

Clinical sensitivity and specificity

Vitassay Rotavirus+Norovirus

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An evaluation was performed in order to compare the characteristics of functionality of the evaluated immunocromatographic tests:

- **Vitassay Rotavirus+Norovirus** (Vitassay Healthcare, S.L.U., Spain)

Versus a commercial available test:

- **Ridascreen®Rotavirus ELISA test** (r-Biopharm) for strip A (Rotavirus)
- **Simple Norovirus** (Operon, Spain) for strip B
- **PCR technique**

In order to detect rotavirus antigens and norovirus (GI and GII) in stool samples.

TRIAL LOCATION

This evaluation was performed in an independent laboratory.

SAMPLES

Samples were prepared from our internal bank.

EVALUATION AND RESULTS

Samples were processed following up the instructions for use related to each commercial kit:

- **Vitassay Rotavirus+Norovirus** (Vitassay Healthcare, S.L.U. Spain)

- **Ridascreen®Rotavirus ELISA Test** (r-Biopharm)
- Simple Norovirus (Operon, Spain)
- **PCR technique**

Sensitivity and specificity was obtained using standard methods and the measure of concordance was calculated using Cohen's kappa coefficient.

The interpretation of the kappa value should be as follows:

- **Valor Kappa (IK) <0.4 – Weak concordance**
- **Valor Kappa (IK) between 0.4 to 0.6 – High concordance**
- **Valor Kappa (IK) >0.6 – Excellent concordance**

- **Vitassay Rotavirus+Norovirus** compared with other comercial test Ridascreen®Rotavirus ELISA Test, Simple Norovirus and PCR technique:

Ridascreen®Rotavirus ELISA Test				
Vitassay Rotavirus+Norovirus (Rotavirus)		Positive	Negative	Total
	Positive	18	1	19
	Negative	0	43	43
	Total	18	44	62

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

Simple Norovirus				
Vitassay Rotavirus+Norovirus (Norovirus GI)		Positive	Negative	Total
	Positive	2	0	2
	Negative	0	48	48
	Total	2	48	50

Vitassay Rotavirus+Norovirus (Norovirus GI) vs Simple Norovirus			
Sensitivity	Specificity	PPV	NPV
>99%	>99%	>99%	>99%

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PCR				
		Positive	Negative	Total
Vitassay Rotavirus+ Norovirus Norovirus GI	Positive	2	0	2
	Negative	0	48	48
	Total	2	48	50

Vitassay Rotavirus+Norovirus (Norovirus GI) vs PCR			
Sensitivity	Specificity	PPV	NPV

>99% >99% >99% >99%

Simple Norovirus				
		Positive	Negative	Total
Vitassay Rotavirus+ Norovirus (Norovirus GII)	Positive	10	0	10
	Negative	0	48	48
	Total	10	48	58

Vitassay Rotavirus+Norovirus (Norovirus GII) vs Simple Norovirus			
Sensitivity	Specificity	PPV	NPV

>99% >99% >99% >99%

PCR				
		Positive	Negative	Total
Vitassay Rotavirus+ Norovirus Norovirus GII	Positive	8	0	8
	Negative	2	48	48
	Total	10	48	58

Vitassay Rotavirus+Norovirus (Norovirus GII) vs PCR			
Sensitivity	Specificity	PPV	NPV

80% >99% >99% 96%

Kappa value: 1

CONCLUSION:

Vitassay Rotavirus+Norovirus GI+GII showed a high sensitivity (>99%, >99%, >99%, >99%, 80%) and a high specificity (98%, >99%, >99%, >99%, >99%) to detect rotavirus and genogroup I and II of Norovirus compared with other assays.

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