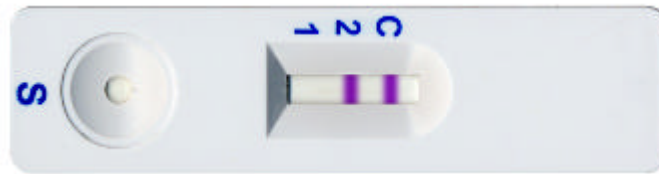


MICROGEN BIOPRODUCTS LTD



NOROSCREEN

**A rapid lateral flow immunoassay for the detection of
Norovirus antigen in faeces**

Noroscreen Rapid Cassette detects and differentiates
Norovirus Genogroup 1 and Genogroup II from faecal samples:

- **Simply:** cassette format and one-step procedure (no need to add additional conjugates or substrates).
- **Rapidly:** results within 15 minutes
- **Controls:** each cassette comes with a built in control line.
- **Ease of Reading:** clear distinct reaction lines with a clean background
- **Reliably:** high sensitivity (95.65%) and specificity (91.67%)

Protecting Food and Health

MICROGEN BIOPRODUCTS LTD

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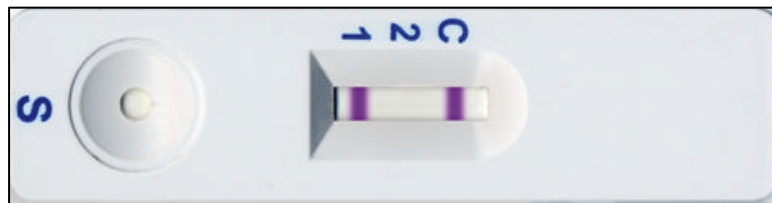
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Noroscreen is a one-step rapid cassette which detects and differentiates *Norovirus* Genogroup 1 and Genogroup II antigen in faecal samples. Noroscreen complements the rapid Rota/adenoscreen cassette for the detection and differentiation of *Rotavirus* and *Adenovirus* in faecal specimens, allowing a laboratory to rapidly test for the 3 leading causes of viral gastroenteritis, *Norovirus*, *Rotavirus* and *Adenovirus*, with highly specific and sensitive, easy-to-use cassettes.

Noroscreen is an easy-to-use cassette with a one-step procedure which does not require the addition of conjugates or substrates:

1. Remove sample probe from preparation device and coat liberally with sample. Replace probe in vial and shake to dispense solid material.
2. Allow mixture to stand for 3 minutes.
2. Snap top from preparation device and invert. Add 2 drops to sample well of test cassette.
2. Leave the test at room temperature and read the results within 15 minutes.



Positive for Genogroup 1



Positive for Genogroup II

Product Code	Description	Kit Size
M586CE	Noroscreen cassette	10
M585CE	Rota/Adenoscreen cassette	25

Performance of Rapid Noroscreen Test vs RT-PCR

Noroscreen, a rapid antigen test for the detection and differentiation of Norovirus Genogroup I and Genogroup II antigen in faeces was extensively evaluated and compared to RT-PCR.

Sample Panel for Analysis

Sample	Origin	Determination criteria	
		GII	GI
NVP-1 WP	Weak positive	-	+
NVP-1 P	positive	-	+
NVP-2 WP	Weak positive	+	-
NVP-2 P	positive	+	-
NVP neg -1	Extraction buffer	-	-
NVP neg -2	RT-PCR Norovirus negative stool specimen	-	-

Sensitivity

The panel of samples was tested with three batches of Noroscreen and in triplicate.

Assay	Lot	Replicate	NVP-1 WP	NVP-1 P	NVP-2 WP	NVP-2 P	NVP neg-1	NVP neg-2
Analytical sensitivity	001	n=1	+	+	+	+	-	-
		n=2	+	+	+	+	-	-
		n=3	+	+	+	+	-	-
	002	n=1	+	+	+	+	-	-
		n=2	+	+	+	+	-	-
		n=3	+	+	+	+	-	-
	003	n=1	+	+	+	+	-	-
		n=2	+	+	+	+	-	-
		n=3	+	+	+	+	-	-

(+) positive: presence of band

(-) negative: absence of band

A second sensitivity study was performed using 10 positive specimens and 5 negative specimens:

Samples	Details	Determination criteria	Noroscreen	
			Genogroup I	Genogroup II
Novovirus 1	GII/4 29,4 ng/mL	1+ to 3+	-	3+
Novovirus 2	GII/4 14,7 ng/mL	1+ to 3+	-	2+
Novovirus 3	GII/4 5,9ng/mL	1+ to 3+	-	1+
Novovirus 4	GI/1 58,8 ng/mL	1+ to 3+	3+	-
Novovirus 5	GI/1 29,4 ng/mL	1+ to 3+	2+	-
Novovirus 6	GI/1 14,7 ng/mL	1+ to 3+	2+	-
Novovirus 7	Culture media	neg	-	-
Novovirus 8	Negative stool solid form	neg	-	-
Novovirus 9	Negative stool solid form	neg	-	-
Novovirus 10	Negative stool liquid form	neg	-	-
Novovirus 11	Negative stool liquid form	neg	-	-
Novovirus 12	Positive specimen	1+ to 3+	3+	-
Novovirus 13	Positive specimen	1+ to 3+	3+	-
Novovirus 14	Positive specimen	1+ to 3+	2+	-
Novovirus 15	Positive specimen	1+ to 3+	2+	-

Criteria

Intensity of color at the test line was indicated as follows:

- 3+ strong positive
- 2+ positive
- 1+ weak positive
- Neg negative

Noroscreen was tested with different Genogroup types:

Norovirus	Type
Genogroup I	1,4,8,11
Genogroup II	1,2,3,4,5,6,7,12,13,14,15

type		Noroscreen	
		GII	GI
Norovirus GI	1	-	+
	4	-	+
	8	-	+
	11	-	+
Norovirus GII	1	+	-
	2	+	-
	3	+	-
	4	+	-
	5	+	-
	6	+	-
	7	+	-
	12	+	-
	13	+	-
14	+	-	
15	+	-	

- (+) positive: presence of band
- (-) negative: absence of band

Assay Correlation

Samples analyzed previously by RT-PCR method were tested with Noroscreen.

		RT-PCR		
		positive	negative	Total
Noroscreen	positive	44	2	46
	negative	2	22	24
	Total	46	24	70

Noroscreen has a sensitivity of 95.6%, accuracy of 91.7% and correlation of 94.3%.

Discussion

In situation where the rapid demonstration of Norovirus is required, for example; patient isolation policy or prior to admission, Noroscreen is a valuable addition to the testing regime. Although the clinical utility of determining the Genogroup has not been established, it has the potential to provide valuable epidemiological information.

Conclusion

According to the data Noroscreen is a sensitive and specific rapid test for the immediate determination of Norovirus in stool samples.