QuickStripe™ Adenovirus

A rapid, one-step test for the qualitative detection of *Adenovirus* respiratory antigens from human nasopharyngeal specimens (swab, nasopharyngeal wash, and aspirate).

Instruction Manual

Test kit for 25 determinations
(Catalog No. 41206)

For professional in vitro diagnostic use only
Store at 2-30°C. **Do Not Freeze**

Savyon® Diagnostics Ltd.
3 Habosem St. Ashdod 77610
ISRAEL
Tel.: +972.8.8562920
Fax: +972.8.8523176
E-mail: support@savyondiagnostics.com

INTENDED USE

The *QuickStripe™ Adenovirus* is a rapid immunochromatographic assay for the qualitative detection of *Adenovirus* antigens in human nasopharyngeal specimens (swab, nasopharyngeal wash and aspirate) to aid in the diagnosis of *Adenovirus* respiratory infection. This test is for professional use.

SUMMARY AND EXPLANATION

Most infections with *adenovirus* result in infections of the upper respiratory tract. *Adenovirus* infections often show up as conjunctivitis, tonsillitis (which may look exactly like strep throat and cannot be distinguished from strep except by throat culture), an ear infection, or croup. A combination of conjunctivitis and tonsillitis is particularly common with *adenovirus* infections. Some children (especially small ones) can develop *adenovirus* bronchiolitis or pneumonia, both of which can be severe. In babies, a*denoviruses* can also cause coughing fits that look almost exactly like whooping cough.

There are 57 described *adenoviruses* serotypes in humans, differentiated primarily by serological and DNA analysis, which are responsible for 5–10% of upper respiratory infections in children, and many infections in adults as well. Many serotypes are known to cause specific syndromes in humans. Morphologically, the *adenoviruses* are non-enveloped icosahedral structures about 80 nm in diameter.

PRINCIPLE OF THE PROCEDURE

The *QuickStripe™ Adenovirus* is a qualitative lateral flow immunoassay for the detection of *adenovirus* antigens in human nasopharyngeal samples.
The *QuickStripe™ Adenovirus* test employs an anti-adenovirus antibody-dye conjugate and a solid phase antibody to selectively identify *Adenovirus*. As the test sample flows through the test strip, the labeled antibody-dye conjugate binds to the *adenovirus* antigen forming an antibody-antigen complex. The complex binds to the anti-adenovirus antibodies in the test zone producing a blue color band. In the absence of *Adenovirus* antigens there is no line in the test zone. The reaction mixture continues flowing through the test strip, producing a green color band in the control zone. The green control line serves as verification that sufficient volume of specimen has been added and as an internal control for the integrity of the reagents.

MATERIALS PROVIDED

- 25 aluminium pouches, each containing one *QuickStripe™ Adenovirus* test strip and a desiccant bag
- 25 disposable test tubes
- 1 dropper containing 15 ml of sample diluent B
- 1 Instruction for Use

WARNING AND PRECAUTIONS

- For professional in vitro diagnostic use only.
- Do not use beyond the expiration date. The test should remain in the sealed pouch until use. Do not use the test if pouch is damaged.
- Follow Good Laboratory Practices, wear protective clothing, use disposal gloves, do not eat, drink or smoke in the area.
- All the specimens should be considered potentially hazardous and handled as an infectious agent. The test should be discarded in a proper biohazard container after use.
- The test must be carried out within 2 hours of opening the sealed bag.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at refrigerated or room temperature (2-30ºC). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.**

SPECIMEN COLLECTION AND HANDLING

Nasopharyngeal swab method:
- Bend shaft to follow curve of nasopharynx;
- Insert swab through nostril to the posterior nasopharynx.
- Rotate swab a few times to obtain infected cells
- For an optimal sample, repeat procedure using other nostril

Nasopharyngeal aspirate method (suction apparatus, sterile suction catheter):
- Instill several drops of solution saline into each nostril
- Place catheter through the nostril to posterior nasopharynx;
- Apply gentle suction. Using rotating motion, slowly withdraw catheter

- For an optimal sample, repeat procedure using other nostril
- Send specimen to lab immediately (testing sensitivity decrease over time)
- Cool specimen to 2º-4ºC during storage and transport.

PROCEDURE

Allow the tests, samples and buffer to reach room temperature (15-30ºC) prior to testing. Do not open pouches until ready to perform the assay.

To process the collected nasopharyngeal wash or aspirate samples (see illustration 1):

1. Use a separate testing tube or vial for each sample. Add 300 µL of the nasopharyngeal wash or aspirate sample. Add 3 drops (150 µL) of diluent B and mix.
2. Remove the *QuickStripe™ Adenovirus* test strip from its sealed pack and use it as soon as possible. Use a separate test strip for each sample.
3. Immerse the *QuickStripe™ Adenovirus* test strip vertically into the extracted specimen solution with the white end pointing toward the specimen and then start the timer.
4. Read the result at 10 minutes.

To process the collected nasopharyngeal swab (see illustration 2):

1. Use a separate test tube or vial for each sample (swab). Add 15 drops (500 µL) of diluent B into the test tube.
2. Insert the nasopharyngeal swab, mix and extract as much liquid as possible from the swab. Discard the swab into hazardous waste container.
3. Remove the *QuickStripe™ Adenovirus* test strip from its sealed pack and use it as soon as possible. Use a separate strip for each sample.
4. Immerse the *QuickStripe™ Adenovirus* test strip vertically into the extracted specimen solution with the white end pointing toward the specimen and then start the timer.
5. Read the result at 10 minutes.

Illustration 1 Nasopharyngeal aspirate or wash

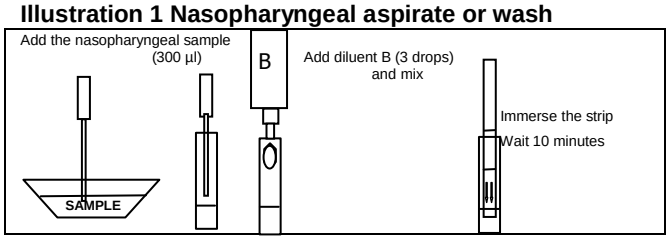
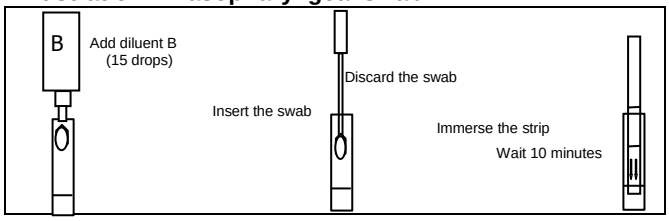
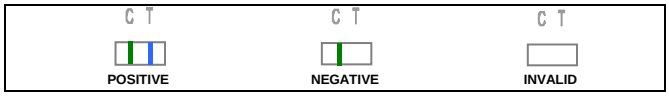


Illustration 2 Nasopharyngeal swab



INTERPRETATION OF RESULTS

Illustration 3



Positive: Two lines appear on the test membrane. A **blue** test line (marked in the illustration with the letter T) in the test zone and a **green** control line (marked in the illustration with the letter C) in the control zone.

Negative: Only one **green** band appears in the control zone of the test window (marked in the illustration with the letter C). No band is visible in the test window.

Invalid: A total absence of the green control band regardless of the appearance or not of the blue test line. Note: 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 blue band in the result line region (T) 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

Internal procedural controls are included in the test:
A green line appearing in the control line region (C) confirms sufficient specimen volume and correct procedural technique.

LIMITATIONS OF THE PROCEDURE

1. The *QuickStripe™ Adenovirus* will only indicate the presence of adenovirus in the specimen (qualitative detection) and should be used for the detection of adenovirus respiratory antigens in nasopharyngeal specimens only (from swab, aspirate, or wash). Neither the quantitative value nor the rate of increase in adenovirus antigens concentration can be determined by this test.
2. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of adenovirus infection.
3. This test provides a presumptive diagnosis of adenovirus respiratory infections. All results must be interpreted together with other clinical information and laboratory findings available to the physician.

EXPECTED VALUES

Everyone is at risk of adenovirus infection, but patients with weak immune systems or with underlying respiratory or cardiac disease are most at risk for severe complications from any respiratory infection, including *adenovirus* infections.

PERFORMANCE CHARACTERISTICS

The performance of the *QuickStripe™ Adenovir*us was compared to the performance of the commercially available immunofluoresncence PathoDx®Adenovirus Kit (Remel) and the immunochromatographic Adenovirus Respi rapid test (CorisBioConcept).

Quickstripe *Adenovirus*	PathoDx®Adenovirus Adeno Resp. Test		
	+	-	Total
+	20	0	20
-	0	5	5
Total	20	5	25

Quickstripe *Adenovirus*	Adenovirus Respi Rapid Test		
	+	-	Total
+	20	0	20
-	0	5	5
Total	20	5	25

Correlation between the results of Quickstripe Adenovirus and both PathoDx®Adenovirus Kit (Remel) and Adenovirus Respi-Strip rapid test (CorisBioConcept) was 100% in the specimens tested.

Cross-Reactivity

There is no cross reactivity with common respiratory viruses occasionally present in nasopharyngeal samples:
Respiratory syncytial virus
Influenza A&B

REFERENCES

1. BARENFANGER et al., "Clinical and Financial Benefits of Rapid Detection of Respiratory Viruses: an Outcomes Study". Journal of Clinical Microbiology. August 2000, Vol 38 No 8, p. 2824-2828.

Savyon® Diagnostics Ltd.
3 Habosem St. Ashdod 77610
ISRAEL
Tel.: +972.8.8562920
Fax : +972.8.8523176
E-mail: support@savyondiagnostics.com

CE
European Authorized Representative: Obelis s.a.
Boulevard Général Wahis 53, B-1030 Brussels
Tel: +32.2.732.59.54 Fax: +32.2.732.60.03
E-mail:mail@obelis.net