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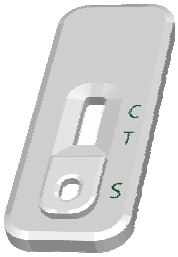
ADENOIRUS ANTIGEN TEST

Cat. No. R13-513

Immunochromatographic rapid assay for the Detection of Adenovirus Antigens in Human Stool Specimens

For Professional Use Only



Adenovirus Antigen Test Card


Sample bottle

INTENDED USE

Immunospec Adenovirus Test is an *in vitro* qualitative immunochromatographic assay for the rapid detection of *adenovirus* antigens in human stool specimen. The test results are intended to aid in the diagnosis of *adenovirus* infection and to monitor the effectiveness of therapeutic treatment.

INTRODUCTION

Adenovirus is the second most common cause of viral gastro-enteritis in Children (10-15%). This virus may also cause respiratory diseases and, depending on the serotype, also diarrhea, conjunctivitis, cystitis, etc. At lease 47 serotypes of adenovirus have been described, all sharing a common hexon antigen. Serotypes 40 and 41 are the ones associated with gastro-enteritis. The main syndrome is diarrhea that may last between 9 and 12 days associated with fever and vomits.

PRINCIPLE OF THE TEST

Immunospec Adenovirus Antigen Test is a sandwich solid phase immunochromatographic assay. To perform the test, an aliquot of diluted stool sample is added to the sample well of the test cassette. The sample flows through a label pad containing adenovirus antibody coupled to red-colored colloidal gold. If the sample contains adenovirus antigens, the antigen will bind to the antibody coated on the colloidal gold particles to form antigen-antibody-gold complexes. These complexes move on the nitrocellulose membrane by capillary action toward the test line region on which adenovirus specific antibodies are immobilized. As the complexes reach the test line, they will bind to the antibody on the membrane in the form of a line. A second red control line will always appear in the result window to indicate that the test has been correctly performed and the test device functions properly. If adenovirus antigen is not present or lower than the detection limit of the test, only the control line will be visible. If the control line dose not developed, the test is invalid.

MATERIALS PROVIDED

1. Immunospec Adenovirus Antigen test card
   Each cassette contains a test strip with adenovirus specific antibody on the test region of the membrane and colored adenovirus antibody-gold conjugate pad.
2. Sample bottle
   Each sample bottle contains 1.5 ml of stool specimen collection buffer. Store at 2-30^{o}C

MATERIALS NOT PROVIDED

1. Specimen collection container
2. Timer.

WARNINGS AND PRECAUTIONS

1. For professional use only.
2. Wear protective glove while handling kit components and test specimens.
3. Patient specimens and inactivated Positive Control may contain infectious agents and should be handled and disposed of as potential biohazards.
4. Do not use kit components beyond expiration date.
5. Dispose all used materials in appropriate container. Treat as potential biohazard.

STORAGE INSTRUCTION

1. The expiration date is indicated on the package label.
2. Store Sample Collection Tubes at 2-30^{o}C.
3. Store test device at 2-30 ^{o}C.

SPECIMEN COLLECTION AND STORAGE

Stool samples must be taken as soon as the symptoms appear. Viral particles decrease in number after one week.
Stool specimens should be collected in containers that do not contain media, preservatives, animal serum or detergents as any of these additives may interfere with the Immunospec Adenovirus Antigen Test.
Specimens may be stored at 2-8^{o}C for 2 days without interfering with the assay performance. For long-term storage of specimens, -20^{o}C or colder is recommended. Repeated freezing and thawing of specimens is not recommended and may cause erroneous results. Do not store specimens in self-defrosting freezers.

REAGENT PREPARATION

Bring all reagents, including test device, to room temperature (20-30^{o}C) before use.

SPECIMEN PREPARATION

1. Unscrew the sample bottle, use the attached applicator stick attached on the cap to transfer small piece of stool (4-6 mm in diameter; approximately 50 mg – 200 mg) into the sample bottle containing specimen preparation buffer.
   For liquid or semi-solid stools, add 100 microliters of stool to the vial with an appropriate pipette.

2. Replace the stick in the bottle and tighten securely. Mix stool sample with the buffer thoroughly by shaking the bottle for a few seconds.

PROCEDURE

1. Bring all materials and specimens to room temperature (8 – 30°C).
2. Remove the test card from the sealed foil pouch.
3. Hold the sample bottle upright with the tip point toward the direction away from the test performer, snap off the tip.
4. Hold the bottle in a vertical position over the sample well of the test card, deliver 3 drops (120 -150 µL) of diluted stool sample to the sample well.
5. Read the result between 5 - 10 minutes. A strong positive sample may show result earlier.

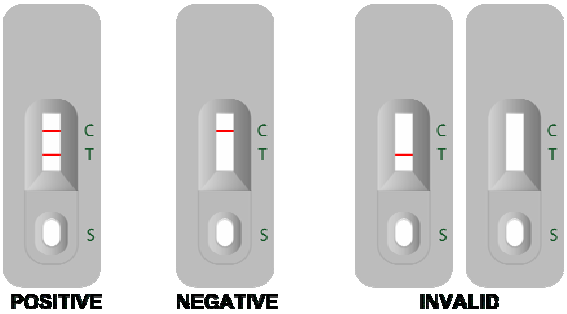
Note: Results after 10 minutes may not be accurate.

INTERPRETATION OF RESULTS

Positive result: A distinct pink colored band appears on test line regions, in addition to a pink line on the control line region.

Negative result: No line appears in the test line region. A distinct pink line shows on the control line region.

Invalid: The control line next to the test line does not become visible within 10 minutes after the addition of the sample.



QUALITY CONTROL

1. The control band is an internal reagent and procedural control. It will appear if the test has been performed correctly and the reagents are reactive.
2. Good Laboratory Practice recommends the daily use of control materials to validate the reliability of the device. Control materials which is not provided with this test kit may be commercially available.

LIMITATIONS

1. The test is for qualitative detection of adenovirus antigen in stool sample and does not indicate the quantity of the antigens.
2. The test is for professional use only.
3. The test result should be used only to evaluate with patient with signs and symptoms of the disease. A definitive clinical diagnosis should only be made by the physician after all clinical and laboratory finding have been evaluated.

EXPECTED VALUES

Immunospec Adenovirus Antigen Test detects the presence of *adenovirus* antigens in stool specimens. Expected values for any given population should be determined for each laboratory. The positivity rate of any given laboratory may vary depending on geographic location, season, and living environment.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

Immunospec Adenovirus antigen test card showed concordance with other commercial tests when tested with commercial performance panels.

Reproducibility

Reproducibility of Immunospec Adenovirus Antigen Test was determined using negative, low positive, and high positive controls. These samples were tested in replicates of 10 in a blind study by 3 operators working independently in the same laboratory. The agreement of the expected result was 100%.

Cross Reactivity

Immunospec Adenovirus Antigen Test may cross with the adenovirus antigen from monkey and porcine.

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