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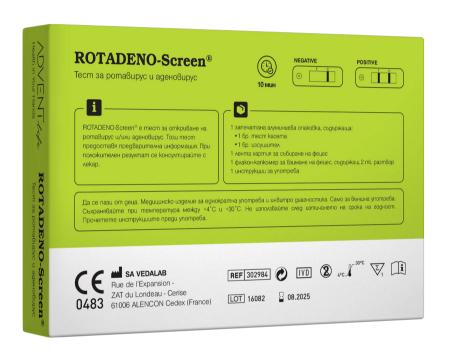
Self-diagnostic test for detection of rotavirus and/or adenovirus in faeces (at-home test)













ROTADENO-Screen®

Our ambition is to make healthcare widely accessible by empowering self-care globally.

Driven by our spirit of innovation, **Advent Life** specialises in self-tests for a wide range of medical conditions, while also offering other products that allow everyone to take health into their own hands. We enable people to take the first step themselves and at their own convenience.

Advent Life focuses on bringing the best from the world while prioritising safety and easy-to-use products. We design premium brands that are delivered to pharmacies, hospitals, laboratories, public organisations and government institutions.

For more information, visit www.adventlife.net.



ROTAVIRUS

Rotaviruses are a genus of viruses in the Reoviridae family. They are the most common cause of diarrhoea among infants and young children. This and several similar viruses are also the most common cause of so-called stomach flu. By age 5, almost all children get the virus at least once. With each illness, the body's resistance to the virus becomes stronger and stronger, and subsequent inflammation is increasingly minor; adults are rarely affected.

ADENOVIRUS

Adenovirus infection causes a variety of diseases. Young people and children are most commonly affected, especially in infancy. It has been shown that most children experience infections with one or more types of adenovirus. Those who have had and survived the infection acquire immunity. Adenovirus infection has multiple manifestations, which necessitates their division into distinct syndromes: Acute respiratory illness, Pharyngoconjunctival fever, Acute conjunctivitis, Epidemic keratoconjunctivitis, Acute haemorrhagic cystitis, Gastroenteritis.

WHAT ARE THE SYMPTOMS?

Rotavirus and adenovirus infections spread easily on contact with contaminated objects or other surfaces in the environment contaminated with faeces. Annual outbreaks usually occur during the fall and spring seasons, but may be less seasonal depending on the geographic area. Adenovirus is usually associated with:

- Gastroenteritis
- Bronchitis

Pharyngitis

• Keratoconjunctivitis when present in the respiratory tract.



SELF-DIAGNOSTIC TEST FOR DETECTION OF ROTAVIRUS AND/OR ADENOVIRUS IN FAECES

PURPOSE

Rotavirus and Adenovirus are both a major cause of infectious gastroenteritis and related syndromes in humans and especially in children and elderly. Adenovirus is generally associated to gastroenteritis but also to many other illnesses such pharyngitis, bronchitis or keratoconjunctivitis when present in the respiratory tract. The infections caused by these viruses can be severe in young children, elderly or immunocompromised patients. Rotavirus and Adenovirus infection spread easily through contacts with contaminated objects or other environmental surfaces contaminated by stool. Annual epidemics usually appear in fall and spring period but can be less seasonal depending on geographic areas.

The ROTADENO-Screen® is a rapid immunodiagnostic test for the immunological detection of rotavirus and/or adenovirus in faeces sample. The test device consists of a plastic housing containing two reactive strips, ie one for rotavirus and another one for adenovirus, each of them having distinct zones for the virus detection and for the control.



FAST AND RELIABLE RESULTS

Time: 10-15 minutes. Store between +4°C and +30°C. Do not freeze! 1 test per box.

When present in infected people, Rotavirus or Adenovirus are excreted in the faeces. The ROTADENO-Screen® test is designed to detect both Rotavirus and Adenovirus antigens through two distinct strips located into the same test device. Each strip contains a specific pair of antibodies to either Rotavirus or Adenovirus. On each strip, one antibody is immobilized on the test zone (T) and another antibody is coupled to red colloidal gold particles to visualize the positive reaction when occurring (red line) in the test zone (T) of both reading windows. The control line (C) indicates if the test performed correctly.

Easy to read.

The ROTADENO-Screen® test is accurate and has been used for more than 20 years by professionals (hospitals, laboratories) in the field. Evaluation reports show an overall agreement higher than 92% (CI 95% [92.30 – 100.00]*) with a reference method. Although this test is very reliable, false positive or false negative results could occur.



PROVIDED MATERIALS:

1 sealed aluminium pouch containing:

1 test device

1 desiccant bag

Only open the protective pouch when you are ready to use the test. The desiccant bag should not be used.

1 faeces collection vial containing 2 mL of diluent.

1 special paper strip.

1 instruction leaflet.





Before performing the tests, the faeces sample should be collected according to the instructions below:

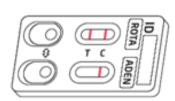
A. Faeces sample collection

- 1. Wash your hands thoroughly. Use soap and warm water. Dry your hands with a clean towel.
- 2. The faeces have to be collected using the dedicated paper strip supplied in the box.
- 3. Unscrew the cap of the collection vial and dip the stick (about 2 cm) in the faeces at 3 different places.
- 4. Place the cap with the stick back into the vial containing the solution. Screw the cap firmly and shake well to resuspend the faeces sample into the diluent.
- 5. Dispose of the paper strip in the toilet.

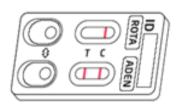
B. Test procedure

- 1. Open the protective pouch using the notches and take out the test device. Discard the small desiccant bag.
- 2. Break the tip of the collection vial.
- 3. Hold the vial vertically and slowly add exactly 5 drops of the extract with an interval of 2-3 seconds between each drop into each sample well.
- 4. Note: It is necessary to add 5 drops of extract into each sample well as there are 2 reactive strips in the device, i.e. one for rotavirus and another one for adenovirus.
- 5. Read the result after 10 minutes. Do not interpret after 15 minutes.

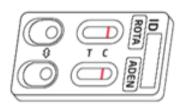




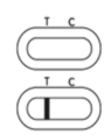
Positive for Rotavirus: Two coloured lines appear in the upper reading window. The intensity of the test line above the T mark may be clearer than the intensity of the control line (C). This result means that Rotavirus antigen is present in the sample and that you should consult a doctor.



Positive for Adenovirus: Two coloured lines appear in the lower reading window. The intensity of the test line below the T mark may be clearer than the intensity of the control line (C). This result means that Adenovirus antigen is present in the sample and that you should consult a doctor.



Negative: Only one coloured line appears in the control zone (C) of both the upper and lower reading windows. This result means that no rotavirus nor adenovirus antigens are detected in the faeces sample.



Invalid: When no line appears in the control zone (C) for either the Rotavirus part or for the Adenovirus part of the device, the test result is not valid. The test should be repeated using a new ROTADENOScreen [®] and a new sample of faeces.

NOTE:

The intensity of the line color does not have any importance for the interpretation of the test result.



This test is exclusively intended for in vitro diagnostics use. External use only. DO NOT SWALLOW.

Carefully read the instructions before performing the test. The test is only interpretable if the instructions are carefully respected.

Follow strictly the indicated number of drops as well as reaction time.

Store between +4°C and +30°C. Do not freeze.

Do not use after the expiry date printed on the box label and on the aluminum pouch or if the protective pouch is damaged.

Do not reuse the ROTADENO-Screen® test.

Keep out of the reach of children.

After use, all the components can be discarded in a dustbin.

