SENSITIVITY OF RIDA® QUICK NOROVIRUS NEAR PATIENT TEST COMPARED TO PCR

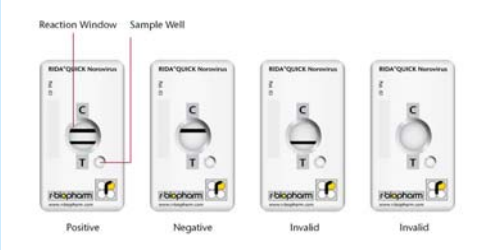
J Miller and WF Carman.
West of Scotland Specialist Virology Centre

Introduction

Real time PCR is now widespread use for the diagnosis of outbreaks and sporadic cases of presumed norovirus gastroenteritis. However, there are inherent delays in diagnosis using PCR because of the need of transport to a regional centre. At present minimal PCR is being performed in small laboratories. The disadvantage of EIA formats so far described is lack of sensitivity. This might lead to an incorrect negative diagnosis of an outbreak. The study compares the use of the RIDA® Quick Norovirus kit, a flow through enzyme linked rapid assay and an "in house" real time PCR assay.

Methods

An initial evaluation was performed on 50 frozen PCR positive samples. Based on those results, a further prospective evaluation was performed on samples from presumed viral outbreaks. Fresh samples had to arrive within 3 days of collection and had to take the shape of the container. 157 samples were evaluated over a period of 7 weeks. The RIDA® Quick Norovirus test was performed according to the kit insert.



Interpretation of results

The results obtained with the assay were easy to read and no difficulty was found in their interpretation. All the samples tested gave a band at the control position (see above). It should be noted that a lack of this band would invalidate the test. Positive test bands could be faint but were still easily identified.

Results

42/50 (84%) of the retrospective samples were positive by the RIDA® Quick Norovirus test compared to 67/157 (43%) positive by PCR. No samples were RIDA® Quick norovirus test positive, PCR negative (Table 1).

	Real-time PCR Norovirus Positive	RIDA®Quick Norovirus Test Norovirus Positive
RETROSPECTIVE SAMPLES	50	42
PROSPECTIVE SAMPLES	67	53

Table 1 – Comparison of Norovirus Positive results.

Outbreaks were considered to be positive where a minimum of 3 samples from the outbreak had been received and at least one sample was positive for norovirus. Of the 24 positive PCR outbreaks tested (158 samples) in the study, all were confirmed as positive by the RIDA® Quick Norovirus test. (Tables 2 and 3).

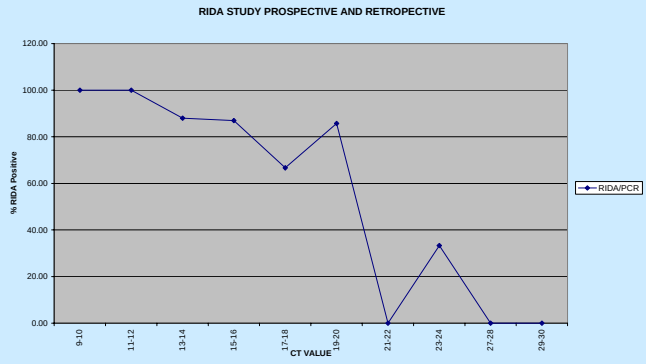
Outbreak	Real-time PCR Norovirus Positive	RIDA® Quick Norovirus Test Norovirus Positive
1	6	4
2	3	2
3	2	2
4	3	3
5	5	4
6	4	3
7	5	3
8	4	4
9	15	14
10	3	3

Table 2 – Results for Outbreaks in Retrospective Study

Outbreak	Real-time PCR Norovirus Positive	RIDA® Quick Norovirus Test Norovirus Positive
1	4	3
2	7	5
3	2	1
4	7	6
5	2	2
6	3	1
7	3	3
8	2	2
9	5	4
10	12	10
11	2	2
12	7	6
13	2	2
14	2	1

Table 3 – Results for Outbreaks in Prospective Study

At a CT of 16 and below 94% of the PCR positive samples were also RIDA® Quick Norovirus positive. No sample of a CT of 24 or above was positive by the RIDA® Quick Norovirus test. (Figure 1)



Fiure 1: Comparison of CT value to RIDA®

Conclusions

Overall, the sensitivity for individual samples was 81%. Specificity appeared excellent. No outbreaks were missed by the RIDA® Quick Norovirus test. In 2 outbreaks, only one of 2 samples positive by PCR were RIDA® Quick Norovirus positive and in another only one out of 3 PCR positives was also RIDA® positive. As samples with a higher CT may be found in asymptomatics, the positive predictive value for disease of the RIDA® Quick Norovirus test is likely to be better than PCR. This test is likely to be a useful adjunct to norovirus outbreak diagnosis and the rapid institution of infection control measures.

References

Kageyama et al. J Clinical Microbiol. 2003 Apr;41(4):1548-57.
Lindell et al. J Clinical Microbiol. 2005 43: 1086-1092.