

Evaluation of Automated Fluorescent Immunoassay System for Detection of Norovirus in Stool Samples

Department of Laboratory Medicine, Hallym University Medical Center, Anyang, Korea

Han-Sung Kim, Ho Young Kim

Background

Antigen test are widely used for the detection of enteric adenoviruses. AFIAS Noro assay (Biotech Med, Korea) is an automated fluorescent immunoassay for detections of norovirus. We evaluated the performance of this assay to detect norovirus compared with that of real-time PCR (Allplex GI-Virus Assay; Seegene, Korea).

Results

The sensitivity and specificity of AFIAS assay were 79.2% and 100%, respectively, in detecting norovirus when compared to real-time PCR. Nineteen samples were positive for both AFIAS assay and real-time PCR, while 28 samples were negative for both AFIAS assay and real-time PCR. Five samples were positive only for real-time PCR. The overall concordance rate between AFIAS assay and real-time PCR was 90.4%.

Methods

- Specimens
24 norovirus-positive and 30 norovirus-negative stool samples (confirmed by real-time PCR).
- Real-time PCR
 - Allplex GI-Virus Assay (Seegene, Korea)
 - CFX96 Real-time PCR Detection System (Bio-Rad, USA)
 - Seegene Viewer software (Seegene)
- AFIAS Noro assay
 - Fluorescence-based lateral flow immunoassay
 - Instrument : AFIS-6 analyzer (Biotech Med, Korea)
 - Reagent : AFIAS Noro test kit (Biotech Med, Korea)

Comparison of AFIAS antigen assay and real-time PCR

Real-time RT-PCR	Rapid antigen test*		
	Positive	Negative	Total
Positive	19 (35.2)	5 (9.3)	24 (44.4)
Negative	0 (0)	30 (55.6)	30 (55.6)
Total	19 (31.5)	35 (64.8)	54 (100)

*No. (%) of specimens

Results of AFIAS antigen assay based on real-time PCR Ct values

Ct values	AFIAS antigen test*		
	Positive	Negative	Total
<25	4	0	4
25~30	10	0	10
30~35	5	2	7
>35	0	3	3
Total	19	5	24

*No. of specimens

Conclusion

The AFIAS Noro assay showed high sensitivity, specificity and good correlation with real-time PCR and is likely to be as useful in detection of norovirus in stool samples.



AFIAS-6 analyzer



AFIAS Noro test kit