).
7. Use appropriate precautions in the collection, handling, storage, and disposal of patient samples and used kit contents.[6]
8. Use of Nitrile or Latex gloves is recommended when handling patient samples.[6]
9. Dispose of containers and used contents in accordance with Federal, State and Local requirements.
10. Do not reuse kit components or test devices.
11. The Test Cassettes must remain sealed in the protective foil pouch until use.
12. To obtain accurate results, you must follow the Package Insert.
13. Inadequate or inappropriate specimen collection, storage, and transport may yield false test results.
14. Seek specific training or guidance if you are not experienced with specimen collection and handling procedures.[7]

STORAGE INSTRUCTION

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

SPECIMEN COLLECTION AND HANDLING

Collect patient specimen by following the recommended guideline[7] or your institution's protocol for obtaining NP swab and NP wash / aspirate specimen. For NP wash / aspirate specimen, use the minimal amount of saline that your procedure allows, as excess volume will decrease the concentration of antigen in the specimen.

ASSAY PROCEDURE

Performing the assay outside the time and temperature ranges provided may produce invalid results. Assays not performed within the established time and temperature ranges must be repeated.

Expiration date:
Check expiration on each individual test package or outer box before using. Do not use any test past the expiration date on the label.

NP Swab Test Procedure

1. Place the swab with sample into the reagent tube. Roll the swab at least five (5) times while pressing the head of swab against the tube bottom and the side of the reagent tube. Leave the swab in the reagent tube for one (1) minute.
2. Roll the swab head against the inside wall of reagent tube as you remove it. Dispose of the used swab according to the biohazard waste disposal protocol.
3. Use the disposable dropper to transfer 3 drops of sample extract buffer from the reagent tube to the sample well of the cassette.
4. Read result at 10 minutes. Some positive results may appear sooner. Do not read the result after 10 minutes.

NP Wash/Aspirate Test Procedure

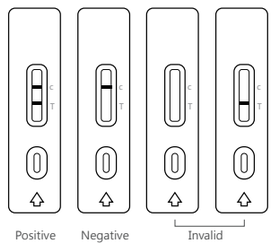
1. Use the disposable dropper to draw 0.5 ml of the NP wash/aspirate sample and add to the extraction tube.
2. Screw the cap of the extraction tube and swirl it to mix. Wait 1 minute to allow the mixture to react.
3. Use the disposable dropper (the same dropper of item 1) to transfer 3 drops of sample extract buffer from the reagent tube to the sample well of the cassette.
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, a visible reddish-purple line appears in the window next to the Test Line (T), and a reddish-purple line next to the Control Line (C). This indicates RSV antigen was detectable in the specimen.

Negative Result
At 10 minutes, the appearance of only one reddish-purple line in the Control Line (C) and no reddish-purple line in the Test Line (T) indicates that the sample is negative for RSV antigen or the antigen level is below the detection limit.

Invalid
If at 10 minutes, a reddish-purple line next to the Control (C) is not visible or the background color interferes with interpretation of the test or control lines, the test is uninterpretable. An uninterpretable test must be repeated, a new specimen obtained and retested, or the specimen sent to the clinical laboratory for culture isolation.



QUALITY CONTROL

The Positive Controls should be assayed once upon receipt of the kit. Internal procedural controls are included in the test. A reddish-purple line appearing in the control region is an internal control. It confirms sufficient specimen volume and correct procedural technique. The Positive Controls, a visible reddish-purple line appears in the window next to the Test Line (T). 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/ Negative Control Test Procedure
1. Add 3 drops of control solution to the sample well on the cassette directly.
2. Read the result at 10 minutes. Do not read result after 10 minutes.

LIMITATIONS OF THE PROCEDURE

1. The contents of this kit are to be used for the qualitative detection of RSV antigen from the NP swab and NP wash / aspirate specimen.
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-RSV viral infections. Negative results should be confirmed by cell culture.
6. Positive test results do not rule out co-infections with other pathogens.
7. Monoclonal antibodies may fail to detect, or detect with less sensitivity, RSV viruses that have undergone minor amino acid changes in the target epitope region.

PERFORMANCE CHARACTERISTICS

Analytical sensitivity (Limit of Detection)
The analytical sensitivity was evaluated using 2 RSV strains. Each strain was serially diluted in Vstrip extraction buffer. Strains were assayed in triplicate using the Vstrip RSV Rapid Test until no positive signal could be observed. Results are summarized below:

Subgroup	RSV strain	$TCID_{50}$/ mL
A	A2 (ATCC VR-1540)	1.12×10^3
B	18537 (ATCC VR-1580)	8.89×10^3

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

Cross reactivity study

The Vstrip RSV Rapid Test was evaluated with a total of 15 bacteria, 7 viruses. Bacteria were evaluated at 10^7 CFU/mL. Viruses were evaluated at a concentration of at least 10^6–10^8 $TCID_{50}$/mL. None of the microorganisms tested in the following table gave a positive result in the Vstrip RSV Rapid Test.

Bacterial Panel

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 cholerae	

Viral Panel

Adenovirus type 7	Human parainfluenza virus type 2
Echovirus type 11	Herpes simplex virus type2
Influenza A virus H1N1	Influenza A virus H3N2
Influenza B virus	

Interfering Substances

Hemoglobin, common chemicals and a commercial nasal spray product were evaluated and did not interfere with the Vstrip RSV Rapid Test at the levels tested below:

Interference substances/ Concentration

Hemoglobin (2%)	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)	

PACKAGING

Vstrip RSV Rapid Test.....20 Tests/Kit

ORDERING INFORMATION

Product No. : IG02020C

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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+ / CONTROL−	Positive Control / Negative 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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