ROTA-CHECK-1

Immunochromatographic rapid test for the detection of Rotavirus in feces

I. PRINCIPLE

Rotavirus, a 65-nm RNA virus of the family *Reoviridae*, is a major cause of infectious gastroenteritis in infants and young children (1) with the illness also being observed in older children and adults (2, 3). Rotaviral gastroenteritis may result in mortality for populations at risk such as infants, the elderly and immunocompromised patients (4, 5).
In temperate climates, Rotavirus infections occur mainly in the winter months. Endemics as well as epidemics affecting some thousand people have been reported (6). With hospitalised children suffering from acute enteric disease up to 50 % of the analysed specimen were positive for Rotavirus (7).
Rotavirus infection can be easily transferred as the virus breeds in the gut and is secreted with feces.
Therefore, nosocomial infections with Rotaviruses are dangerous, particularly in paediatric wards and neonatal nurseries, and their management is difficult.

ROTA-CHECK-1, contrary to the classical methods (electron microscopy and cell cultures) which are laborious and time consuming, is a fast, simple and highly sensitive test for the rapid and reliable detection of rotavirus antigen in the feces.
The method employs a unique combination of monoclonal dye conjugate and polyclonal solid phase antibodies to selectively identify rotavirus with a high degree of sensitivity and specificity. After collection in a tube containing extraction solution, the sample is dissolved and a few drops of this extract are added to the sample well (A) of the reaction device.
As the test sample flows through the absorbent device, the labelled antibody-dye conjugate binds to the rotavirus antigen (when present in the sample) forming an antibody antigen complex.
This complex binds to the polyclonal antibody in the positive reaction window (B) producing a rose-pink coloured band.
In the absence of rotavirus, there is no band in the positive reaction zone. The reaction mixture continues flowing through the absorbent device, past the positive reaction zone and control zone.
Unbound conjugate binds to the reagent in the control window (C) producing a pink-rose coloured band demonstrating that the reagents are functioning correctly.

II. ROTA-CHECK-1 KIT COMPONENTS

Each kit contains everything needed to perform 10 or 20 tests.

- ROTA-CHECK-1 devices	10	20
- Disposable plastic pipettes	10	20
- Plastic tubes filled with 2 mL of extraction solution	10	20
- Sample applicators	10	20
- Instructions leaflet	1	1

III. STORAGE AND STABILITY

1- All ROTA-CHECK-1 kit components are to be stored at room temperature (+4°C to +30°C).
2- ***Do not freeze the test kit.***
3- ROTA-CHECK-1 is stable until the expiry date stated on the package label.

IV. PRECAUTIONS

1- This test is designed for *in vitro* diagnostic use and professional use only.
2- Read carefully instructions before using the test.
3- Do not use beyond the expiry date which appears on the package label.
4- All reagents and materials coming in contact with potential infectious specimens must be treated with appropriate disinfectants or autoclaved at 121°C for at least one hour.
5- Do not use the test from a damaged protective wrapper.

V. SPECIMEN COLLECTION AND PREPARATION

1- Preliminary notes

Stool specimens should be collected as soon as possible after onset of symptoms.
Peak viral counts are reported to occur on days 3-5 after onset of symptoms.
Samples collected 8 days or more after onset of symptoms may not contain enough Rotavirus antigen to produce a positive reaction.
Diluted samples may be stored at +2°C to +8°C for 3 days without interference with the assay performance.
For long term storage of undiluted specimens, storage at -20°C or colder is recommended. Repeated freezing and thawing of samples is not recommended and may cause erroneous results.

Caution !
Do not collect specimens in containers having media, preservatives, animal serum or detergents, as any of these may interfere with the test.

2- Procedure

1- Label the plastic tube containing the extraction solution with patient's name or control number.
2- Open the tube and using the sample applicator, transfer a stool sample (volume of a pea) into the tube in case of solid stool. If the stool is liquid, transfer 200 µL of liquid into the tube.

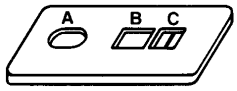
3- Tighten the cap and mix the stool sample and the diluent by shaking well until the sample is dissolved.
4- Let the tube stand long enough for the large particles to settle to the bottom of the tube. Alternatively, centrifuge the tube at 500-1 000 RPM for 1 minute.

VI. ASSAY PROCEDURE

1- Bring all reagents at room temperature.
2- Remove the test device from the pouch.
3- Open the plastic tube containing the extracted sample.
4- Using the plastic pipette, add 6 drops (200 µL) of the extracted solution into the sample well (A).
5- Read the results of the test 10 minutes after addition of the sample to the device.

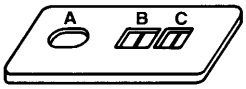
VII. READING TEST RESULTS

A. Negative
Only one coloured band shows in the control window (C). No band is visible in the test window (B).
The sample does not contain Rotavirus.



Negative

B. Positive
In addition to the control band, a clearly distinguishable band also shows in the test window (B).
The sample contains Rotavirus.



Positive

C. Inconclusive
If there is no distinct coloured band visible in both test and control windows, the test is inconclusive. In this case, it is recommended to repeat the test with another device.

VIII. PERFORMANCES CHARACTERISTICS

a) Sensitivity and specificity
A study was performed on 70 stool samples pretested with FUMOUZE latex (ROTALEX) and gave positive results.

		ROTA-CHECK-1	
		+	-
LATEX	+	30	0
	-	0	40

Table 1 : Evaluation results

From the above table, there was 100% correlation for sensitivity and specificity between the ROTALEX test and ROTA-CHECK-1 rapid test.

b) Cross reactivity
Stool samples enterovirus or astrovirus positive showed negative results when tested using ROTA-CHECK-1 rapid test.
Adenovirus concentrated cellular cultures showed repeatedly negative results when tested with ROTA-CHECK-1.

IX. LIMITATIONS

1- ROTA-CHECK-1 is specifically designed to detect rotavirus antigen in the stool samples.
2- As for any diagnostic procedure, the physician should confirm the data obtained using this test by other clinical methods.
3- The presence of blood in the feces samples in significant quantity may lead to false positive results in limited cases.

X. BIBLIOGRAPHY

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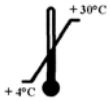

Temperature limitations


Consult operating instructions


Do not re-use

In vitro diagnostic use

Manufactured by VEDALAB - France