COMPARISON OF A THIRD GENERATION ENZYME IMMUNOASSAY TO RT-PCR FOR DETECTION OF NOROVIRUS IN STOOL SAMPLES

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Noroviruses (NoVs) are considered the leading cause of outbreak gastroenteritis in humans worldwide, and probably represent the second most common etiological agent of sporadic diarrhea in young children after rotavirus. A major obstacle in establishing the diagnosis of NoV infection has been the absence of a rapid and sensitive diagnostic method suitable for use in health laboratories and hospitals. The RT-PCR is the gold standard test for the diagnosis of NoV, although it is expensive, time-consuming and not practical in a diagnostic laboratory. Recently, a number of second generation enzyme immunoassay (EIA) kits have been commercialized; however, low sensitivities were reported. The goal of this study was to compare the performance of the RIDASCREEN® Norovirus EIA (R-Biopharm AG, Darmstadt, Germany), a third generation kit, for antigen NoV detection in stool samples previously screened by RT-PCR assay. Stool specimens were obtained from 76 symptomatic individuals of sporadic cases and outbreaks of nonbacterial acute gastroenteritis in Brazil, during 2006 to 2008. All stool specimens were examined by RIDASCREEN®, and carried out according to the manufacturer's protocol. Thirty-two (42.1%) stool specimens were positive by EIA and RT-PCR assays; 25 (32.9%) were negative by both tests. Seventeen samples originally positive by RT-PCR were negative for EIA, and two samples negatives by RT-PCR were positives by EIA. Compared to the RT-PCR, sensitivity of 65.3% and specificity of 92.3% were found for RIDASCREEN® Norovirus EIA. The new version of the RIDASCREEN® Norovirus EIA has shown high specificity, and acceptable sensitivity. This assay will be very useful in surveillance of gastroenteritis outbreak, as a simple and quick preliminary screening test to identify norovirus positives samples. Furthermore, only negatives samples by EIA would be tested with RT-PCR to identify additional positives.