Rota/Adenovirus 2in1Test

Catalog No.: BG302S

INTRODUCTION

Rotavirus is the primary causative agent of acute gastro-enteritis, especially in children less than 2 years old. Its discovery in 1973 and its association with infantile gastro-enteritis represented a very important advance in the study of gastro-enteritis not caused by acute bacterial infection. Rotavirus is transmitted by oral-faecal contact with an incubation period of 1-3 days etc.

The 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 least 47 serotypes of adenovirus have been described, all sharing a common hexon antigen. Serotypes 40 and 41 are the ones associated with gastro-enteritis, whose main symptom is diarrhoea that may last between 9 and 12 days associated with temperature and vomits.

SUMMARY AND PRINCIPLE OF THE TEST

The test uses new homogenous immunochromatographic system with gold particules. It is a ready to use test which only needs a faecal sample dilution with the supplied ready to use dilution buffer. Specificity is ensured by using a monoclonal antibody conjugated with gold particules and directed against specific human genus-specific Rotavirus antigen or Adenovirus antigens. The immunochromatographic stick is coated with a monoclonal immunoreagent specific for genus-specific Adenovirus hexon antigens or rotavirus VP6 antigen. Liquid sample and gold conjugate both migrate by capillarity and reach the first specific anti-Adenovirus monoclonal reagent. If Adenovirus is present in the sample, it is blocked and immunoreactions appear as a red-pink line. As sample still migrates, it reaches the second non specific anti-mouse IgG which gives rise to a second red-pink line. This rear line indicates that the chromatography has been developed without hindrance. It appears also with negative samples.

REAGENTS AND MATERIALS

Strip	25T
Extraction Buffer	15ml
Instruction for use	1

PRECAUTION FOR USERS

1. For in-vitro diagnostic use only.
2. Handle all specimens as if they contain infectious agents. When the assay procedure is completed, dispose of specimens carefully after autoclaving for at least one hour. Alternatively, treat with a 0.5 or 1% solution of sodium hypochlorite for one hour before disposal.
3. Wear protective clothing (laboratory coats and disposable gloves) when assaying samples.
4. Do not eat, drink or smoke in areas where specimens and kit reagents are handled.
5. Avoid contact between hands and eyes or nose during specimen collection and testing.

SPECIMEN COLLECTION

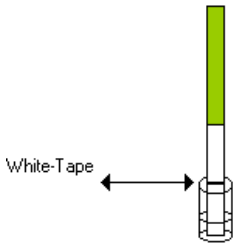
Stool samples must be taken as soon as the symptoms appear. Viral particles decrease in number after one week, making the diagnosis more difficult. The samples can be stored in the refrigerator for 1 to 2 days. For longer storage they must be kept frozen at -20 ℃. In this case, the sample should be totally thawed, and brought to room temperature and homogenized before testing.

STORAGE OF TEST KIT

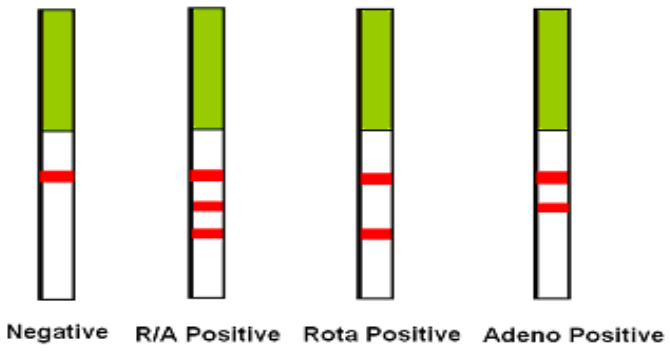
The Rota/Adeno Rapid Test Strip can be stored at any temperature between 4-30 ℃. **Do not freeze**. The stability of the kit under these storage conditions is 24 months. Use up the reagents as soon as possible after the kit is unpacked.

ASSAY PROCEDURES

1. Allow all reagents to reach room temperature before use.
2. Place 0.5-1ml of extraction buffer in a properly marked testing tube.
3. Add a sample portion of approximately 5-6 mm size (25-100mg), with a swab, a wooden applicator or a bacteriology loop. Press the applicator to the tube and rotating it at the same time. For liquid or semi-solid stools add 100 micro liters of stool using an appropriate pipette.
4. Shake vigorously in order to resuspend it into the buffer. If needed Vortex for 15 seconds.
5. Dip the reaction strip in the test tube with the arrow pointing to the bottom.
6. Incubate the test at room temperature and read the test in **5-15 minutes.**



INTERPRETATION OF RESULTS



Negative: One pink line appears in control line, showing the test has been carried out correctly. There will be no line in test region

Positive: In addition to a pink colored control line, for adenovirus positive, an upper test line will appear, for rotavirus positive, a lower test line will appear.

Invalid: A total absence of color in both regions is an indication of procedure error and/or that the test reagent has deteriorated. The test should be repeated using a new strip.

LIMITATIONS OF THE ASSAY

1. The test should be used only for the detection of rotavirus and adenovirus antigen in faecal samples.
2. The test is qualitative and no quantitative interpretation should be made with respect to the intensity of the positive line, when reporting the result
3. More than 200 samples were evaluated to assure the correct performance of the test. The correlation of the results with other techniques (ELISA) was excellent. However, interferences in the performance of the tests should not be excluded.
4. No cross-reactions with other viruses or substances were observed during the evaluation of the test. A negative result does not totally exclude a possible rotavirus infection. The significance of the results must be evaluated in relation to the patient's clinical symptoms.

PERFORMANCE

Specificity: 97 % (in comparison with an ELISA test)

Sensitivity: 98 % (in comparison with an ELISA test)

Inter-series and intra-series accuracy: 100 %

Interference: Cross reactivity has been evaluated and found to be negative compared to positive specimens of *Cryptosporidium Parvum*, rotavirus.