Vstrip

Vstrip 腺病毒快速檢驗試劑
說明書

REF IG05020S　IVD 20 TEST KIT　15°C/30°C　CE

體外診斷使用 2016/09 V1.0
腺病毒快速檢驗試劑
衛部醫器製壹字第 005973 號

Vstrip 腺病毒快速檢驗試劑用於檢測人類糞便中的腺病毒抗原。

效能

Vstrip 腺病毒快速檢驗試劑是一種體外快速定性檢測，可偵測人類糞便中的腺病毒抗原。本試劑僅適用於實驗室及專業用途，旨在於協助腺病毒感染之早期診斷。

闡釋

腺病毒是在兒童病毒性腸胃炎中最常見的原因之一。根據不同的血清型，該病毒也可能引起呼吸疾病，結膜炎和膀胱炎等。腺病毒是無包膜的雙鏈 DNA 病毒，直徑 70-80 奈米，具有二十面體對稱結構。至少已經有 53 個腺病毒血清型被發現，都具有六鄰體抗原。血清 40 型和 41 型與胃腸炎型疾病有明確相關，其主要症狀是腹瀉，並且可能伴隨高溫和嘔吐持續 5-9 天 [1,2]。

實驗原理

Vstrip 腺病毒快速檢驗試劑使用彩色微粒的免疫層析技術。執行測試時，試紙條放入含有樣品之含稀釋液糞便收集管中，藉由毛細現象，樣品稀釋液流經接合墊，內含彩色微粒 (接合抗腺病毒單株抗體) ，若樣品稀釋液中含有腺病毒抗原，抗原將結合至抗體上，形成抗原 – 抗體 – 彩色微粒複合物。當樣品稀釋液沿著硝化纖維膜以毛細作用持續向上移動，而此膜已於測試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，則表示含有腺病毒抗原；若無腺病毒抗原或低於偵測極限則只有藍色控制線。添加樣品測試後應出現藍色控制線則表示為有效。Vstrip 腺病毒快速檢驗試劑可以準確地在 10 分鐘內偵測腺病毒的存在。如果藍色控制線無呈現，則此測試是無效的。

提供的材料

1. Vstrip 腺病毒快速檢驗試劑 (20) – 試紙條含腺病毒單株抗體
2. 含稀釋液糞便收集管 (20) – 稀釋液含 0.02% 防腐劑
3. 腺病毒陽性控制組 (1)
4. Vstrip 腺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 [3]。
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. 請勿重複使用本試劑或其他配件。
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. 本試劑套組的溶液不可飲用。
12. 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。
13. 請勿交換使用不同批號之檢驗試劑 , 陽性控制組或其配件。
14. 請勿使用過期的檢驗試劑。
15. 請勿直接將試紙條插入嘴 , 眼及鼻腔中。
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 [3]。
18. 為了獲得正確的測試結果，請確實遵照說明書指示操作。
19. 陽性控制組應該在糞便收集管中加入 4-5 滴，使用前輕輕混勻。
20. 使用適當的預防措施收集、處理，貯存，處置患者樣本並用產品內容物 [3]。
21. 不足或不當的樣本採集，儲存和運輸可能會產生偽陽性或偽陰性的測試結果。
22. 如果對樣本採集和處理程序並不清楚，請尋找特定的培訓或指導 [4,5]。
23. 含有高濃度的血液樣品可能會造成 Vstrip 腺病毒快速檢驗試劑的測試失敗，從而導致無效 / 偽陽性測試結果。
24. 在樣本或試劑盒組件的周邊請勿吸煙以及請勿飲食。

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。試紙條必須保持在密封鋁袋中，直到使用前拆開。不要冷凍或加熱本試劑套組。

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，為獲得最佳結果，糞便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。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腺病毒抗原檢測的添加劑的乾淨容器中。
糞便樣本在可以保存於 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。

樣本製備

糞便樣本：

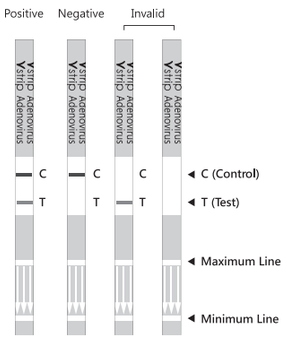
1. 將內含稀釋液糞便收集管瓶蓋打開，使用採檢棒挖取少量糞便檢體 (直徑約 2-5 mm; 約 30-50 mg 或 30-50 ul)，放入含稀釋液糞便收集管中。
2. 旋緊採樣瓶蓋並搖動糞便收集管，使糞便檢體充分溶解於稀釋液中。
3. 標示與病患或其他相關信息於糞便收集管上。

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。

1. 從鋁箔袋中取出試紙條。
2. 旋開稀釋液糞便收集管瓶蓋。
3. 將試紙條標示之箭頭朝下插入瓶中。直到測試完成前請勿將試紙條移除。
4. 於 10 分鐘內讀取結果，強陽性的結果有可能更快出現，超過 10 分鐘請勿判讀其結果。

結果判讀



陽性結果 (Positive)：
目視可觀察到測試區 (T) 出現鮮明的紅色線且控制區 (C) 出現藍色線。陽性結果表示腺病毒抗原的存在。

陰性結果 (Negative)：
目視可觀察到測試區 (T) 並無出現紅色線但控制區 (C) 顯示了一條明顯的藍色線。陰性結果表示腺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或無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。

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，於測試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. 打開腺病毒陽性控制組，加入 4-5 滴於含稀釋液糞便收集管。
2. 混合倒置溶液或搖晃至少一次。
3. 使用前將試紙條從鋁袋中拿出。
4. 將試紙條放入糞便收集管中 (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。

產品限制

1. 如果樣品中抗原的濃度低於試驗的檢測極限，可能會出現陰性的測試結果。如果症狀或狀況仍然存在，應與其它數據來進行更進一步的確定。
2. 感染一周後，病毒在糞便的數量減少，使得樣品反應性較低。糞便樣品應在出現症狀後一個星期內收集。
3. 檢測結果為陰性並不能排除其他潛在的病毒感染。
4. 糞便樣品過量可能會導致無效結果或可能造成褐色線出現。使用緩衝液稀釋樣品並重複測試。
5. 測試結果必須提供給醫師並與其他臨床數據結合進行評估。
6. 陽性檢測結果不排除合併感染其他病原體或病毒。
7. 陽性檢測結果無法確定具體的腺病毒血清型。

期望值

Vstrip 腺病毒快速檢驗試劑用於檢測糞便中存在的腺病毒抗原。腺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腺病毒存在。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 腺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
腺病毒檢測結果顯示具有 >99% 的靈敏度。

■專一性
腺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 腺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 腺病毒快速檢驗試劑之檢測極限做測試，如下表，檢測的測試極限是 $1.25X10^2$ $TCID_{50}$/ mL 的濃度。

Adenovirus	Type	Limit of detection (LOD)
Adenovirus type	7	2.81×10^4 (TCID)
Adenovirus type	41	1.25×10^2 (TCID)
Adenovirus antigen	6	15.6 ng/ml

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

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
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

病毒：

Human respiratory syncytial virus
Human rotavirus
Human parainfluenza virus type 2
Herpes simplex virus type2
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
Bilirubin/ 0.25 mg/ml
Hemoglobin/ 0.25 mg/ml
Voren Supp./ 12.5mg/ml
PECOLIN/ 5%

包裝

Vstrip 腺病毒快速檢驗試劑　20 組 / 盒

訂購資訊

產品型號 :IG05020S

參考資料

1. David A. Warrell, Timothy M. Cox, and John D. Firth Oxford Textbook of Medicine (5 ed.)
2. Chetana Vaishnavi infections of the Gastrointestinal System
3. Biosafety in Microbiological and Biomedical Laboratories, 5th Edition. U.S. Department of Health and Human Services, CDC, NIH, Washington, DC (2007).
4. Henretig F.M. MD, King C. MD, Textbook of Pediatric Procedures, Chapter 123 – Obtaining Biologic Specimens Williams and Williams (April 1997).
5. 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.t
www.pbf.com.tw
www.vstriptech.com

Vstrip

Vstrip Adenovirus Rapid Test
Package Insert

REF IG05020S IVD 20 TEST KIT 15°C 30°C CE

IVD Use 2016/09 V1.0
Vstrip Adenovirus Rapid Test
Registration Number:
MOHW-MD-(I)-No.005973

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

INTENDED USE
Vstrip Adenovirus Rapid Test is an *in vitro* immunochromatographic assay for the qualitative detection of Adenovirus antigen in human stool specimen. The test is intended to aid in the early diagnosis of Adenovirus infection. This test is for professional use only.

SUMMARY AND EXPLANATION
Adenovirus is one of the most common cause of viral gastroenteritis in children. Depending on the serotype, this virus may also cause respiratory diseases, conjunctivitis and cystitis, etc.
Adenovirus is non-enveloped, double-stranded DNA virus, 70-80 nm diameter, with icosahedral symmetry. At least 53 serotypes of Adenoviruses have been described in humans, all sharing a common hexon antigen. Serotypes 40 and 41 have been clearly associated with gastroenteritis disorders, whose main symptom is diarrhea, and may last for 5-9 days associated with temperature and vomits.[1, 2]

PRINCIPLE OF THE TEST
Vstrip Adenovirus Rapid Test is based on an immunochromatographic technology with colored microspheres. During testing, the sample is allowed to react with the colored conjugate (anti- Adenovirus monoclonal antibodies microspheres) which was pre-dried on the test strip. The mixture moves upward on the membrane by capillary action. The membrane is pre-coated with monoclonal antibodies, on the test band region, against viral antigens. If the sample extract contains Adenovirus antigens, these will form an antigen-antibody complex with the colored particles and a visible RED line will appear as the Test band (T). If Adenovirus antigen is not present, or is present at very low level in the specimen, only the BLUE line will be visible as the Control band (C). The BLUE line (C band) should always appear after a sample is applied, indicating a valid result. The device can accurately indicate the presence of Adenovirus in 10 minutes. If the control line does not develop, the test is invalid.

MATERIALS AND REAGENTS PROVIDED
1. Test dipsticks (20): Each strip contains Adenovirus specific monoclonal antibodies.
2. Stool collection tubes with diluent (20): The buffer contains detergent and 0.02% sodium azide.
3. Positive control reagent (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.[3]
5. 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. Do not reuse kit components or test devices.
10. Do not use the test if the foil pouch is damaged.
11. Do not mouth pipette samples or reagents.
12. Patient specimens may contain infectious agents and should be handled and disposed of as potential biohazards.
13. Do not interchange or mix different lots of Vstrip Adenovirus Rapid Test.
14. Do not use the kit components beyond the expiration date, printed on the outside of the box.
15. Do not insert the test strip directly into the month, eye or nasal.
16. Diluent buffer contains sodium azide, which may be a skin irritant. Avoid skin contact with reagents.
17. Dispose all used materials in the appropriate container. Treat as potentially biohazard.[3]
18. To obtain accurate results, you must follow the Package Insert.
19. Positive control reagent should be added 4-5 drops in the test tube and mix gently before use.
20. Use appropriate precautions in the collection, handling, storage, and disposal of patient samples and used kit contents.[3]
21. Inadequate or inappropriate specimen collection, storage, and transport may yield false or negative test results.
22. Seek specific training or guidance if you are not experienced with specimen collection and handling procedures.[4, 5]
23. Specimens containing high levels of blood may fail to flow in the Vstrip Adenovirus Rapid Test device, resulting in an invalid/false positive test result.
24. Do not smoke, eat or drink in areas where specimens or kit components are handled.

STORAGE INSTRUCTION
The expiration date is indicated on the package label. Store kit reagents at 15-30°C, away from direct sunlight. The test must be kept in the sealed pouch until use. 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.
For the best results, stool specimens should be collected after onset of symptoms. Do not leave specimens at room temperature for prolonged periods. 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 with the Adenovirus antigen test.
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.

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 or 30-50 ul) into the stool collection tube with diluent buffer.
2. Close the vial and tighten securely. Mix thoroughly by inversion, shaking or vortex in order to assure good sample dispersion.
3. Label the sample diluent vial with a patient or other control information.

ASSAY PROCEDURE
All clinical specimens must be at **room temperature** before beginning the assay.

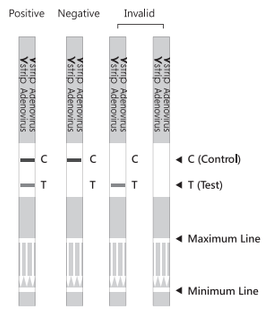
Expiration date:

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. Remove a test strip from a foil pouch.
2. Unscrew the cap of the stool collection tube.
3. Place the test strip into the stool collection tube with the arrows on the test strip pointing down. Do not handle or move the test strip until the test is complete and ready for interpretation.
4. 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:
A distinct RED colored line appears in the test region (T), in additional to a BLUE line appears in the control region (C). A positive result indicates the presence of Adenovirus antigen.

Negative result:
No RED line appears in the test region (T). A distinct BLUE line shows on the control line region (C). A negative result indicates that Adenovirus 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. An excess of sample, incorrect procedure is mostly the main 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.



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 positive control reagent and add 4-5 drops into the stool collection tube with diluent buffer.
2. Close the cap and mix the solution by inversion or shaking at least one time.
3. Remove the test strip from its foil pouch before using it.
4. The test strip put into the tube (arrows down).
5. Read the result at 10 minutes. Do not read result after 10 minutes.

LIMITATIONS OF THE PROCEDURE
1. A negative test result may occur if the level of antigen in a sample is below the detection limit of the test. If the symptoms or situation still present, a further determination should be carried out with other technique.
2. After one week of infection, the number of viruses in stool is decreasing, making the sample less reactive. Stool samples should be collected within one week of the onset of symptoms.
3. A negative test result does not rule out other potential viral infections
4. An excess of sample could cause invalid result or may cause brown bands appearance. Dilute the sample with the diluent buffer and repeat the test.
5. Test Results must be evaluated in conjunction with other clinical data available to the physician.
6. A positive test result does not rule out co-infections with other pathogens or viruses.
7. A positive test result does not identify specific Adenovirus subtypes.

EXPECTED VALUES
Vstrip Adenovirus Rapid Test detects the presence of Adenovirus antigen in stool. Expected values for a given population should be determined for each laboratory. The prevalence of Adenovirus 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 Adenovirus. 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 Adenovirus Rapid Test to another commercially available Adenovirus Rapid Test.

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

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

■ **Reproducibility**
Three different lots of the Vstrip Adenovirus 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 Adenovirus Rapid Test. The study used human Adenovirus as following table. Results are summarized below:

Adenovirus	Type	Limit of detection (LOD)
Adenovirus type	7	2.81 x 10^4 (TCID)
Adenovirus type	41	1.25 x 10^2 (TCID)
Adenovirus antigen	6	15.6 ng/ml

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

Cross reactivity study
The cross reactivity of the Vstrip Adenovirus 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 Adenovirus Rapid Test.

Bacterial Panel

Pseudomonas aerugiosa
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

Viral Panel

Human respiratory syncytial virus
Human parainfluenza virus type 2
Herpes simplex virus type2
Human rotavirus
Echovirus type 11

Interfering Substances
Common the-counter medication, anti-diarrhea drug and substances occasionally present in feces were tested with the Vstrip Adenovirus Test in order to verify that they did not interfere with the test.

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 Adenovirus Rapid Test.....20 Tests/Kit

ORDERING INFORMATION
Product No. : IG05020S

REFERENCES
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2. Chetana Vaishnavi infections of the Gastrointestinal System
3. Biosafety in Microbiological and Biomedical Laboratories, 5th Edition. U.S. Department of Health and Human Services, CDC, NIH, Washington, DC (2007).
4. Henretig F.M. MD, King C. MD, Textbook of Pediatric Procedures, Chapter 123 – Obtaining Biologic Specimens Williams and Williams (April 1997).
5. 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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