Evaluation of RIDA® QUICK Norovirus test in detecting Norovirus Outbreaks

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Background

Norovirus is a major cause of gastroenteritis worldwide. It is characterized by projectile vomiting and profuse diarrhoea and is easily spread from person to person and by consuming contaminated food and water. Infection is extremely common and can be as high as 5% of the population each year. Noroviruses are frequently involved in outbreaks in communal settings such as hospitals and nursing homes and cause a considerable burden to the health care system. Real Time-PCR is the gold standard diagnostic technique in detecting noroviruses. It has high sensitivity and specificity but it also has high costs and it is labour intensive requiring specialized molecular laboratories with unidirectional work flow. The National Guidelines on the Management of Norovirus Infection in Healthcare Settings states that laboratory confirmation of an outbreak requires a maximum of two norovirus positive results. The key to controlling norovirus is early detection and isolation of those infected (http://www.hpsc.ie/). It has been reported that diagnosis within three days instead of four days of the first case reduces outbreak duration by seven days (Lopman et al. 2004). The RIDA® QUICK Norovirus test is a rapid easy test making it particularly suitable for preliminary screening of suspected norovirus outbreaks.

Objective

- This study evaluated the RIDA® QUICK Norovirus test (R-Biopharm AG) for use in the diagnosis of norovirus outbreaks.

Methods

- The standard method used for norovirus is an internally controlled, multiplex, one-step, real-time RT-PCR assay. Degenerate primers and genogroup specific taqman probes were used to amplify and detect a 95bp region of the ORF1/ORF2 junction of norovirus. The primers and probes are designed to detect primarily GGI and GGII norovirus although they should also detect GGIV norovirus (Rolfe *et al.,* 2007, Kageyama *et al.,* 2003).

- The RIDA® QUICK Norovirus is a multi-step immunochromatic membrane test for detecting genogroup 1 and genogroup2 noroviruses in stool samples. It uses specific antibodies directed against noroviruses. Results are read visually (Figures 1&2). The test requires no specialized laboratory equipment.

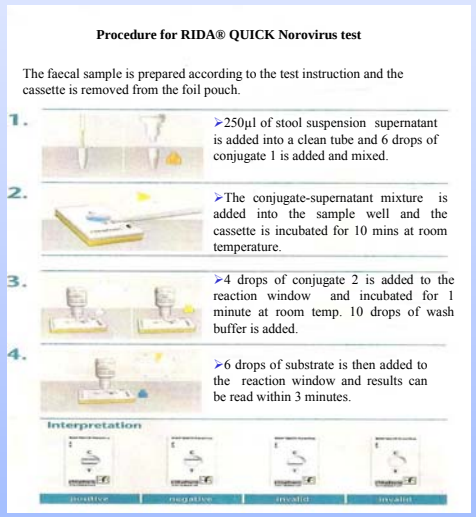

Figure 1: A diagram detailing the steps of the RIDA® QUICK Norovirus test.

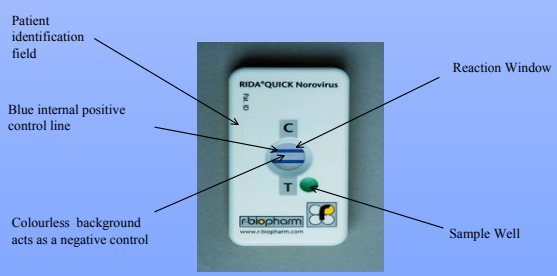

Figure 2: A photograph of a positive sample on a RIDA ® QUICK Norovirus cassette showing the reaction window, the sample well, patient identification field and the internal controls.

- The performance of the RIDA® QUICK Norovirus test was compared with that of Real Time – PCR by testing a panel of patient faecal samples suspected of norovirus infection.

- The panel consisted of 50 samples (35 positive and 10 negative samples and 5 confirmed cases of rotavirus/adenovirus).

- 6 confirmed norovirus outbreaks were also tested to examine if the outbreaks could also be confirmed by the RIDA® QUICK Norovirus test.

Interpretation of RIDA® QUICK Norovirus Test Results and Quality Control

- See figures 1& 2 for interpretation of results. These figures show positive, negative and invalid results.

- See figure 2 for quality control (positive and negative internal controls).

Results

- Twenty-three of the thirty-five positive samples tested showed up positive on the RIDA® QUICK Norovirus test giving a sensitivity of 65.7%.

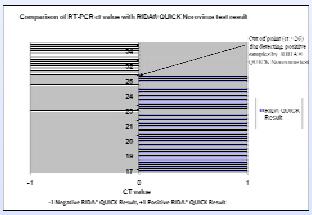

Figure 3: Comparison of RT-PCR ct value with RIDA® QUICK Norovirus test result: This graph shows that samples with a ct value of 26 or less are most likely to be confirmed by the RIDA® QUICK Norovirus test. Samples with a ct value of greater than 26 are not generally confirmed by this test.

- Ten of the ten negative samples tested showed up negative on this test giving 100% specificity.

- Five of the five rota/adeno samples confirmed by electron microscopy showed up negative on this test showing no cross reactivity in this small sample set.

- This test is ideal for diagnosing norovirus samples that are more highly positive with ct values of ≤26 (Figure 3).

- All 6 of the norovirus outbreaks were confirmed by the R IDA® QUICK Norovirus test. Two or more samples in each outbreak showed up positive (Figure 4).

Outbreak No.	HSE Area	Location	No. Samples submitted	Mean Age
1	MHB	Hospital	4	90
2	NWHB	Hospital	4	60
3	SEHB	Hospital	4	79
4	EHB	Hospital	4	77
5	MHB	Hospital	4	74
6	NWHB	Hospital	5	72

Table 1: Norovirus Outbreaks examined in this evaluation.

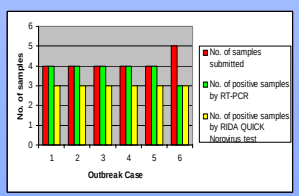

Figure 4: Comparison of number of positive samples in each outbreak confirmed by RT-PCR and RIDA® QUICK Norovirus test: This graph shows the outbreaks examined. It compares the number of positive samples confirmed by RT-PCR and by RIDA® QUICK Norovirus test. For example in outbreak one 4 of the samples received were positive by RT-PCR. 3 of these were found to be positive by RIDA® QUICK Norovirus test. All outbreaks were confirmed by both tests with ≥2 samples from each outbreak being confirmed as positive**.**

Conclusions

- The RIDA® QUICK Norovirus test is a rapid test with results in less than twenty minutes allowing a timely diagnosis for GG1 and GG11 viruses which represent 99% of all outbreaks in Ireland.

- It is easy to perform and does not require any specialised laboratory equipment. It can therefore be carried out easily within the hospital setting .

- It has potential for use in the hospital setting for preliminary screening of suspected norovirus outbreaks.

Acknowledgments

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References

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