VITASSAY

Rotavirus+Adenovirus+ Astrovirus+Norovirus +Enterovirus

Rapid test for the simultaneous qualitative detection of rotavirus, adenovirus, astrovirus, norovirus and enterovirus in human stool samples.

IUE-7715050 Ed00 October 2019

CE IVD EN

Vitassay

For professional *in vitro* diagnostic use only.

INTENDED USE

Vitassay Rotavirus+Adenovirus+Astrovirus+Norovirus+ Enterovirus is a rapid, immunochromatographic assay for the simultaneous qualitative detection of rotavirus, adenovirus, astrovirus, norovirus and enterovirus in human stool samples.

Simple, non-invasive and highly sensitivity immunoassay to make a presumptive diagnosis of rotavirus, adenovirus, astrovirus, norovirus and/or enterovirus infection.

INTRODUCTION

Rotavirus is the leading cause of severe dehydration in children <5 years of age.

Most rotavirus infections are community-acquired and transmitted by the feco-oral route and peak the winter season between November and February in temperate climates.

Adenovirus, initially recognized as a cause of respiratory disease, is associated also with gastrointestinal, ophthalmological, and neurological infections. Watery, non-bloody diarrhea typically precedes vomiting and children admitted to the hospital for adenovirus gastroenteritis are more likely to present diarrhea that usually lasts more than in rotavirus gastroenteritis (more than 5 days).

Astrovirus, especially classic astrovirus, are considered gastrointestinal pathogens affecting children worldwide, with very few reports of astrovirus-mediated disease in normal healthy adults. Immunocompromised individuals and the elderly also represent high-risk groups.

Norovirus represents the most common cause of gastroenteritis outbreaks and causes acute, self-limiting gastroenteritis in people from all age groups.
Watery diarrhea occurs several times a day. Rotavirus,adenovirus, astrovirus and norovirus infection occasionally leads to severe dehydration in infants and children. Symptoms of dehydration include lethargy, dry, cool skin, absence of tears when crying, dry mouth, sunken eye and extreme thirst.
In general, the symptoms begin 1 to 2 days following infection with a virus that causes gastroenteritis and may last from 1 to 10 days, depending on which virus causes the illness (Rotavirus 3 days, Adenovirus 5-8 days and Astrovirus 3 days).

The human enteroviruses belong to the genus *Enterovirus* and *Picornaviridae* family. These agents infect millions of people worldwide each year, resulting in a wide variety of clinical conditions ranging from unapparent infection, undifferentiated fevers, common cold to serious diseases such as aseptic meningitis, hand-foot-mouth disease, acute hemorrhagic conjunctivitis, myocarditis, encephalitis and paralytic poliomyelitis. The average incubation period for enteroviral contagious is from 3-10 to 30 days.

PRINCIPLE

Vitassay Rotavirus+Adenovirus+Astrovirus+Norovirus+ Enterovirus is a qualitative immunochromatographic assay to make a presumptive diagnosis of rotavirus, adenovirus, astrovirus, norovirus and/or enterovirus infection.

Strip A: The test line zone of the nitrocellulose membrane is pre-coated with monoclonal antibodies against rotavirus.

Strip B: The test line zone of the nitrocellulose membrane is pre-coated with monoclonal antibodies against adenovirus.

Strip C: The test line zone of the nitrocellulose membrane is pre-coated with monoclonal antibodies against astrovirus.
Strip D: The test line zone of the nitrocellulose membrane is pre-coated with monoclonal antibodies against norovirus.
Strip E: The test line zone of the nitrocellulose membrane is pre-coated with monoclonal antibodies against enterovirus.

During the process, the sample reacts with the antibodies against rotavirus (strip A) and/or adenovirus (strip B) and/or astrovirus (strip C), and/or norovirus (strip D) and/or enterovirus (strip E) forming conjugates. The mixture moves upward on the membrane by capillary action. If the sample is rotavirus positive, antibodies present on the membrane (test line) capture the conjugate complex and a red line will be visible in the strip A, if the sample is adenovirus positive, antibodies present on the membrane (test line) capture the conjugate complex and a red line will be visible in strip B, if the sample is astrovirus positive, antibodies present on the membrane (test line) capture the conjugate complex and a red line will be visible in strip C, if the sample is norovirus positive, antibodies present on the membrane (test line) capture the conjugate complex and a red line will be visible in strip D and if the sample is enterovirus positive, antibodies present on the membrane (test line) capture the conjugate complex and a red line will be visible in strip E. Although the sample is positive or negative, the mixture continues to move across the membranes and the green control line always appears (for all the strips).

The presence of these green lines (in the control zone (C)) indicates that sufficient volume is added; proper flow is obtained and serves as an internal control for the reagents.

PRECAUTIONS

- For professional *in vitro* use only.
- Do not use the test if its pouch is damaged.
- Do not use after expiration date.

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- Specimens should be considered as potentially hazardous and handle in the same manner as an infectious agent.
- A new test must be used for each sample to avoid contaminations errors.
- Tests should be discarded in a proper biohazard container after testing.
- Reagents contain preservatives. Avoid any contact with the skin or mucous membrane. Consult safety data sheet, available on request.
- Components provided in the kit are approved for use with the **Vitassay Rotavirus+Adenovirus+Astrovirus+Norovirus +Enterovirus**. Do not use any other commercial kit component.
- Follow Good Laboratory Practices, wear protective clothing, use disposal gloves, goggles and mask. Do not eat, drink or smoke in the working area.
- The presence of yellow lines in the result window (control line zone and test line zone), before using the test, is completely normal and does not imply failure of the test functionality.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at refrigerated or room temperature (2-30ºC/35.6-86ºF).

The test is stable until the expiration date printed on the sealed pouch.

The test must remain in the sealed pouch until use.

Do not freeze.

MATERIALS

MATERIAL PROVIDED	MATERIAL REQUIRED BUT NOT PROVIDED
▪ **10** tests/kit **Vitassay Rotavirus+Adenovirus +Astrovirus+Norovirus+Enterovirus** ▪ Instructions for use. ▪ **10** vials with diluent for sample dilution.	▪ Specimen collection container. ▪ Disposable gloves. ▪ Timer. ▪ Spatula.

SPECIMEN COLLECTION

Stool samples should be collected in clean and dry containers. Collect sufficient quantity of feces: 1-2 g or mL for liquid samples.

The samples can be stored in the refrigerator (2-8ºC/35.6-46.4ºC) for 1-2 days prior to testing. For longer storage, maximum 1 year, the specimen must be kept frozen at -20ºC/4ºF. The samples will be brought to room temperature before to testing.

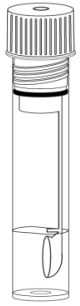
Homogenise stool sample as thoroughly as possible prior to preparation.

SPECIMEN PREPARATION

1 Remove the cap of the vial with diluent for sample dilution (figure 1) and use the spoon to collect sufficient sample quantity. For solid stool, insert the spoon in 4 different areas of the stool sample (figure 2), remove any excess sample with a spatula (figure 3), and place the spoon cap back into the vial for sample dilution (figure 4). For liquid stool, take a spoonful of the sample (figure 3) and transfer it into the vial for sample dilution.

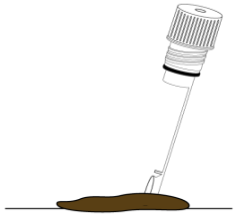
2.Close the vial for sample dilution tightly and shake it to dilute and mix the sample with the diluent (figure 4).

1



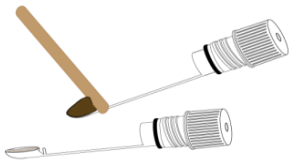
Vial for sample dilution

2



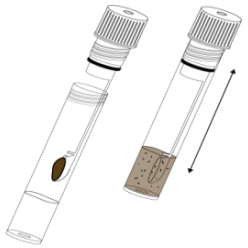
Insert the spoon in 4 different areas of the stool.

3



Remove excess sample with a spatula. Liquid samples: full spoon.

4



Put the sample into the vial, close the cap and shake.

PROCEDURE

Allow the test, stool sample, controls and diluent to reach room temperature (15-30ºC/59-86ºF) prior to testing. Do not open pouches until the performance of the assay.

1. Shake the vial with the sample vigorously to obtain a good sample dilution.

2. Remove the **Vitassay Rotavirus+Adenovirus+Astrovirus+ Norovirus+Enterovirus** from its sealed bag just before using it (figure 5).

3. Take the vial for sample dilution containing the diluted sample (figure 6), place it inside the multiplex tube (figure 7). Screw the cap of the multiplex tube tightly (figure 8). The bottom of the vial for sample dilution will break and the diluent+sample solution reaches the sample zone of the strips (figure 9).

4. Leave the multiplex tube vertically on a flat surface and read the results at **10 minutes**. Do not read the test results later than 10 minutes.

If the test does not run due to solid particles (the sample is not homogenized), migration process can stop on one or more strips. In this case, tap the end of the multiplex tube on hard surface to allow migration to start again.

5

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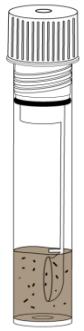
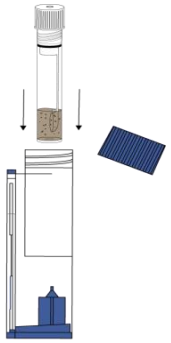
6



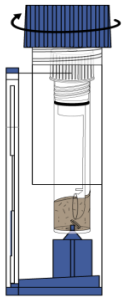
Vial with the diluted sample inside.

7



Introduce the vial with the diluted sample into the multiplex.

8



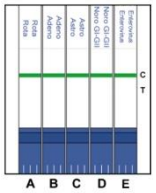
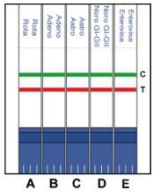
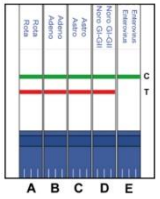
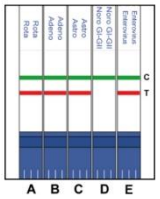
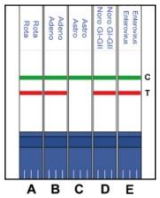
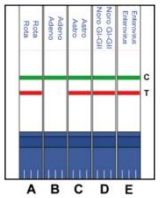
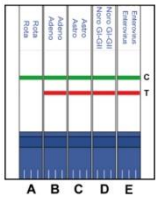
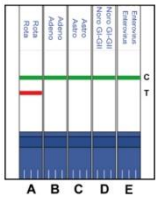
Close the cap and the bottom of the diluent vial will break.

9

Reaction takes place. **Read results at 10 minutes.**

INTERPRETATION OF THE RESULTS

Strip A: rotavirus, Strip B: adenovirus, Strip C: astrovirus ,Strip D: norovirus, Strip E: Enterovirus

	**NEGATIVE** Only one green line in the control zone (C) in the four strips (A,B,C D and E)	There is no rotavirus, adenovirus, astrovirus, norovirus and enterovirus presence.
	**POSITIVE** In addition to the green line (control line C), a red line appears in each strip, test line (T)	There is rotavirus, adenovirus, astrovirus, norovirus and enterovirus presence.
	**NEGATIVE** Strip E (enterovirus)→ green line **POSITIVE** Strip A (rotavirus)→ green/red lines Strip B (adenovirus)→ green/red lines Strip C (astrovirus)→ green/red lines Strip D (norovirus)→ green/red lines	There is rotavirus, adenovirus, astrovirus, norovirus presence. Viral infection caused by rotavirus, adenovirus, astrovirus and norovirus.
	**NEGATIVE** Strip D (norovirus)→ green line **POSITIVE** Strip A (rotavirus)→ green/red lines Strip B (adenovirus)→ green/red lines Strip C (astrovirus)→ green/red lines Strip E (enterovirus)→ green/red lines	There is rotavirus, adenovirus, astrovirus and enterovirus presence. Viral infection caused by rotavirus, adenovirus, astrovirus and enterovirus.
	**NEGATIVE** Strip C (astrovirus)→ green line **POSITIVE** Strip A (rotavirus)→ green/red lines Strip B (adenovirus)→ green/red lines Strip D (norovirus)→ green/red lines Strip E (enterovirus)→ green/red lines	There is rotavirus, adenovirus, norovirus and enterovirus presence. Viral infection caused by rotavirus, adenovirus, norovirus and enterovirus.
	**NEGATIVE** Strip B (adenovirus)→ green line **POSITIVE** Strip A (rotavirus)→ green/red lines Strip C (astrovirus)→ green/red lines Strip D (norovirus)→ green/red lines Strip E (enterovirus)→ green/red lines	There is rotavirus, astrovirus, norovirus and enterovirus presence. Viral infection caused by rotavirus, astrovirus, norovirus and enterovirus.
	**NEGATIVE** Strip A (rotavirus)→ green line **POSITIVE** Strip B (adenovirus)→ green/red lines Strip C (astrovirus)→ green/red lines Strip D (norovirus)→ green/red lines Strip E (enterovirus)→ green/red lines	There is adenovirus, astrovirus, norovirus and enterovirus presence. Viral infection caused by adenovirus, astrovirus, norovirus and enterovirus.
	**NEGATIVE** Strip B (adenovirus)→ green line Strip C (astrovirus)→ green line Strip D (norovirus)→ green line Strip E (enterovirus)→ green line **POSITIVE** Strip A (rotavirus)→ green/red lines	There is rotavirus presence. Viral infection caused by rotavirus.

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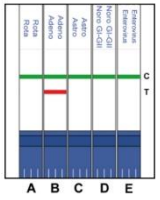
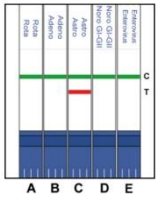
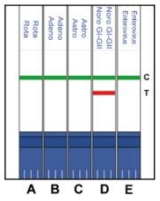
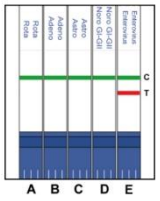
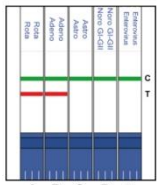
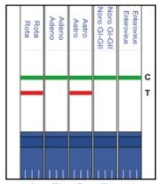
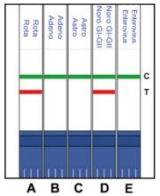
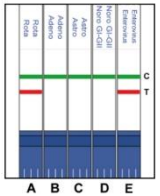
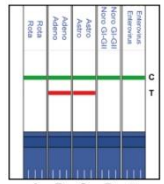
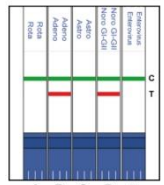
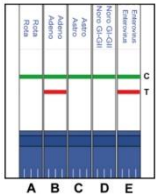
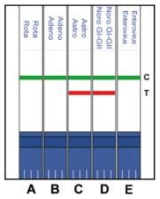
	**NEGATIVE** Strip A (rotavirus)→ green line Strip C (astrovirus)→ green line Strip D (norovirus)→ green line Strip E (enterovirus)→ green line **POSITIVE** Strip B (adenovirus)→ green/red lines	There is adenovirus presence. Viral infection caused by adenovirus.
	**NEGATIVE** Strip A (rotavirus)→ green line Strip B (adenovirus)→ green line Strip D (norovirus)→ green line Strip E (enterovirus)→ green line **POSITIVE** Strip C (astrovirus)→ green/red lines	There is astrovirus presence. Viral infection caused by astrovirus.
	**NEGATIVE** Strip A (rotavirus)→ green line Strip B (adenovirus)→ green line Strip C (astrovirus)→ green line Strip E (enterovirus)→ green line **POSITIVE** Strip D (norovirus)→ green/red lines	There is norovirus presence. Viral infection caused by norovirus.
	**NEGATIVE** Strip A (rotavirus)→ green line Strip B (adenovirus)→ green line Strip C (astrovirus)→ green line Strip D (norovirus)→ green line **POSITIVE** Strip E (enterovirus)→ green/red lines	There is enterovirus presence. Viral infection caused by enterovirus.

	**NEGATIVE** Strip C (astrovirus)→ green line Strip D (norovirus)→ green line Strip E (enterovirus)→ green line **POSITIVE** Strip A (rotavirus)→ green/red lines Strip B (adenovirus)→ green/red lines	There is rotavirus and adenovirus presence. Viral infection caused by rotavirus and adenovirus.
	**NEGATIVE** Strip B (adenovirus)→ green line Strip D (norovirus)→ green line Strip E (enterovirus)→ green line **POSITIVE** Strip A (rotavirus)→ green/red lines Strip C (astrovirus)→ green/red lines	There is rotavirus and astrovirus presence. Viral infection caused by rotavirus and astrovirus.
	**NEGATIVE** Strip B (adenovirus)→ green line Strip C (astrovirus)→ green line Strip E (enterovirus)→ green line **POSITIVE** Strip A (rotavirus)→ **green**/red lines Strip D (norovirus)→ **green**/red lines	There is rotavirus and norovirus presence. Viral infection caused by rotavirus and norovirus.
	**NEGATIVE** Strip B (adenovirus)→ green line Strip C (astrovirus)→ green line Strip D (norovirus)→ green line **POSITIVE** Strip A (rotavirus)→ green/red lines Strip E (enterovirus)→ green/red lines	There is rotavirus and enterovirus presence. Viral infection caused by rotavirus and enterovirus.

	**NEGATIVE** Strip A (rotavirus)→ green line Strip D (norovirus)→ green line Strip E (enterovirus)→ green line **POSITIVE** Strip B (adenovirus)→ green/red lines Strip C (astrovirus)→ green/red lines	There is, adenovirus and astrovirus presence. Viral infection caused by adenovirus and astrovirus.
	**NEGATIVE** Strip A (rotavirus)→ green line Strip C (astrovirus)→ green line Strip E (enterovirus)→ green line **POSITIVE** Strip B (adenovirus)→ green/red lines Strip D (norovirus)→ green/red lines	There is, adenovirus and norovirus presence. Viral infection caused by adenovirus and norovirus.
	**NEGATIVE** Strip A (rotavirus)→ green line Strip C (astrovirus)→ green line Strip D (norovirus)→ green line **POSITIVE** Strip B (adenovirus)→ green/red lines Strip E (enterovirus)→ green/red lines	There is adenovirus and enterovirus presence. Viral infection caused by adenovirus and enterovirus.
	**NEGATIVE** Strip A (rotavirus)→ green line Strip B (adenovirus)→ green line Strip E (enterovirus)→ green line **POSITIVE** Strip C (astrovirus)→ green/red lines Strip D (norovirus)→ green/red lines	There is astrovirus and norovirus presence. Viral infection caused by astrovirus and norovirus.

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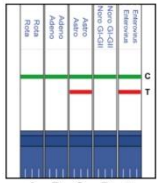
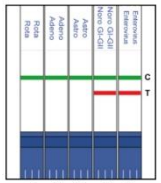
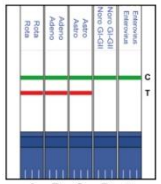
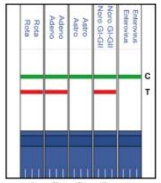
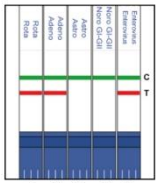
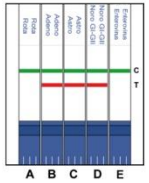
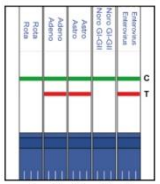
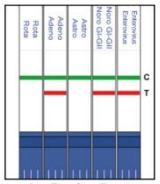
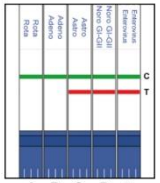
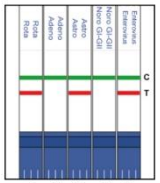
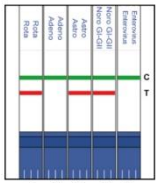
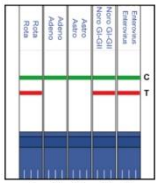
	**NEGATIVE** Strip A (rotavirus)→ green line Strip B (adenovirus)→ green line Strip D (norovirus)→ green line **POSITIVE** Strip C (astrovirus)→ green/red lines Strip E (enterovirus)→ green/red lines	There is astrovirus and enterovirus presence. Viral infection caused by astrovirus and enterovirus.
	**NEGATIVE** Strip A (rotavirus)→ green line Strip B (adenovirus)→ green line Strip C (astrovirus)→ green line **POSITIVE** Strip D (norovirus)→ green/red lines Strip E (enterovirus)→ green/red lines	There is norovirus and enterovirus presence. Viral infection caused by norovirus and enterovirus.
	**NEGATIVE** Strip D (norovirus)→ green line Strip E (enterovirus)→ green line **POSITIVE** Strip A (rotavirus)→ green/red lines Strip B (adenovirus)→ green/red lines Strip C (astrovirus)→ green/red lines	There is rotavirus adenovirus and astrovirus presence. Viral infection caused by rotavirus adenovirus and astrovirus.
	**NEGATIVE** Strip C (astrovirus)→ green line Strip E (enterovirus)→ green line **POSITIVE** Strip A (rotavirus)→ green/red lines Strip B (adenovirus)→ green/red lines Strip D (norovirus)→ green/red lines	There is rotavirus, adenovirus and norovirus presence. Viral infection caused by rotavirus, adenovirus and norovirus.

	**NEGATIVE** Strip C (astrovirus)→ green line Strip D (norovirus)→ green line **POSITIVE** Strip A (rotavirus)→ green/red lines Strip B (adenovirus)→ green/red lines Strip E (enterovirus)→ green/red lines	There is, rotavirus, adenovirus and enterovirus presence. Viral infection caused by rotavirus, adenovirus and enterovirus.
	**NEGATIVE** Strip A (rotavirus)→ green line Strip E (enterovirus)→ green line **POSITIVE** Strip B (adenovirus)→ green/red lines Strip C (astrovirus)→ green/red lines Strip D (norovirus)→ green/red lines	There is adenovirus astrovirus and norovirus presence. Viral infection caused by adenovirus astrovirus and norovirus.
	**NEGATIVE** Strip A (rotavirus)→ green line Strip D (norovirus)→ green line **POSITIVE** Strip B (adenovirus)→ green/red lines Strip C (astrovirus)→ green/red lines Strip E (enterovirus)→ green/red lines	There is adenovirus astrovirus and enterovirus presence. Viral infection caused by adenovirus, astrovirus and enterovirus.
	**NEGATIVE** Strip A (rotavirus)→ green line Strip D (astrovirus)→ green line **POSITIVE** Strip B (adenovirus)→ green/red lines Strip C (norovirus)→ green/red lines Strip E (enterovirus)→ green/red lines	There is adenovirus, norovirus and enterovirus presence. Viral infection caused by adenovirus, norovirus and enterovirus.
	**NEGATIVE** Strip A (rotavirus)→ green line Strip B (adenovirus)→ green line **POSITIVE** Strip C (astrovirus)→ green/red lines Strip D (norovirus)→ green/red lines Strip E (enterovirus)→	There is astrovirus, norovirus and enterovirus presence. Viral infection caused by astrovirus, norovirus and enterovirus.

	green/red lines	
	**NEGATIVE** Strip B (adenovirus)→ green line Strip D (norovirus)→ green line **POSITIVE** Strip A (rotavirus)→ green/red lines Strip C (astrovirus)→ green/red lines Strip E (enterovirus)→ green/red lines	There is rotavirus, astrovirus and enterovirus presence. Viral infection caused by rotavirus, astrovirus and enterovirus.
	**NEGATIVE** Strip B (adenovirus)→ green line Strip E (enterovirus)→ green line **POSITIVE** Strip A (rotavirus)→ green/red lines Strip C (astrovirus)→ green/red lines Strip D (norovirus)→ green/red lines	There is rotavirus, astrovirus and norovirus presence. Viral infection caused by rotavirus, astrovirus and norovirus.
	**NEGATIVE** Strip B (adenovirus)→ green line Strip C (astrovirus)→ green line **POSITIVE** Strip A (rotavirus)→ green/red lines Strip D (norovirus)→ green/red lines Strip E (enterovirus)→ green/red lines	There is rotavirus, norovirus and enterovirus presence. Viral infection caused by rotavirus, norovirus and enterovirus.
Any other results	Invalid result either A, B, C, D or E, we recommend repeating the assay using the same sample with another test.	

Notes: The intensity of the red coloured test line in the result line region (T) will vary depending on the concentration of antigens in the specimen.

Positive results detailed in the above table should be followed up with additional confirmatory diagnostic procedures.

Single or dual simultaneous virus infections are more frequent than triple,quadruple or fivefold.

Invalid results: Total absence of any control coloured lines (green) indicates an invalid result, regardless of the appearance or

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not of the test lines (red**).** Wrong procedural techniques or deterioration of the reagents are mostly the main reasons for control line failure. Review the procedure and repeat the assay with a new test. If the problem persists, discontinue using the kit and contact your local distributor.

QUALITY CONTROL

Internal procedural controls are included in **Vitassay Rotavirus+Adenovirus+Astrovirus+Norovirus+Enterovirus**. Green lines appearing in the results window are internal controls, which confirm sufficient specimen volume and correct procedural technique.

LIMITATIONS

- **Vitassay Rotavirus+Adenovirus+Astrovirus+Norovirus +Enterovirus** must be carried out within 2 hours of opening the sealed bag.
- An excess of stool sample could cause wrong results (brown bands appear). Dilute the sample with the diluent and repeat the test.
- The intensity of test line may vary depending on the concentration of antigens.
- After one week of infection, the number of viruses in faeces is decreasing, making the sample less reactive. Stool samples should be collected within one week of the onset symptoms.
- The use of other samples different from human fecal samples has not been established.
- The quality of **Vitassay Rotavirus+Adenovirus+Astrovirus+ Norovirus** depends on the quality of the sample; Proper fecal specimens must be obtained.
- Positive results determine the presence of rotavirus, adenovirus, astrovirus, norovirus and/or enterovirus in fecal samples. A positive result should be followed up with additional laboratory techniques to confirm the results. A confirmed infection should only be made by a physician after the evaluation of all clinical and laboratory findings and must be based in the correlation of the results with further clinical observations.
- Negative results should not be considered as conclusive; it is possible that the concentration of antigen is lower than the detection limit value. If symptoms or situation still persist a rotavirus, adenovirus and/or astrovirus determination should be carried out with another technique.
- Bloody stool samples and/or mucous stool samples can be cause non-specific reactions in the test. These types of samples whose result is positive should be followed up with other techniques of diagnosis to confirm the result.

EXPECTED VALUES

Currently, rotavirus, norovirus, astrovirus and adenovirus 40/41 have been recognized as the most significant etiological agents of childhood viral gastroenteritis in industrialized countries.

In children, group A rotavirus is the major etiologic agent of viral gastroenteritis and is responsible for 29 to 45% of hospitalizations worldwide. Recent work has showed that noroviruses are the second most frequent etiologic agents of viral gastroenteritis in children.

In the European Union, it is estimated that 3.6 million episodes of rotavirus gastroenteritis occur annually. Rotavirus gastroenteritis is estimated to occur at a rate of 1 symptomatic infection in every 7 children each year, accounting for 231 deaths, more than 87000 hospitalizations, and almost 700000 outpatient visits. It has been estimated that rotavirus accounts for 39% diarrheal hospitalizations and from 25.3% to 63.5% of community-acquired acute gastroenteritis in children <5 years of age.

The incidence and severity of enterovirus infections among infants are inversely related to their age, being more common in neonates and preterm infants.

Human enterovirus type 71 (EV71) has emerged as a major cause of viral encephalitis in children worldwide.

PERFORMANCE CHARACTERISTICS

Clinical sensitivity and specificity

An evaluation was performed using **Vitassay Rotavirus+ Adenovirus+Astrovirus+Norovirus+Enterovirus** and other commercial test (Ridascreen®Rotavirus ELISA Test, r-Biopharm).

Results were as follows:

		Ridascreen®Rotavirus ELISA Test		
		Positive	Negative	Total
Vitassay Rotavirus+ Adenovirus+Astrovirus+ Norovirus +Enterovirus Rotavirus	Positive	18	1	19
	Negative	0	43	43
	Total	18	44	62

Vitassay Rotavirus+Adenovirus+Astrovirus+Norovirus+Enterovirus (Rotavirus) vs Ridascreen®Rotavirus ELISA Test			
Sensitivity	Specificity	PPV	NPV
>99%	98%	>94%	>99%

And evaluation was performed using **Vitassay Rotavirus+ Adenovirus+Astrovirus+Norovirus+Enterovirus** and PCR.

Results were as follows:

		PCR		
		Positive	Negative	Total
Vitassay Rotavirus + Adenovirus + Astrovirus+Norovirus +Enterovirus Adenovirus	Positive	7	0	7
	Negative	0	52	52
	Total	7	52	59

Vitassay Rotavirus+Adenovirus+Astrovirus+Norovirus+Enterovirus (Adenovirus) vs PCR			
Sensitivity	Specificity	PPV	NPV
>99%	>99%	>99%	>99%

And evaluation was performed using **Vitassay Rotavirus+ Adenovirus+Astrovirus+Norovirus+Enterovirus** and an Elisa assay (Ridasscreen@Astrovirus Test, r-Biopharm).

Results were as follows:

		Ridascreen®Astrovirus Test		
		Positive	Negative	Total
Vitassay Rotavirus + Adenovirus + Astrovirus+Norovirus +Enterovirus Astrovirus	Positive	16	0	16
	Negative	1	11	12
	Total	17	11	28

Vitassay Rotavirus+Adenovirus+Astrovirus+Norovirus+Enterovirus (Astrovirus) vs Ridascreen®Astrovirus Test			
Sensitivity	Specificity	PPV	NPV
>94%	>99%	>99%	>92%

And evaluation was performed using **Vitassay Rotavirus+ Adenovirus+Astrovirus+Norovirus+Enterovirus** and other commercial test (Simple Norovirus, Operon).

Results were as follows:

		Simple Norovirus		
		Positive	Negative	Total
Vitassay Rotavirus + Adenovirus + Astrovirus+Norovirus +Enterovirus Norovirus GI	Positive	2	0	2
	Negative	0	48	48
	Total	2	48	50

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Vitassay Rotavirus + Adenovirus + Astrovirus+Norovirus (Norovirus GI) **vs Simple Norovirus**			
Sensitivity	**Specificity**	**VPP**	**VPN**
>99%	>99%	>99%	>99%

		Simple Norovirus		
		Positive	**Negative**	**Total**
Vitassay Rotavirus + Adenovirus + Astrovirus+Norovirus +Enterovirus Norovirus GII	**Positive**	10	0	10
	Negative	0	48	48
	Total	10	48	58

Vitassay Rotavirus+Adenovirus+Astrovirus+Norovirus (Norovirus GII) **vs Simple Norovirus**			
Sensitivity	**Specificity**	**VPP**	**VPN**
>99%	>99%	>99%	>99%

And evaluation was performed using **Vitassay Rotavirus+ Adenovirus+Astrovirus+Norovirus+Enterovirus** and a commercial test (IDEIA Enterovirus assay, Dako and IMAGEN™ Enterovirus, Oxoid).

		IDEIA Enterovirus assay and IMAGEN™ Enterovirus		
		Positive	**Negative**	**Total**
Vitassay Rotavirus + Adenovirus + Astrovirus+Norovirus +Enterovirus Enterovirus	**Positive**	3	0	3
	Negative	0	32	32
	Total	3	32	35

Vitassay Rotavirus+Adenovirus+Astrovirus+Norovirus+Enterovirus (Enterovirus) **vs Ridascreen®Astrovirus Test**			
Sensitivity	**Specificity**	**PPV**	**NPV**
>99%	>99%	>99%	>99%

The results showed that **Vitassay Rotavirus+Adenovirus+Astrovirus+Norovirus+Enterovirus** has a high sensitivity and specificity to detect rotavirus, adenovirus, astrovirus, norovirus (GI and GII) and/or enterovirus.

Cross reactivity

No cross reactivity was detected against other gastrointestinal pathogens that are occasionally present in feces.

Adenovirus (Strip A, C, D and E)	*Escherichia coli O157:H7*	*Salmonella typhimurium*
Astrovirus (Strip A, B, D and E)	*Giardia lamblia*	*Salmonella typhi*
Campylobacter coli	*Hepatitis A*	*Shigella boydii*
Campylobacter jejuni	*Helicobacter pylori*	*Shigella dysenteriae*
Clostridium difficile	*Listeria monocytogenes*	*Shigella flexneri*
Cryptosporidium parvum	*Norovirus (Strip A, B, C and E)*	*Shigella sonnei*
Enterovirus (Strip A, B, C, and D)	*Rotavirus (Strip B, C, D and E)*	*Staphylococcus aureus*
Entamoeba hystolitica	*Salmonella enteritidis*	*Yersinia enterocolitica*
Escherichia coli O111	*Salmonella paratyphi*	*RSV*

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SYMBOLS FOR IVD COMPONENTS AND REAGENTS

IVD	*in vitro* diagnostic device		Keep dry
	Consult instructions for use		Temperature limitation
	Use by		Manufacturer
LOT	Batch code	Σ n	Contains sufficient for <n> test
DIL	Sample diluent	REF	Catalogue number

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