REF: 20109

Adenovirus Antigen Rapid Test Cassette (Swab)
Package Insert

A rapid test for the qualitative detection of adenovirus antigen in eye conjunctive swab, throat swab and nasal swab.

For professional in vitro diagnostic use only.

【INTENDED USE】

The Adenovirus Antigen Rapid Test Cassette (Swab) is a rapid chromatographic immunoassay for the qualitative detection of Adenovirus antigen in eye conjunctive swab, throat swab and nasal swab as an aid in the diagnosis of adenovirus infections.

【SUMMARY】

Although there are a variety of viruses that can cause infections in the lower respiratory tract in children and adults, influenza A & B, respiratory syncytial virus (RSV), influenza For 1, 2 and 3 and Adenovirus are often the most common. Symptoms of respiratory disease caused by Adenovirus includes from the common cold to pneumonia, "croup", and bronchitis. There are 47 serotype of adenovirus, causing different disease from conjunctivitis, bronchitis, pneumonia, diarrhea and other symptoms. 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 has 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 Adenovirus Antigen Rapid Test Cassette (Swab) is a qualitative membrane-based immunoassay for the detection of adenovirus antigen in eye conjunctive swab, throat swab and nasal swab. In this test, antibody specific to the adenovirus is separately 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 antibody to adenovirus on the membrane and generate a color line in the test line region. The presence of this color line in the test line region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control region if the test has performed properly.

【REAGENTS】

The test cassette contains anti-adenovirus particles and anti- adenovirus coated on the membrane.

【PRECAUTIONS】

- For professional in vitro diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test should be discarded according to local regulations.

【STORAGE AND STABILITY】

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

【SPECIMEN COLLECTION AND PREPARATION】

It is applicable to the diagnosis of the Adenovirus antigen from the samples of eye conjunctive swab, throat swab and nasal swab with the Adenovirus Antigen Rapid Test Cassette. Use freshly collected samples for optimal test performance. Inadequate sample collection or improper sample handling may yield a false-negative result.

- 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 swab surrounds mandible tonsil and posterior hypo pharyngeal for several times to collect the epidermal cells of the mucus. Caution has to be paid to avoid the swab to be contaminated with saliva.
- Nasopharyngeal swab sample

  Insert the sterilized swab supplied in this kit into the nasal basin, and swab several times to collect the epidermal cells of the mucus.

【MATERIALS】

Materials provided

- Test cassettes
- Sterile Swabs
- Extraction Tube Tips
- Extraction Reagent
- Package insert
- Extraction Tubes
- Workstation

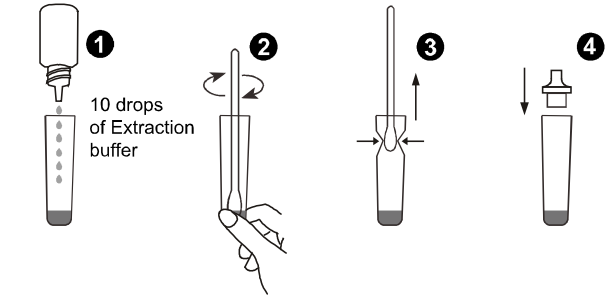
Materials required but not provided

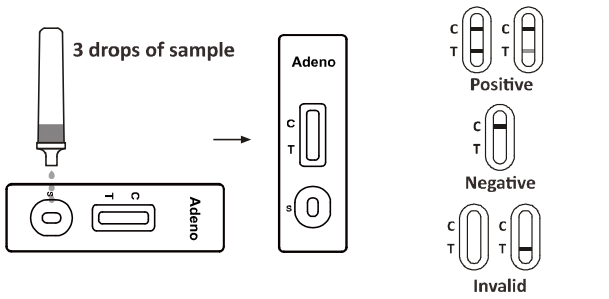
- Timer

【DIRECTIONS FOR USE】

Allow the test, specimen, extraction buffer to equilibrate to room temperature (15-30°C) prior to testing.

1. 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.
2. 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. See illustration 1.
3. 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. See illustration 2.
4. 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. See illustration 3.
5. Fit the dropper tip on top of the extraction tube. Place the test cassette on a clean and level surface. See illustration 4
6. 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】

(Please refer to the illustration above)

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

*NOTE: The intensity of the color in the test line region (T) will vary depending on the concentration of adenovirus present in the specimen. Therefore, any shade of red in the test region should be considered positive.

NEGATIVE: One color line appears in the control region (C). No apparent red or pink line appears in the test region (T).

INVALID: Control line fails to appear. Insufficient specimen 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. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

【QUALITY CONTROL】

Internal procedural controls are included in the test. A color line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.

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 Adenovirus Antigen Rapid Test Cassette (Swab) is for in vitro diagnostic use only. The test should be used for the detection of adenovirus antigen in eye conjunctive swab, throat swab and 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 Adenovirus Antigen Rapid Test Cassette (Swab) will only indicate the presence of adenovirus in the specimen and should not be used as the sole criteria for the diagnosis of adenovirus.
3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. 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.
5. The Adenovirus Antigen Rapid Test Cassette is an acute-phase screening test for qualitative detection. Sample collected may contain antigen titles below the reagent's sensitivity threshold, so a negative test result does not exclude infection with adenovirus.
6. Performance of the test has not been established for monitoring antiviral treatment of adenovirus.
7. The 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.

【EXPECTED VALUES】

The Adenovirus Antigen Rapid Test Cassette has been compared with a leading commercial PCR test. The correlation between these two systems is 98.2%.

【PERFORMANCE CHARACTERISTICS】

Sensitivity and Specificity

The Adenovirus Antigen Rapid Test Cassette (Swab) has been evaluated with specimens obtained from a population of symptomatic and asymptomatic individuals. Results were confirmed by a leading commercial PCR test.

The results show that the relative sensitivity of the Adenovirus Antigen Rapid Test Cassette (Swab) is 98.6%, and the relative specificity is 98.1%, and the relative accuracy is 98.2%.

Method		PCR		Total Result
Adenovirus Antigen Rapid Test Cassette (Swab)	Results	Positive	Negative	
	Positive	68	4	72
	Negative	1	203	204
Total Result		69	207	276

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

Precision

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 Adenovirus Antigen Rapid Test Cassette (Swab) have been tested using these specimens. The specimens were correctly identified >99% of the time.

Cross-reactivity

The Adenovirus Antigen Rapid Test Cassette (Swab) has been tested by Acinetobacter baumannii, Bordetella pertussis, Branhamella catarrhalis, Candida albicans, Candida glabrata, Cardiobacterium hominis, Eikenella corrodens, Enterococcus faecalis, Enterococcus gallinarum. Escherichia coil, Group C streptococcus, Group G streptococcus, Haemophilu saphrophilus, 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, Influenza B, Respiratory Syncial Virus, Coxsackie virus Type A16, B1 ～ 5,Cytomegalovirus, Echovirus Type 3,6,9,11,14,18,30, Enterovirus Type 71, HSV-1, Mumps virus,Tyep I simple herpes virus Parainfluenza virus Type 1 ～ 3, Poliovirus Type 1 ～ 3, Respiratory syncytial virus, Rhinovirus Type 1A,13,14, Type I simple herpes virus positive specimens. The results showed no cross-reactivity.

【BIBLIOGRAPHY】

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

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