

PathFlow™ Adenovirus antigen Rapid Test Cassette (EN)

Instructions for Use

INTENDED USE

The PathFlow™ Adenovirus antigen Rapid Test Cassette (Swab) is a rapid chromatographic immunoassay for the qualitative detection of Adenovirus antigen in eye conjunctive swabs, throat swabs and nasal swabs to aid in the diagnosis of adenovirus infections.

SUMMARY

Although there are a variety of viruses that can cause infections in the lower respiratory tract (for example, Influenza & RSV) Adenovirus are often the most common.^[1] Symptoms of respiratory disease caused by Adenovirus range from being as mild as the common cold, to pneumonia, "croup", and bronchitis. In total, there are 47 different serotypes of adenovirus, all being causative of different symptoms; including conjunctivitis, bronchitis, pneumonia, diarrhoea and others. Among them, the serotypes of 8, 14, 16 and 17 have been shown to cause conjunctivitis, while serotypes 7, 14, 21 cause respiratory symptoms. The antibodies used in the current test kit have a wide range of reactivity against many serotypes of adenovirus, including serotypes of 1, 2, 3, 4, 5, 6, 7, 8, 11, 14, 16, 17, 19 and 37.

The Adenovirus Antigen Rapid Test Cassette (Swab) is a rapid chromatographic immunoassay for the qualitative detection of adenovirus in eye conjunctive swab, throat swab and nasal swab specimen, providing results in 15 minutes. The test utilizes antibody specific for adenovirus to selectively detect adenovirus from eye conjunctive swab, throat swab and nasal swab specimens.

PRINCIPLE

The PathFlow™ Adenovirus antigen Rapid Test Cassette (Swab) is a qualitative membrane-based immunoassay for the detection of adenovirus antigen in eye conjunctive swabs, throat swabs and nasal swabs. In this test, adenovirus specific antibodies are coated on the test line regions of the test cassette. During testing, the extracted specimen reacts with the antibody to adenovirus that are coated onto particles. The mixture migrates up the membrane to react with the corresponding adenovirus antibodies on the membrane and generate a coloured line in the test line region. The presence of this coloured line indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a coloured line will always appear in the control region if the test has performed successfully.

REAGENTS

The test contains anti-Adenovirus antibody particles and anti-Adenovirus antibodies coated on the membrane.

MATERIALS

Provided: Test cassettes, Package insert, Extraction Reagent, Extraction Tubes, Sterile Swabs, Workstation, Extraction Tube Tips.

Not Provided but required: Timer.

WARNINGS AND PRECAUTIONS

- For professional in vitro diagnostic use only. Do not use after expiration date.
- The test cassette should remain in the sealed pouch until use.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.

- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- The used test materials should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

- Store as packaged at room temperature or refrigerated (2-30°C).
- The test is stable until the expiration date printed on cassette pouch.
- The test **must** remain in the sealed pouch until use.
- **DO NOT FREEZE**
- Do not use beyond the expiration date.

SPECIMENS

It is advised the test is to be used in conjunction with freshly collected samples to provide optimal results. Inadequate sample collection or improper sample handling could potentially yield a false-negative result. Ensure that the specimen(s) are not treated with cleaning solutions containing formaldehyde or its derivatives.

Eye conjunctive swab sample:

Use the sterilized swab supplied in this kit to gently wipe the eye conjunctive several times to collect the eye secretions.

Throat Swab Sample:

Insert the sterilized swab into the throat and the surface surrounding mandible tonsil/posterior hypo-pharyngeal to collect the epidermal cells of the mucus. Caution **must** be paid to avoid swab contamination with saliva.

Nasopharyngeal Swab Sample:

Insert the sterilized swab, supplied with the PathFlow™ Adenovirus antigen Rapid Test Cassette kit into the nasal basin; swab several times to collect the epidermal cells of the mucus.

DIRECTIONS FOR USE

Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.

Remove the test cassette from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed immediately after opening the foil pouch.

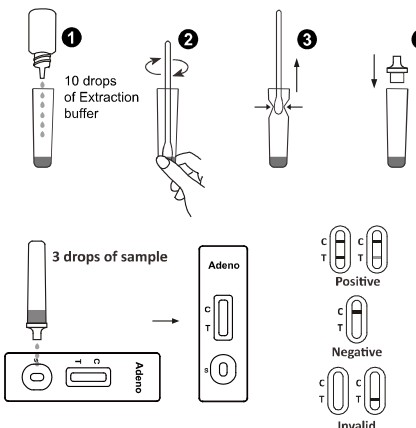
1. Place the Extraction Tube in the workstation. Hold the extraction reagent bottle upside down vertically. Squeeze the bottle and let the solution drop into the extraction tube freely without touching the edge of the tube. Add 10 drops of solution (Approx. 400µl) to the Extraction Tube.
2. Place the swab specimen in the Extraction Tube. Rotate the swab for approximately 10 seconds while pressing the head against the inside of the tube to release the antigen in the swab.
3. Remove the swab while squeezing the swab head against the inside of the Extraction Tube as you remove it to expel as much liquid as possible from the swab. Discard the swab in accordance with your biohazard waste disposal protocol.
4. Fit the dropper tip on top of the extraction tube. Place the test cassette on a clean and level surface.
5. Add three drops of the solution (approx.120µl) to the sample well and then start the timer. Read results at 15 minutes and disregard after 60 minutes. A positive result may be visible at 3 minutes; however, the complete reaction time of 15 minutes is required to confirm a negative result.

INTERPRETATION OF RESULTS

POSITIVE: *Two distinct coloured lines appear. One coloured line should be present in the control line region (C) and another in the test region (T).

***NOTE:** The intensity of the colour in the test line region (T) will vary depending on the concentration of test antigens present in the specimen. *Any shade of colour in the test line region should be considered positive.*

NEGATIVE: One coloured line appears in the control line region (C). No line appears in the test line region (T).



INVALID: Colour line (C) fails to appear. Insufficient specimen volume or incorrect procedural technique are the most likely reasons for control line failure.

Review the procedure and repeat the test with a new cassette. If the problem persists, discontinue using the cassette immediately and contact your local distributor.

QUALITY CONTROL

Internal procedural controls are included in the test. A coloured line appearing in the control region (C) is an internal valid procedural control. It confirms that sufficient specimen volume has been used and correct procedural technique has been followed.

Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. The PathFlow™ Adenovirus antigen Rapid Test Cassette is for in vitro diagnostic use only. The test should be used for the detection of adenovirus antigen in eye conjunctive swabs, throat swabs and/or nasal swab specimens only. Neither the quantitative value nor the rate of increase in adenovirus antigen concentration can be determined by this qualitative test.
2. The PathFlow™ Adenovirus antigen Rapid Test Cassette will only indicate the presence of adenovirus in the specimen and should not be used as the sole criteria for the diagnosis of adenovirus.

- As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
- 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.
- The PathFlow™ Adenovirus antigen Rapid Test Cassette is an acute-phase screening test for qualitative detection. Sample collected may contain antigen titres below the reagent's sensitivity threshold, so a negative test result does not exclude infection with adenovirus.
- Performance of the test has not been established for monitoring antiviral treatment of adenovirus.
- The PathFlow™ Adenovirus antigen Rapid Test Cassette detects both viable and non-viable adenovirus antigen. Test performance depends on antigen load in the sample and may not correlate with cell culture performed on the same sample. A positive test does not rule out the possibility that other pathogens may be present. Therefore, the results must be compared with all other available clinical and laboratory information to make an accurate diagnosis.

PERFORMANCE CHARACTERISTICS

The PathFlow™ Adenovirus antigen Rapid Test Cassette has been evaluated with specimens obtained from a population of symptomatic and asymptomatic individuals. A commercial leading competitor PCR test served as the reference method – results were found as followed:

Method	PCR		Total Result
	Positive	Negative	
PathFlow™ Adenovirus	Positive	68	72
	Negative	1	203
Total Result		69	207

Relative sensitivity: 98.6% (95%CI*: 92.2%~100.0%);

Relative specificity: 98.1% (95%CI*: 95.1%~99.5%);

Accuracy: 98.2% (95%CI*: 95.8%~99.4%).

*Confidence Intervals

The results show that the relative sensitivity of PathFlow™ Adenovirus antigen Rapid Test Cassette is 98.6%, relative specificity is 98.1% and the relative accuracy is 98.2%.

INTRA-ASSAY

Within-run precision has been determined by using 15 replicates of four specimens: a negative, a low positive, a medium positive and a high positive.

The specimens were correctly identified >99% of the time.

INTER-ASSAY

Between-run precision has been determined by 15 independent assays on the same four specimens: a negative, a low positive, a medium positive and a high positive. Three different lots of the PathFlow™ Adenovirus antigen Rapid Test Cassette (Swab) have been tested using these specimens. The specimens were correctly identified >99% of the time.

CROSS-REACTIVITY

The PathFlow™ Adenovirus antigen Rapid Test Cassette (Swab) has been tested for cross-reactivity using:

Acinetobacter baumannii, Bordetella pertussis, Branhamella catarrhalis, Candida albicans, Candida glabrata, Cardiobacterium hominis, Eikenella corrodens, Enterococcus faecalis, Enterococcus gallinarum, Escherichia coli, Group C streptococcus, Haemophilus aphrophilus, Haemophilus influenzae, Haemophilus paraphrophilus, Klebsiella pneumoniae, Neisseria gonorrhoeae, Peptococcus asaccharolyticus, Peptostreptococcus anaerobius, Proteus

mirabilis, Proteus vulgaris, Pseudomonas aeruginosa, Serratia marcescens, Staphylococcus epidermidis, Streptococcus agalactiae (group B), Streptococcus mutans, Streptococcus pneumoniae, Streptococcus pyogenes (group A)

Veillonella parvula, Influenza A + B, Respiratory Syncytial Virus, Coxsackie virus, Type A16, B1 ~ 5, Cytomegalovirus, Echovirus Type 3,6,9,11,14,18,30, Enterovirus Type 71, HSV-1, Mumps virus, Type I simple herpes virus, Parainfluenza virus Type 1 ~ 3, Polio virus Type 1 ~ 3, Rhinovirus Type 1A,13,14. The results showed no cross-reactivity.

INTERFERING SUBSTANCES

The following analytes were tested as interfering substances (swabs spiked with 100µl): Cherry Halls cough drops, Menthol Halls cough drops, Robitussin cough syrup, Dimetapp cough syrup, Vicks Chloraseptic spray, Cepacol Chloraseptic spray, Listerine mouthwash, Scope mouthwash. No substances showed any interference with the test.













LIMIT OF DETECTION

The detection limits for PathFlow™ Adenovirus Antigen Rapid Test is 1.0×10³ particle/test.


BIBLIOGRAPHY

- Barenfanger et al. J. Clin.Micr. Aug. 2000. Vol. 38 N 8, p. 2824-2828.

TABLE OF SYMBOLS

SYMBOL	DEFINITION
	Batch Code/Lot Number
	In Vitro Diagnostic Medical Device
	Catalogue Reference
	Upper and Lower Temperature Limits
	Expiry Date
	Manufacturer and Address Details
	Date of Manufacture
	Please consult IFU
	Sufficient for
	Do not use if package is damaged
	CE Mark
	Caution

This document applies to the following product codes:
M592CE

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