Evaluation of the Newly Developed Immunochromatography Test Kit for Rapid Detection and Differentiation of Norovirus GI and GII

Viral gastroenteritis is one of the most common illnesses in humans worldwide [1]. Noroviruses (NoVs) are considered as the major cause of acute gastroenteritis in both children and adults in community-based gastroenteritis, and responsible for sporadic cases and several outbreaks in various epidemiological settings, including restaurants, schools, day-care centers, hospitals, nursing homes and cruise ships, resulting in over 267,000,000 annual infections worldwide. The common NoV found in humans was GII and GI genogroups [2]. When outbreaks of diarrhea occur in communities, rapid virus identification is essential to ensure administration of the appropriate treatment and control. For this reason, a rapid and sensitive diagnostic tool, such as the immunochromatography (IC) test, is required. Recently, broad reactive monoclonal antibody against several NoV genogroups and genotypes had been produced in our laboratory [3] and several studies on the evaluation of IC test for NoV detections have been reported [4–7].

In this study, the efficacy of the newly developed IC assay (NoV IC; ImmunoProbe Co., Ltd, Saitama, Japan) was evaluated for the rapid detection and differentiation of NoV GI and GII genogroups. By using this kit, NoV could be differentiated as GI or GII genogroup according to the tested line appeared into the strip test. A total of 139 stool specimens collected from children who suffered from acute gastroenteritis in Japan were tested for NoV GI and GII by this NoV IC kit and by a gold standard RT-monoplex PCR method. To evaluate the sensitivity, specificity and agreement for NoV GI and GII genogroups, all of the 139 samples were tested/differentiated as NoV GI and GII by this kit. The NoV IC test kit was performed according to the manufacturer’s directions. It took only 15–20 min to obtain the result. A positive result consisted of two or three lines; the left control line (C), the middle positive line for NoV GI (B) and the right positive line for NoV GII (A). A negative result consisted of a single left control line (Fig. 1). To evaluate sensitivity and specificity of the NoV IC kit, a panel of 139 stool samples was tested and the results were compared with those of the RT-PCR method. These results revealed 71.4 and 88.8% of sensitivity, 99.2 and 84.7% of specificity and 95.0 and 87.1% of

![Fig. 1. Detection of NoV in a stool sample by the NoV IC kit. The test is positive for NoV GII if two lines appear in the membrane at A and C positions (A), and positive for GI if the lines appear in the membrane at B and C positions (B). The test is negative when only one line appears in the control area (C).](image)
agreement for NoV GI and GII detections, respectively (Table 1).

The importance of NoV as human pathogen has been recognized increasingly according to the improvement of the molecular detection methods [8]. The clinical presentation of patients with acute gastroenteritis symptom is generally not indicative of a specific pathogen. Therefore, a rapid and sensitive diagnosis tool for virus detection could be helpful in the therapeutic decision making. For this reason, a new NoV IC kit was developed. This rapid diagnostic test is easy to perform at the bedside, as it takes only 15–20 min to reach a diagnosis with a simple procedure, and does not require special equipments. However, our analysis demonstrated that the sensitivity for NoV GI detection was quite lower than that of GII. Therefore, improvement of the NoV GI detection may need before applying the kit with clinical tests. In conclusion, this study demonstrated that the NoV IC kit was the rapid method for detection and differentiation of NoV GI and GII genogroups directly from stool samples.

<table>
<thead>
<tr>
<th>NoVIC</th>
<th>Sensitivity n (%)</th>
<th>Specificity n (%)</th>
<th>Agreement n (%)</th>
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<tbody>
<tr>
<td>GI genogroup</td>
<td>71.4</td>
<td>99.2</td>
<td>95.0</td>
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<tr>
<td>GII genogroup</td>
<td>88.8</td>
<td>84.7</td>
<td>87.1</td>
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PATTARA KHAMRIN,1 WISOOT CHAN-IT,2 KENJI SATOU,3 YUKO NANBA,3 YASUTAKA YAMASHITA,4 SHOKO OKITSU,5 NIWAT MANEEKARN,6 and HIROSHI USHIJIMA1,2

1Aino Health Science Center, Aino University, Tokyo, Japan, 2Department of Developmental Medical Sciences, Institute of International Health, Graduate School of Medicine, The University of Tokyo, Tokyo, Japan, 3ImmunoProbe Co. Ltd, Kamaagata, Ranzan-machi, Saitama, Japan, 4Ehime Prefecture Institute of Public Health and Environmental Science, Ehime, Japan, 5Aino Health Science Center, Aino college, Tokyo, Japan and 6Department of Microbiology, Faculty of Medicine, Chiang Mai University, Chiang Mai, Thailand
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Correspondence: Hiroshi Usuijima, MD, PhD, Aino Health Science Center, Aino University, 2-17-3 Shibuya, Shibuya-ku, Tokyo 150-0002, Japan. Tel./Fax: +81 3 3486 8481. E-mail <ushijima-hiroshi@jcom.home.ne.jp>. 