

Adenovirus (Respiratory) Antigen Rapid Test Kit (Fluorescence Immunochromatography) User Manual

(For Medical Professional Use Only)

1. Product Name

Adenovirus (Respiratory) Antigen Rapid Test Kit
(Fluorescence Immunochromatography)

2. Package Specification

20 T/box

3. Intended Use

The rapid detection kit for Adenovirus (Respiratory) antigen aims to qualitatively detect Adenovirus (Respiratory) antigen in nasopharyngeal swab samples in vitro.

4. Summary

Adenovirus (ADENO) is one of the important causes of respiratory diseases. However, depending on the serum classification, they may also cause other diseases, such as gastroenteritis, conjunctivitis, cystitis and eruptive diseases. The symptoms of respiratory diseases caused by adenovirus are similar to the common cold symptoms in the early stage of pneumonia, pseudomembranous laryngitis and bronchitis. Patients with immune dysfunction are particularly vulnerable to serious complications of adenovirus infection. Adenovirus is transmitted through direct contact, feco-oral route and occasionally through water. Some types will cause tonsils, tonsillar hypertrophy and long-term asymptomatic after intestinal infection, which will last for several months or years.

5. Test Principle

The adenovirus antigen assay kit (fluorescence immunochromatography) uses double antibody sandwich fluorescence immunochromatography. The NC membrane test line (T line) on the test card is coated with anti-AdV antibody, and the quality control line (C line) is coated with anti-DNP antibody. During the test, the AdV in the sample combines with the anti-AdV antibody labeled by fluorescent microsphere to form a reaction complex [fluorescent microsphere - (anti-AdV antibody) - (AdV)]. The reaction complex moves forward along the nitrocellulose membrane under the action of

chromatography and moves to the detection line (T line). The reaction complex is captured by the anti-AdV antibody coated by the detection line to form the final reaction complex. The fluorescent microsphere emits fluorescence signal under excitation of excitation, and the AdV concentration in the sample is positively correlated with the fluorescence signal. The concentration of AdV in the sample is calculated according to the relative fluorescence signal intensity of the sample through the fluorescence immunoassay analyzer.

Detection principle of the supporting instrument: insert the reaction detection card into the supporting fluorescence immunoassay quantitative analyzer, and the measuring system of the instrument will automatically scan the binding area of the fluorescent marker and the object to be measured and obtain the optical signal. The instrument quantitatively obtains the concentration of the measured substance by analyzing and processing the obtained optical signal.

6. Components

This test kit consist of :

- ① Individually Packaged Test Cassette
 - a. One kit device
 - b. One desiccant
- ② Sample buffer: 1.5mL/bottle/test
- ③ ID Card
- ④ Quick Reference Instructions

7. Materials Required but not Provided

- (1) Timer or watch
- (2) Fluorescent Immunoanalyzer
(Model type: GTF2600, GTF3000B. Manufactured for International Biomedical Supplies INC.)

8. Storage and Expiration Date

It is stored at 2~30°C, and its validity period is 24 months. After the aluminum foil bag is opened, the test card should be used within 60 minutes. See the product label for the production date and expiration date.

9. Specimen Requirements

1. Nasal swab: let the patient's head relax naturally, slowly rotate the swab against the wall of the nostril into the patient's nostril to the nasal palate, and then slowly rotate and take it out when wiping. Wipe the other nostril with the same cotton swab and use the same method; Put the swab sample into the extraction tube, roll the swab 3 to 5 times (3-5 times), and leave the swab in the extraction tube for 1

minute. Pinch and pull out the tube with your fingers, and take out the solution from the cotton swab as much as possible.

2. Pharyngeal swab: make the patient's head slightly backward, open his mouth, and make a "ah" sound. Gently wipe both sides of the patient's pharyngeal tonsils with a hand swab that exposes the tonsils, and then rub at least three times on the back wall of the pharynx. Put the specimen into the extraction tube with a mop, roll the cotton swab 3 to 5 times (3-5 times), and leave the cotton swab in the extraction tube for 1 minute. Pinch the tube with your fingers and take out as much solution as possible from the cotton swab.

3. Nasopharyngeal swab: put the nasal swab into the sampling tube of the collected pharyngeal swab. In this way, there are throat swabs and nasal swabs in the sampling tube, namely the so-called nasopharynx swab tube. Put the swab sample into the extraction tube, roll the swab 3 to 5 times (3-5 times), and leave the swab in the extraction tube for 1 minute. Pinch and pull out the tube with your fingers, and take out the solution from the cotton swab as much as possible.

4. Samples should be used as soon as possible after collection (within half an hour).

5. The sample should not be inactivated.

10. Testing Procedures

Open the test bag after the test is ready. It is recommended to conduct a one-time test at low ambient humidity ($RH \leq 70\%$) within 1 hour. Before the test, the room temperature is required to reach $18^\circ\text{C} \sim 26^\circ\text{C}$. Remove the test card from the aluminum foil bag and place it on a clean and dry surface.

● Machine operate

1. Before the experiment, take out the samples and test reagents to be tested from the storage conditions and balance them to room temperature.

2. Take out the kit ID card and store the kit data in the fluorescence immunoassay analyzer.

3. Put the test card in the card warehouse.

4. Remove the soft glue plug from the buffer tube.

5. Put the swab sample into the extraction buffer tube, roll the swab 3 to 5 times.

6. Break the swab head in the test tube. Press the cover tightly on the tube to avoid any leakage.

7. Shake the specimen collection tube vigorously to mix the specimen and the dilution buffer.

8. The main end of the swab tube is down, make sure the liquid soak the swab, leave the tube alone for 2 minutes.

9. The specimen collection tube was shaken, placed on the test tube rack, and tested by machine.

10. Select the sample type on the machine, establish the test task, and give the results after 15min.

● Manual operate

1. Before the experiment, take out the samples and test reagents to be tested from the storage conditions and balance them to room temperature.

2. Take out the kit ID card and store the kit data in the fluorescence immunoassay analyzer.

3. Remove the soft glue plug from the buffer tube.

4. Put the swab sample into the extraction buffer tube, roll the swab 3 to 5 times.

5. Leave the head of the swab inside the tube. Press the cover tightly on the tube to avoid any leakage.

6. Shake the specimen collection tube vigorously to mix the specimen and the dilution buffer. Make sure the liquid soak the swab, leave the tube alone for 2 minutes.

7. Shake the specimen collection tube and add $100\ \mu\text{L}$, put the liquid into the sample hole of the test card and start the timing.

8. React at room temperature for 15 minutes, use fluorescence immunoassay analyzer to test, read or print the test results.

11. Expected Value

Negative judgment value: $ADV < 0.5\text{ng/mL}$, Positive judgment value: $ADV \geq 0.5\text{ng/mL}$.

The test results of this reagent are only for reference, and the patient's diagnosis results need to be judged in combination with clinical diagnosis.

12. Interpretation of Test Result

1. Use fluorescent immunoanalyzer to analyze the test card and issue quantitative test results. Professional personnel are responsible for the review and analysis of test results, which are usually considered normal within the reference range and are influenced by age, sex, diet and region.

2. The test results of this reagent are for clinical reference only, and the clinical diagnosis and treatment of patients should be considered in combination with their symptoms/signs, medical history, other laboratory tests and treatment response.

13. Limitation of Test Method

1. This kit is suitable for testing nasopharyngeal swabs. Testing with other samples or solutions, errors in operation, and the presence of interfering substances in the sample may result in incorrect results.
2. The test results of this kit can only be used as an auxiliary reference for clinical diagnosis. If the test results are inconsistent with the clinical evaluation, further examination is required.

14. Warnings and Precautions

For *in Vitro* Diagnostic Use

1. The reagent is a disposable diagnostic reagent *in vitro*, which is only used to detect human nasal swabs, nasopharyngeal swabs or oropharyngeal swabs. The operation shall be carried out in strict accordance with the instructions. Do not use expired and damaged products.
2. The reagent shall be sealed and kept away from moisture. Reagents or samples stored at low temperature should be taken out and balanced to room temperature before use.
3. The reagent should be used as soon as possible after being taken out of the aluminum foil bag to avoid long-term exposure to the air and affect the test results due to humidity.
4. Do not use samples that have been stored for too long or contaminated.
5. Please follow the infectious disease laboratory testing procedures. The waste after use shall be treated as infectious substances and shall not be discarded anywhere.
6. Incorrect operation may affect the accuracy of the results, such as insufficient sample mixing, insufficient quantity, inaccurate detection time, etc.
7. Components of different batches shall not be mixed.
8. It is recommended to use "fresh samples" for testing. If the test cannot be carried out on the same day, the samples collected with cotton swabs should be kept at minus 20 °C, stored and transferred under dry conditions.
9. There should be appropriate biosafety assurance procedures for substances containing and suspected sources of infection. The following are relevant considerations:
 - 1) Wear gloves to handle samples and reagents;
 - 2) Do not suck the sample with your mouth;
 - 3) When handling these items, do not smoke, eat, drink, make up or handle contact lenses;
 - 4) Disinfect the spilled sample or reagent with disinfectant;
 - 5) Disinfect all samples, reagents and potential pollutants

according to relevant local regulations;

- 6) Within the validity period of the reagent, each component shall be stable under proper handling and storage conditions. Do not use expired reagents.

15. Reference

1. MARCELA ECHAVARRIA, JOSEL. SANCHEZ, et al. "Rapid Detection of Adenovirus in Throat Swab Specimens by PCR during Respiratory Disease Outbreaks among Military Recruits", *Journal of Clinical Microbiology*, Feb. 2003, Vol. 41, No. 2, p. 810-812.
2. MARILYN J. AUGUST, AND ANN L. WARFORD; "Evaluation of a Commercial Monoclonal Antibody for Detection of Adenovirus Antigen" *Journal of Clinical Microbiology*, Nov. 1987, Vol. 25, No. 11; p.2233-2235.