Asan Easy Test® Adeno

IVD

ASAN

Diagnostic Kit for Various Adenovirus Serotypes Detection
Nasopharyngeal Secretions and Fecal Sample

Immunochromatography

INTRODUCTION

Adenovirus has six subgenera and 51 serotypes and is an major cause of upper respiratory tract infections and gastroenteritis in infants and young children, also observed in adults.

EXPLANATION OF THE TEST

Asan Easy Test® Adeno is a membrane-based immunogold assay for the qualitative detection of various adenovirus serotypes present in nasopharyngeal swab, aspirate and fecal samples.
The membrane is pre-coated with mouse monoclonal antibodies, on the test band region, against viral antigens. During testing, the sample is allowed to react with the colored conjugate(mouse monoclonal antibodies). The mixture then moves upward on the membrane by capillary action. As the sample flows through the test membrane, the colored particles migrate. In the case of a positive result the specific antibodies present on the membrane will capture the colored conjugate. The mixture continues to move across the membrane to the immobilized antibody placed in the control band region.

MATERIALS PROVIDED

Asan Easy Test® Adeno contains the following items to perform the assay.
1. Test strip in aluminum pouch with a desiccant.
2. Extraction Solution (10㎖/vial).
3. Sample collection swabs.
4. Sample extraction tubes.
5. Disposable droppers.
6. Instruction manual for use.

PRECAUTIONS

1. For *in-vitro* diagnostic use only
2. The test kit should remain in the sealed pouch until ready for use.
3. The test kit is sensitive to humidity and to heat.
4. Do not smoke, eat or drink in areas where specimens or kit component are handled.
5. All specimens and reagents should be considered potentially hazardous and handled in the same manner as an infection agent.
6. Wear protective gloves while handling samples and wash hands thoroughly after the assay is complete.
7. Avoid any contact with the eyes, broken skin or mucous membranes.
8. The test strip and all materials should be discarded in a proper biohazard container after testing.

SPECIMEN COLLECTION AND STORAGE

Specimens should be obtained and handled by standard methods for the collection of nasopharyngeal swab and aspirate.

A. Nasopharyngeal swab:
1. Sterile swab is inserted into one or both nostrils to nasopharyngeal area and gently rotated against nasopharyngeal inside wall to collect specimen as much as possible.
2. Specimens must be tested as soon as they are collected. If necessary, they may be stored at 2~8℃ for up to 24 hours.

B. Nasopharyngeal aspirate:
1. Nasopharyngeal Aspirate should be collected by a specialist using a mucus trap and a catheter.
2. Specimens must be tested as soon as they are collected. If necessary, they may be stored at 2~8℃ for up to 48hours or at -20 for longer periods.

C. Fecal samples:
Approximately 30㎎ of stool should be collected using disposable sample collection swab.

TEST PROCEDUERE

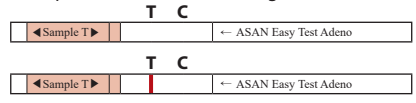
1. All materials should be equilibrated to room temperature (4~30℃) before performing the test.
2. Prepare sample collection swabs and sample extraction tubes as you need.
3. a. Nasopharyngeal Swabs:
   Add 300㎕ of extraction solution (up to 2nd marked in disposable dropper) into extraction tube. Swirl the swab at least 10times in the tube and then discard the swabs squeezing against the wall of the extraction tube .
   b. Nasopharyngeal Aspirates:
   Mix 150㎕ of aspirates with 150㎕ of extraction solution in the extraction tube.
4. Remove the test strip from the its protective pouch.
5. Immerse the test strip in the tube in the direction indicated by the arrow.
   (**NOTE:** Care should be taken not to contact solution or specimen with test line on the strip)
6. Let them react for 15minutes and read the result.

INTERPRETATION OF RESULTS

A. Negative result:
The presence of only one red color band ("C" band) within the result window indicates a negative result.

B. Positive result:
The presence of two red color bands ("T" band and "C" band) within the result window regardless of which band appears first indicates a positive result.

C. Invalid result:
If no band is visible within the window after performing the test, the result is considered invalid. Some causes of invalid results are: not following the directions correctly or the test may have deteriorated beyond the expiration date. It is recommended that the specimen be re-tested using a new test kit.



PERFORMANCE CHARACTERISTICS

A. ACCURACY

This clinical test was performed using a total of 348 specimens confirmed by EIA test method. Each specimen was tested with Asan Easy Test® Adeno and Commercial EIA kit. The results are summarized in the following tables.

n= 348		Commercial EIA kit		Total
		Positive	Negative	
Asan Easy Test® Adeno	Positive	162	7	169
	Negative	8	171	179
Total		170	178	348

※ Relative Sensitivity : 95.2%, Relative Specificity : 96 %

B. CROSS REACTIVITY

Following organisms and viruses have been tested and showed no cross-reactivity
1. Microorganism

1	*Salmonella typhimurium*
2	*Shigella flexneri*
3	*Shigella sonnei*
4	*Staphylococcus aureus*

2. Viruses

1	Respiratory Syncytial Virus
2	Influenza Virus A
3	Influenza Virus B
4	Herpes Simplex Virus 1
5	Herpes Simplex Virus 2
6	Rubella Virus
7	Cytomegalovirus

STORAGE & EXPIRATION

1. Asan Easy Test® Adeno should be stored between 4 to 30℃ (39.2~86℉).
2. Expiration date of this kit is 24 months after its manufacture date.

LIMITATIONS OF THE PROCEDURE

1. Asan Easy Test® Adeno is highly sensitive and specific for adenovirus antigen. The monoclonal antibody in this test reacts with the group specific hexon antigen. It will detect all known serotypes, but cannot be used to differentiate types.
2. A negative result does not exclude the possibility of adenovirus infection in the patient. False negative results may occur due to low concentration levels of the improper sampling or handling of the specimen.
3. Test results depend on the level of antigen in clinical specimens.
4. All positive results should be interpreted with caution, since adenovirus is capable latency and recrudescence.
5. This test provides a presumptive diagnosis for Adenovirus infections. A confirmed infection diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

ASAN
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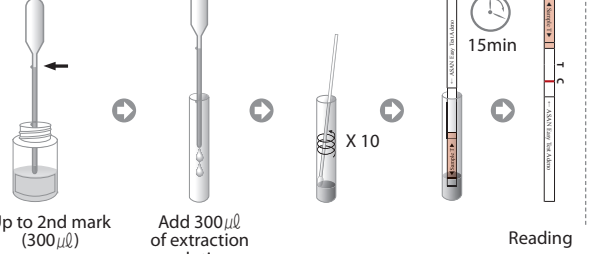
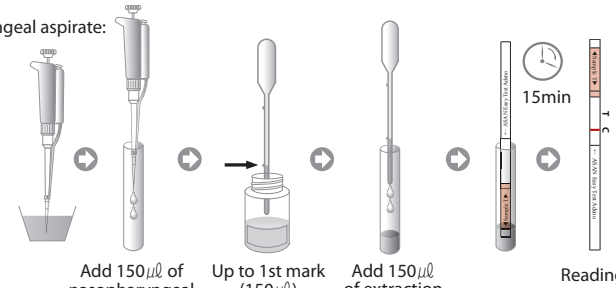
A. Nasopharyngeal swab:



Up to 2nd mark (300㎕) | Add 300㎕ of extraction solution | Reading

B. Nasopharyngeal aspirate:



Add 150㎕ of nasopharyngeal aspirate | Up to 1st mark (150㎕) | Add 150㎕ of extraction solution | Reading