Vstrip

A 型鏈球菌快速檢驗試劑 說明書

體外診斷使用 2016/02 V1.0
Vstrip Strep A Rapid Test
產品型號 : IG03020S
衛署醫器製壹字第 005976 號

產品說明書
此體外檢驗試劑產品為提供給於專業人士使用，利用快速免疫色層分析法原理，去偵測咽喉拭子檢體上是否具有來自 A 型鏈球菌其碳水化合物醣類抗原。

預期使用
PBF Vstrip A 型鏈球菌快速檢驗試劑為一可快速檢測病患咽喉拭子上是否有 A 型鏈球菌抗原的定性免疫色層分析檢測法。此檢測試劑主要是可以幫助臨床上快速診斷病患是否具有 A 型鏈球菌其病原菌之感染。

摘要說明
A 型鏈球菌為造成細菌性咽喉炎最主要的病原菌，而針對這些感染 A 型鏈球菌的患者們，服用抗生素通常為最佳及最有效的治療方式。但若未能及時給予最適切的治療時，A 型鏈球菌的感染常常會轉變成嚴重的急性關節風濕症。然而傳統上偵測 A 型鏈球菌感染的方法為臨床檢體的細胞培養，從採檢病患的喉頭拭子到實驗室培養出具有 beta 型溶血特徵的菌落，常常需要長達 24-48 小時的實驗流程。利用免疫學方法鑑定 A 型鏈球菌的主要原理是偵測 A 型鏈球菌其外膜上碳水化合物醣類抗原。PBF Vstrip A 型鏈球菌快速檢驗試劑是－快速且定性的檢測法，能夠於 5 分鐘的檢測時間內，顯示喉頭拭子檢體上是否具有 A 型鏈球菌病原菌存在。

偵測原理
PBF Vstrip A 型鏈球菌快速檢驗試劑是－種利用硝化纖維膜做免疫色層分析的檢測法，可偵測咽喉拭子上的來自 A 型鏈球菌的抗原。整個檢測過程，首先需要進行咽喉拭子刷的採檢；再利用萃取液 A 與 B 劑的混合液將咽喉拭子上的病原菌抗原萃取出來，最後將檢驗試劑條放入檢體萃取液內進行測試。假如檢體萃取液內含有 A 型鏈球菌病原菌，將與接附於紅色微小乳膠粒子的特異性抗體結合成一複合物，而這些抗原 - 乳膠複合物將會與吸附於硝化纖維上的特異性抗體結合，當累積一定數量的抗原 - 乳膠複合物後，即會形成肉眼可見的紅色測試線，顯示陽性的結果。而藍色的控制線也應同時出現，顯示本測試結果是具有效力的。

試劑與材料
- 20 個 Vstrip A 型鏈球菌快速檢驗試劑
- 20 個檢體萃取軟管
- 20 支無菌咽喉拭子刷
- 10 毫升檢體萃取液 A 劑
- 10 毫升檢體萃取液 B 劑
- 1 毫升陽性控制組 (去活化 A 型鏈球菌菌液，含防腐劑)
- 1 毫升陰性控制組 (去活化 C 型鏈球菌菌液，含防腐劑)
- 使用說明書

未提供材料
- 計時器或手錶

注意事項 (注意)
1. 本產品為體外檢驗試劑使用。
2. 請在有效期限內使用。
3. 任何本產品所使用到的材料或瓶罐請依照相關規範丟棄。
4. 未使用前請勿拆封試劑之鋁箔包裝，以保持產品活性。
5. 試劑及檢體操作區域請勿飲食。
6. 操作所有可能具有感染性的檢體，請遵循所有的防治微生物危害的相關注意事項，任何檢體的丟棄也請遵循標準程序流程進行。
7. 操作檢體時，請穿戴實驗衣、手套及護目鏡。
8. 警告 : 抗原萃取液 A 劑的內含物，若誤食或接觸皮膚將有害人體；也可能對眼睛造成不適。
9. 注意 : 抗原萃取液 B 劑可能造成皮膚、眼睛以及呼吸道的刺激。
10. 陽性與陰性控制組內含疊氮化鈉 (NaN3) 做為防腐劑。
11. 請勿交換試劑組內萃取液 A 劑與 B 劑的瓶蓋。
12. 請勿交換試劑組內陽性與陰性控制組的瓶蓋。
13. 不適當的溫度與濕度將對本產品試驗結果造成不利的影響。

儲存條件
- 本檢驗試劑組請保存於 15-30°C 的環境，並請上緊所有試劑的瓶蓋。
- 請勿使用過期的檢驗試劑或任何試劑溶液。

檢體的收集及處理
請使用本試劑組內附的拭子刷進行檢體的採集 (請使用所檢附之人造纖維材質的拭子刷頭採檢，另外藻酸鈣或棉質刷頭的木質採檢刷不適用)。首先將咽喉拭子刷深入嘴內於喉頭的背部，於懸雍垂的兩側或扁桃腺區域進行採檢，將拭子刷進行來回二至三次的檢體收集。請避免接觸牙齒、牙齦、舌頭或臉頰的表面。採檢後請立即處理咽喉拭子。假如有細菌培養的需求，請先在執行 PBF A 型鏈球菌快速檢試劑的檢測之前，將咽喉拭子進行培養基的接種。將拭子刷於洋菜膠培養基上四分之一的區域，紮實地旋轉拭子刷，進行接種。由於 PBF A 型鏈球菌快速檢驗試劑其檢體萃取液將會使病原菌失去活性，故在未接種培養基前，請勿進行任何檢驗試劑的操作。並且在接種完畢後，立即進行檢驗試劑抗原萃取的步驟，以確保最佳抗原活性存在。如檢體未能立即進行處理，可將拭子刷檢體放置於乾淨的試管內做保存或進行運送。咽喉拭子刷檢體能夠儲存於 2-8 °C 長達 72 小時。此外，本產品不建議使用一般常規使用的傳送培養基 (transport media) 來儲存運送拭子刷檢體。

試劑品質控制
試劑內建品管控制
PBF Vstrip A 型鏈球菌快速檢試劑在每一次進行試驗時，分別有兩處不同類型的內部品管控制的設計，可做為監控本試劑的品質及有效性。我們建議每日的第一次測試的結果，可將這些內部品管控制的結果紀錄下來，做為每日的品質紀錄的內容。在試劑方面，正常有效的抗原萃取液，在混合後，會從先前的粉紅色變為無色或淡黃色。在檢驗試劑方面，在正常操作及合理適當體積的檢體萃取液搭配下，試劑上的控制線將會明顯地轉變為藍色，顯示整個試劑的毛細現象反應正常且有效。

外部品管控制測試
外部控制組的功能同樣也是證明本試劑組內試劑溶液及試劑反應仍是有效的。若有下列任何情形，我們建議使用試劑組內附的陽性與陰性控制組，進行試劑有效性的驗證。
- 未訓練的操作員，進行試劑的標準流程操作
- 每批新進貨的試劑組，進行試劑有效性確認
- 不同批次的試劑組，進行試劑有效性確認
- 法規認證及其他特殊要求，需要進行試劑有效性確認

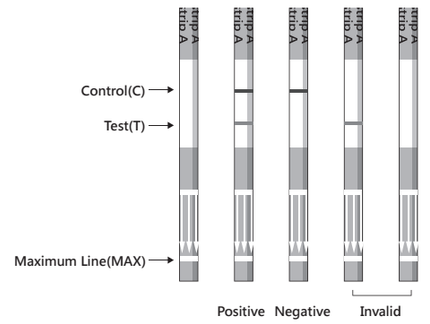
假如控制組試驗反應結果不如預期，請再重複測試一次或與我們寶齡檢驗試劑部。若上述問題尚未得到解決前，請勿操作執行臨床檢體。

試劑分析操作步驟
所有臨床檢體的測試，在測試前都必須要回到一般室溫況態
1. 於檢體萃取軟管內加入 5 滴的檢體萃取液 A 劑 (粉紅色) 與 5 滴的檢體萃取液 B 劑 (混合後溶液應轉變為淡黃色)。
2. 隨即將採檢過後咽喉拭子刷放入檢體萃取軟管內。將咽喉拭子刷抵住萃取軟管管壁，轉動至少 10 次，劇烈地混合萃取液，並放置 1 分鐘反應 (當檢體被萃取的越徹底，越能得到較佳的實驗結果)。
3. 取出拭子刷時，擠壓軟管壁將拭子刷上的萃取液儘可能地留在軟管內，丟棄拭子刷。
4. 打開鋁箔包裝，取出試劑並依照箭頭方向將之放入萃取液軟管內。
5. 等待 5 分鐘後做試劑結果判讀。

結果判讀
陽性結果 : 兩條明顯的判讀線
一條應呈現於控制區，一條應呈現於測試區。陽性結果表示檢體內有 A 型鏈球菌被偵測到。
注意 : 測試線其紅色的強弱主要是取決於檢體內 A 型鏈球菌的菌量。所以，任何肉眼可辨識的紅色線條，於測試區內出現，都應被視為陽性結果。

陰性結果 : 一條明顯的控制線出現
無紅色的判讀線出現於測試區。陰性結果顯示 A 型鏈球菌無出現於檢體內，或低於本產品的偵測極限。病患檢體應該利用培養基培養來真正確認無 A 型鏈球菌的感染。假如病患臨床的症狀與本試劑測試結果不一致，請取得另一臨床檢體進行病原菌的培養。

無效判讀 : 控制線無出現
未足夠的檢體萃取液體積與不正確的試劑操作流程是造成控制線未出現為最常見的原因。發生此現象時，請在仔細閱讀操作說明並且使用新的檢驗試劑條重新進行檢體的測試。假如情況沒有改善，請馬上終止使用此組試劑產品並與寶齡檢驗試劑部聯絡。



產品限制
- PBF A 型鏈球菌快速檢驗試劑並不能區分具有活性或失活的病原菌。病患若是正在進行 A 型鏈球菌感染的治療或相似的感染，本試劑都可能檢測出陽性的結果，且可能持續一段時間，主要是因為在有效治療後，可能會出現有失去活性的病原菌產生。
- 能引起咽喉炎的病原菌不單只有 A 型鏈球菌此病原菌，故如果實驗室檢驗結果與臨床症狀不一致，請在進行其他的檢測或病原菌的培養。
- 喉頭的採檢，若是採集到過多血液或黏液，可能會干擾本檢驗試劑的性能並產生偽陽性的結果。故進行咽喉採檢時，請避免接觸到舌頭、口腔內側臉頰與牙齒或任何口腔內流血的區域。
- PBF A 型鏈球菌快速檢驗試劑並不能區分出無症狀的 A 型鏈球菌帶原者與以發病症狀明顯的 A 型鏈球菌感染患者。
- 陰性的檢測結果有可能來自於萃取出病原菌抗原的濃度已經低於本產品的偵測極限，故任何本試劑所得到的陰性結果，都建議進行病原菌培養基的培養來進行再次確認。
- 使用單一支咽喉拭子刷同時進行病原菌培養基的接種與本快速檢驗試劑的檢測，可能會降低 PBF A 型鏈球菌快速檢驗試劑的檢出率與靈敏性。

產品性能特徵
分析靈敏性 (偵測極限)
測試了所有來自台灣生物資源保存及研究中心所保存的 A 型鏈球菌株，在本試劑檢驗的結果全都顯示為陽性。在所有的菌株都經由微生物學標準定量分析法進行定量的情況下，進行了分析靈敏性分析實驗。其中由 A 型鏈球菌編號 ATCC 19615 此菌株做連續稀釋，進行 PBF A 型鏈球菌快速檢驗試劑的靈敏性測試，可得知最低偵測極限為每一個測試反應中含有 4.0×10^4 CFU 此菌量。

分析特異性 (交叉反應)
為了了解 PBF A 型鏈球菌快速檢驗試劑的特異性，我們收集並測試了 34 株常見於咽喉區域共生或致病的微生物 (包含了 14 株細菌及 20 株病毒)，所有下表列出的微生物在本產品的測試都顯示了陰性的結果。其濃度範圍區間為，病毒方面為 10^2 - 10^9 TCID50/ml，在細菌方面為 10^7 – 10^8 organisms/ml。

病毒株	細菌
Influenza A virus H1N1 (swine) Taiwan 2009	Pseudomonas aeruginosa
Influenza A virus H1N1 (swine) Taiwan 2010	Serratia marcescens
Influenza A virus H1N1 (human) WSN 1933	Staphylococcus aureus
Influenza A virus H1N1 (human) PR 1934	Staphylococcus epidermidis
Influenza A virus H1N1 (swine) Taiwan 2014	Streptococcus Group B
Influenza A virus H1N1 (swine) Taiwan 2011	Streptococcus Group C
Influenza A virus H3N2 Taiwan 2011	Streptococcus Group F
Influenza A virus H3N2 Taiwan 2013	Streptococcus Group G
Influenza A virus H3N2 Taiwan 2014	Streptococcus mutans
Influenza A virus H3N2 Taiwan 2015	Streptococcus pneumoniae
Influenza B virus Taiwan 2014-1	Streptococcus sanguis
Influenza B virus Taiwan 2014-2	Salmonella typhi
Influenza B virus Taiwan 2014-3	Salmonella enteriditis
Adenovirus type 7	Vibrio cholerae
Adenovirus type 41	
Respiratory syncytial virus 2958-14	
Respiratory syncytial virus 2313-15	
Human parainfluenza virus Type 2	
Echovirus Type 11	
Herpes simplex virus Type 2	

干擾物測試
下列物質為可能自然存在或人為添加出現於咽喉部或咽喉採檢檢體內，也都使用 PBF A 型鏈球菌快速檢驗試劑進行測試。下表列出濃度為本產品可容忍範圍。

項目	濃度
Ibuprofen	10 mg/ml
Aspirin/Acetylsalicylic Acid	20 mg/ml
Dextromethorphan	10 mg/ml
Diphenhydramine	5 mg/ml
Oxymetazoline HCl	10 mg/ml
Phenylephrine HCl	100mg/ml
Swinin nasal spray	10%
Hemogloblin	2%
Mucin	1%

臨床相關性
進行中

參考資料
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包裝型式
PBF Vstrip Strep A.....20 Tests/Kit

訂購資訊
產品型號 : IG03020S

符號說明 :

REF	Catalog Number./ **產品型號**
IVD	For In Vitro diagnostic use/ **體外診斷使用**
	Consult instructions for use/ **使用前請看說明書**
	Temperature Limitation/ **溫度限制**
LOT	Batch Code/ **批號**
CONTROL +	Positive Control/ **陽性控制**
CONTROL −	Negative Control/ **陰性控制**
	Use By (Expiration Date)/ **有效期限**
	Manufacturer/ **製造廠**
	Non-reusable/ **不可重覆使用**
CE	CE Marking/CE **標示**

PBF 寶齡富錦生技® Panion & BF Biotech Inc.

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Vstrip

Vstrip Strep A Rapid Test Package Insert

IVD Use 2016/02 V1.0
Vstrip Strep A Rapid Test
Product No. : IG03020S
Registration Number:
MOHW-MD-(I)-No.005976

Immunochromatographic Rapid Test for the detection of Strep A carbohydrate antigens in throat swab specimens. For professional in vitro diagnostic use only.

INTENDED USE
The PBF Vstrip Strep A Rapid Test is a rapid chromatographic immunoassay for the qualitative detection for Group A Streptococcal antigen from throat swabs. The test is used to aid in the diagnosis of Group A Streptococcal infection.

SUMMARY AND EXPLANATION
Group A Streptococcal is the most significant pathogen causing pharyngitis1. In the case of Group A Streptococcus, antibiotic therapy is the treatment of choice. If left untreated, serious such as rheumatic fever may occur. Conventional methods for detecting Group A Streptococcus infection involve 24-48 hour culture of throat swab specimens followed by confirmation of beta-hemolytic colonies as Group A Streptococcus2,3,4. Immunological confirmation of Group A Streptococcus is based on the antigenic characteristics of the group specific carbohydrate5. The PBF Vstrip Strep A Rapid Test is a rapid test to qualitatively detect the presence of Group A Streptococcus antigen in throat swab specimens, providing results within 5 minutes.

PRINCIPLE OF THE TEST
The PBF Vstrip Strep A Rapid Test is an immunochromatographic membrane assay to detect Group A Streptococcus antigen from throat swab. To perform the test, a throat swab specimen is collected. Antigen is extracted from the swab specimen with reagents A and B. The dipstick is the added to the extracted sample. If Group A Streptococcus is present in the sample, it will form complexes with the anti-Group A streptococcus antibody conjugated color particles located at two separate locations on the test stick. The complex will then be bound by the anti-Group A Streptococcus capture antibody and visible red test line will appear to indicate a positive result. A blue control line will also appear to indicate the test is valid.

REAGENTS AND MATERIALS
- 20 Test Dipsticks
- 20 Test Tubes
- 20 Throat Swabs
- 10 ml Extraction Reagent A (2M Sodium Nitrite)
- 10 ml Extraction Reagent B (0.4M Acetic Acid)
- 1 mL Positive Control (Non-viable Strep A containing preservative)
- 1 mL Negative Control (Non-viable Strep C containing preservative)
- Package Insert

MATERIALS NOT SUPPLIED
- Timer or watch

WARNINGS AND PRECAUTIONS
1. For In Vitro Diagnostic Use.
2. Do not use beyond the expiration date
3. Dispose of containers with used contents in accordance to Federal, State and Local requirements.
4. The dipstick must remain sealed in the protective foil pouch until just prior to use.
5. Do not eat, drink or smoke in the area where the specimens and kits are handled.
6. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
7. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
8. WARNING: Extraction Reagent A is harmful if swallowed or absorbed through skin. May cause eye irritation.
9. CAUTION: Extraction Reagent B may cause skin, eye and respiratory tract irritation.
10. The positive and negative controls contain sodium azide (NaN3) as a preservative.
11. Do not interchange reagent bottle caps.
12. Do not interchange external control solution bottle caps.
13. Humidity and temperature can adversely affect results.

STORAGE
- Store Test Sticks and reagents tightly capped at 15°C- 30°C.
- Do not use Test Sticks or reagents after expiration data.

SPECIMEN COLLECTION AND HANDLING
Using the swab provided in the kit (or use rayon tipped swabs to collect throat specimens. Do not use calcium alginate, cotton tipped or wooden shaft swabs.), collect specimen by sampling material from the back of the throat and any while patches in the tonsillar area. Avoid contact with teeth, gums, and tongue or cheek surfaces. Process patient sample immediately following specimen collection. If a culture result is also desired, inoculate the culture plate with the swab prior to performing the PBF Vstrip Strep A Rapid Test by rolling it firmly over a small portion of one quadrant of the agar plate. Do not perform the PBF Vstrip Strep A Rapid Test before inoculating the culture plate, as the extraction reagents render the bacteria on swab nonviable. When immediate testing is not possible, place the patient swab into a dry test tube for transport or storage. Throat swab specimens may be stored refrigerated at 2-8°C for up to 72 hours. The use of transport media is not recommended with the product.

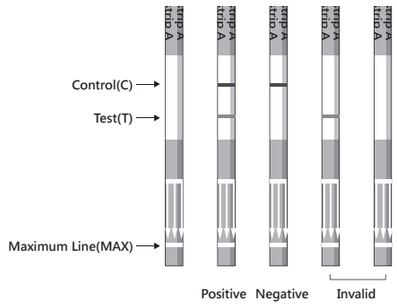
QUALITY CONTROL
Built-in Control Features
The PBF Vstrip Strep A Rapid Test provides three levels of internal procedural controls with each test run. For daily quality control, PBF recommends documenting that these internal controls were checked for the first sample tested each day. The color of the Extraction Reagent changes from pink to clear as the reagents are mixed together. The color change is an internal extraction reagent control and is an indication that the reagents were mixed and functioning properly. The appearance of a blue Control Line is an internal control. The Dipstick must absorb the proper amount of sample and the Dipstick must be working properly for the blue Control Line to appear. Additionally, the appearance of the Control Line indicates that capillary flow occurred. A clear background is an internal background negative control.

External Quality Control Testing
External controls may also be used to demonstrate that the reagents and assay procedure perform properly. PBF recommends that positive and negative controls be run once for each untrained operator, once for each new shipment of kits-provided that each different lot received in the shipment is tested - and as deemed additionally necessary by your internal quality control procedures, and in accordance with local, state, and federal regulations or accreditation requirements. If the controls do not perform as expected, repeat the test or contact PBF Technical Service. Support before testing patient specimens.

ASSAY PROCEDURE
All clinical specimens must be at room temperature before beginning the assay.
1. Just before testing, add 5 drops Reagent A (pink) and 5 drops Reagents B to the Test tube (the solution should turn light yellow).
2. Immediately put the swab into the Tube. Vigorously mix the solution by rotating the swab forcefully against the side of the Tube at least ten (10) times. Best results are obtained when the specimen is vigorously extracted in the solution. Let stand for 1 minutes.
3. Express as much liquid as possible from the swab by squeezing the sides of the tube as the swab is withdrawn. Discard the swab.
4. Remove the Test Stick(s) from foil pouch. Place the Dipstick into the tube with the arrows of the Dipstick pointing down.
5. Read result at five (5) minutes. Some positive results may appear sooner.

Interpretation of Results
Positive result: Two distinct lines
One line should be in the control region (C) and another line should be in the test region (T). A positive result indicates that Strep A was detected in the sample.
NOTE: The intensity of the red color in the test line region (T) will vary depending on the concentration of Strep A present in the sample. Therefore, any visible shade of red in test region (T) should be considered positive.
Negative result: One line in the control region (C)
NO apparent red appears in test region (T). A negative result indicates that Strep A is not present in the sample, or is present below the detectable level of test. The patient's sample should be cultured to confirm the absence of Strep A infection. If clinical symptoms are not consistent with results, obtain another sample for culture.
Invalid: Control line fails to appear.
Insufficient sample volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test dipstick. If the problem persists, discontinue using the kit immediately and contact PBF Technical Service.

LIMITATIONS
- The PBF Strap Strep A Rapid Test does not differentiate between viable and nonviable organisms. Patient that have recently been treated for Strep A or similar infections may postitive results for a period of time following effective treatment due to the presence of Group A strep antigen in nonviable organism.
- Pharyngitis can be caused by organisms other than Group A Streptococcus. Further diagnostic testing, including culture, should be performed if laboratory findings are inconsistent with clinical presentation.
- Excess blood or mucus on the swab specimen may interfere with test performance and may yield a false positive result. Avoid touching the tongue, cheeks, and teeth and any bleeding areas of the mouth with the swab when collecting specimens.
- The PBF Vstrip Strep A will not differentiate asymptomatic carrier of Group A Streptococcus from those exhibiting streptococcal infection.
- A negative result may be obtained if the amount of extracted antigen is below the sensitivity of the test. Culture confirmation is recommended for all PBF Vstrip Strep A Rapid Test negative test results.
- A single swab that is used both to inoculate a culture plate and to perform the rapid test may have reduced sensitivity in the PBF Vstrip Strep A Rapid Test.



PERFORMANCE CHARACTERISTICS
Analytical sensitivity (Limit of Detection)
All of Group A Streptococcus strain from BCRC (Taiwan) were tested as positive results in the PBF Vstrip Strep A Rapid Test. Strep A organisms were quantitated using standard microbiological methods. Analytical sensitivity studies, performed by testing dilutions of culture of Group A Streptococcus, ATCC 19615, determined the PBF Vstrip Strep A Rapid Test limit of detection to be 4.0 x10^4 CFU per test.

Analytical specificity (Cross-Reactivity):
To determine the analytical specificity of the PBF Vstrip Strep A Rapid Test, 34 commensal and pathogenic microorganisms (14 bacteria and 20 viruses) that may be present in the pharynx were tested. All of the following microorganisms were negative when tested at concentrations ranging from 10^2 to 10^9 TCID50/ml (viruses) and 10^7 to 10^8 organisms/ml (bacteria).

Virus	Bacteria
Influenza A virus H1N1 (swine) Taiwan 2009	Pseudomonas aeruginosa
Influenza A virus H1N1 (swine) Taiwan 2010	Serratia marcescens
Influenza A virus H1N1 (human) WSN 1933	Staphylococcus aureus
Influenza A virus H1N1 (human) PR 1934	Staphylococcus epidermidis
Influenza A virus H1N1 (swine) Taiwan 2014	Streptococcus Group B
Influenza A virus H1N1 (swine) Taiwan 2011	Streptococcus Group C
Influenza A virus H3N2 Taiwan 2011	Streptococcus Group F
Influenza A virus H3N2 Taiwan 2013	Streptococcus Group G
Influenza A virus H3N2 Taiwan 2014	Streptococcus mutans
Influenza A virus H3N2 Taiwan 2015	Streptococcus pneumoniae
Influenza B virus Taiwan 2014-1	Streptococcus sanguis
Influenza B virus Taiwan 2014-2	Salmonella typhi
Influenza B virus Taiwan 2014-3	Salmonella enteriditis
Adenovirus type 7	Vibrio cholerae
Adenovirus type 41	
Respiratory syncytial virus 2958-14	
Respiratory syncytial virus 2313-15	
Human parainfluenza virus Type 2	
Echovirus Type 11	
Herpes simplex virus Type 2	

Interfering substances:
The following substances, naturally present in throat specimens or that may be artificially introduced into the pharynx, were evaluated in the PBF Vstrip Strep A Rapid Test at the concentrations listed below and were found not to affect test performance.

Substance	Concentration
Ibuprofen	10 mg/ml
Aspirin/Acetylsalicylic Acid	20 mg/ml
Dextromethorphan	10 mg/ml
Diphenhydramine	5 mg/ml
Oxymetazoline HCl	10 mg/ml
Phenylephrine HCl	100mg/ml
Swinin nasal spray	10%
Hemoglobin	2%
Mucin	1%

Clinical correlation
TBD

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PACKAGING
PBF Vstrip Strep A.....20 Tests/Kit

ORDERING INFORMATION
Product No. : IG03020S

SYMBOL LEGEND

REF	Catalog Number
IVD	For In Vitro diagnostic use
	Consult instructions for use
	Temperature Limitation
LOT	Batch Code
CONTROL +	Positive Control
CONTROL −	Negative Control
	Use By (Expiration Date)
	Manufacturer
	Non-reusable
CE	CE Marking

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