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Multicenter evaluation of the revised RIDA® QUICK test (N1402) for rapid detection of norovirus in a diagnostic laboratory setting

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Background

Noroviruses are the leading cause of nonbacterial acute gastroenteritis in both children and adults and cause both sporadic cases and outbreaks of gastroenteritis. Rapid laboratory diagnosis is essential to implement measures to prevent and control the outbreaks. Recently, the RIDA® QUICK Norovirus (R-Biopharm) was revised and additional antibodies were included for a broad range of detection (article number N1402 instead of the former N1403). Also, the antibodies are dissolved in the reagent, instead of dried on the membrane, converting the test from a two-step flow through immunochromatographic test to a one-step lateral flow assay, thereby reducing the turn-around-time and increasing the ease-of-use. We present a prospective, multicenter study evaluating the performance of the RIDA® QUICK Norovirus N1402 on stool samples.

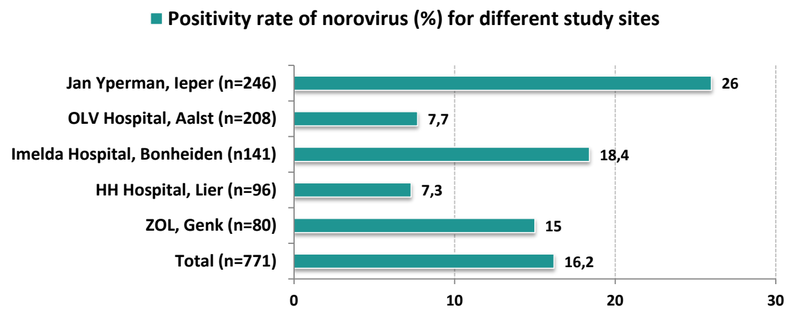
Test cassette of the RIDA QUICK (N1402)

Material/methods:

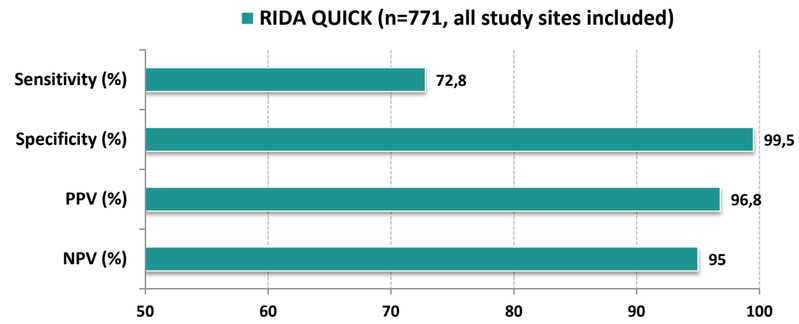
This prospective, multicenter clinical trial was conducted from November 2014 through April 2015 at five study sites in Belgium. A total of 771 samples were tested with the RIDA® QUICK and the RIDA® GENE Norovirus I & II real-time reverse transcriptase (RT-rt)PCR (R-Biopharm). RIDA® QUICK positive samples that were not confirmed by the RIDA® GENE Norovirus I & II RT-rtPCR were further tested by additional PCR testing (in-house SYBR®Green RT-rtPCR with melting peak analysis). A sample was considered positive if one of the RT-rtPCR's was positive. All positive samples were further characterized to genotype level by partial sequencing of the polymerase and capsid regions.

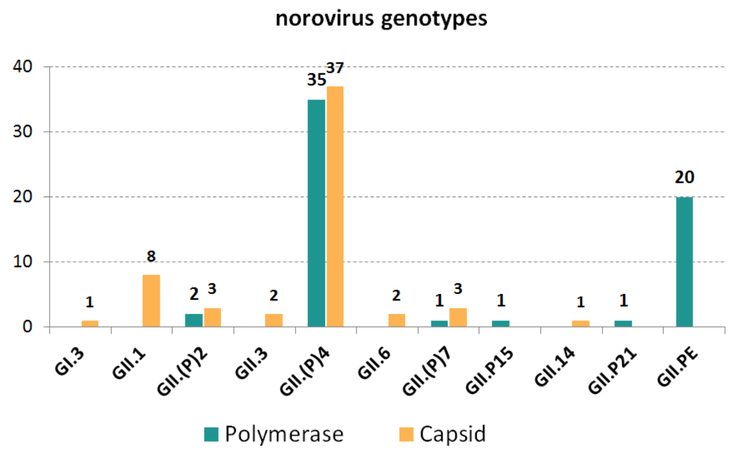
Results

The overall positivity rate of norovirus was 16.2% (125/771) (norovirus GI: 0.6% (5/771) and GII: 15.6% (120/771)), although marked local difference was noticed (range: 7.3% – 26%). Multivariate logistic regression showed that age was the only parameter that was independently correlated with a positive result for norovirus (b = -0.016, p < 0.001). The relative high inclusion rate of children in Jan Yperman probably explains the high positivity rate compared to other centers.



Overall sensitivity and specificity of the RIDA® QUICK for detection of norovirus compared to PCR as gold standard was 72.8% and 99.5%, respectively. The RIDA® GENE, that was used as first line RT-rtPCR test, detected 110 positive samples. Another 15 were only detected by the in-house SYBR®Green RT-rtPCR. By doing a more in depth molecular analysis it was discovered that the false negative results by the RIDA® GENE RT-rtPCR were caused by a deletion in the ORF1-ORF2 junction region which prevented amplification by the RIDA® GENE RT-rtPCR, but not by the in-house RT-rtPCR. Genotyping revealed that the most frequently detected norovirus genotypes in this study were norovirus GII.P4 and GII.4.





Conclusions

The updated RIDA® QUICK N1402 can be used as a reliable test for rapid detection of norovirus in stool samples with less hands-on time compared to the former N1403 assay. However, a negative result does not exclude norovirus infection, although it was shown in this study that RT-rtPCR testing can also suffer from a suboptimal sensitivity.