

ROTADENO-Screen®

Ref. 302984

Self-diagnostic test for the detection of rotavirus and/or adenovirus in faeces

GENERAL POINTS

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 illness 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.

PRESENTATION

The box contains the material necessary to perform a test:

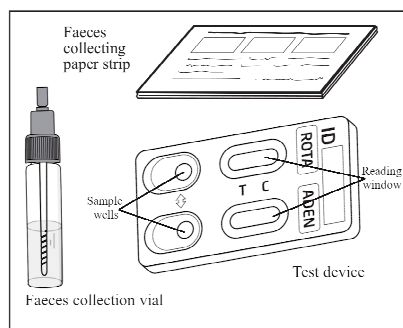
- 1 sealed aluminium pouch containing: 1 test device, 1 desiccant bag.

Only open the protection pouch after having collected the faeces sample. The desiccant bag should be discarded.

- 1 faeces collection vial containing 2 mL of extraction solution.

- 1 faeces collection paper strip

- 1 instruction leaflet



PRECAUTIONS

1. This test is exclusively intended for *in vitro* diagnostic use. External use only. DO NOT SWALLOW.
2. 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.
3. Store between +4°C and +30°C. Do not freeze.
4. Do not use after the expiry date printed on the box label and on the aluminium pouch or if the protective pouch is damaged.
5. Do not reuse the ROTADENO-Screen® test.

6. Keep out of the reach of children.
7. After use, all the components can be discarded in a dustbin.

PROCEDURE

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

A – Faeces sample collection

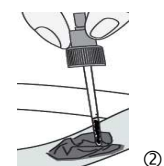
1) Wash your hands thoroughly. Use soap and warm water. Dry your hand with clean towel.



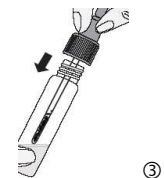
2) The faeces have to be collected using the dedicated paper strip supplied in the box ①.



3) Unscrew the cap of the collection vial and dip the stick (about 2 cm) in the faeces at 3 different places.②.



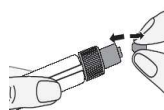
4) Replace the cap containing the faeces into the collection vial containing the diluent. Screw the cap firmly and shake well to resuspend the faeces sample into the diluent③.



5) Remove the collection paper strip and dispose it in the toilets.

B- Test procedure

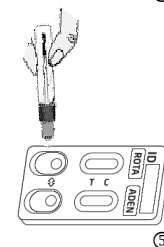
1) Open the protective pouch using the notches and take out the test device. Discard the small desiccant bag.



2) Break the tip of the collection vial④.



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 (♣)⑤.



Note: It is necessary to add 5 drops of extract **into each sample well** as there are 2 reactive strips in the device, ie one for rotavirus and another one for adenovirus.

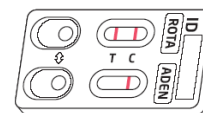
4) Read the result after 10 minutes. Do not interpret after 15 minutes.

RESULT INTERPRETATION

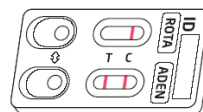
The intensity of the line colour does not have any importance for the interpretation of the test result.

1. Positive result

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.

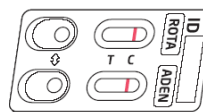


Two coloured lines appear in the **lower** reading window. The intensity of the test line below the T mark may be clearer than the intensity of the control line (C). This result means that **adenovirus** antigen is present in the sample and that you should consult a doctor.



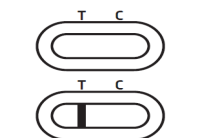
2. Negative result

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.



3. Invalid result

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 ROTADENO-Screen® and a new sample of faeces



QUESTIONS AND ANSWERS

How does ROTADENO-Screen® work?

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 cassette. 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.

A control line (C), indicating that the test performed well, captures the excess of red gold particles and will appear in the control zones of both reading windows.

When should the test be performed?

The ROTADENO-Screen® test should be performed at any time of the day when having a bowel movement.

Can the result be incorrect?

The result is accurate as long as the instructions are carefully respected.

Nevertheless, the result can be incorrect if the ROTADENO-Screen® test gets wet before performing the test, if faeces collecting steps are not correctly performed, if the sample is contaminated or if an incorrect number of drops is dispensed in the sample wells.

How to interpret the test if the colour and the intensity of the T and C lines are different?

The colour and intensity of the lines have no importance for result interpretation. The lines should only be homogeneous and complete.

What is the line that appears in the (C) zones of the windows?

When this line appears, it only means that the test has been performed well.

If I read the result after 15 minutes, will the result be reliable?

No. The test should be read after 10 minutes and before 15 minutes after having added the extract. The results are reliable up to 15 minutes.

What do I have to do if the result is positive?

If the result is positive, it means that rotavirus and/or adenovirus is present in the stool sample and that you should consult a doctor, **especially if you are immunocompromised**, to show him the test results. Then, the doctor will decide what should be further done.

What do I have to do if the result is negative?

If the result is negative, it means that no rotavirus nor adenovirus is present in the stool sample. However, if you still have signs of infection such as diarrhea, painful intestine, bronchitis or conjunctivitis, it is recommended to consult your doctor.

What is the accuracy of ROTADENO-Screen®?

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 be obtained.

* CI 95%: 95% confidence interval.

Information on infections by rotavirus and adenovirus

Web resource:

<https://www.msmanuals.com/professional/infectious-diseases/respiratory-viruses/adenovirus-infections>

Web resource:

<https://www.msmanuals.com/home/children-s-health-issues/viral-infections-in-infants-and-children/rotavirus-infection>



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	Read the instructions before use		For <i>in vitro</i> diagnostic use		Do not reuse
	Store between +4°C and +30°C		Batch number		Expiry date
	Manufacturer				



ROTADENO-Screen® Ref. 302984

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