Diagnostic Microbiology and Infectious Disease 76 (2013) 147–152

Contents lists available at SciVerse ScienceDirect

Diagnostic Microbiology and Infectious Disease

journal homepage: www.elsevier.com/locate/diagmicrobio

Evaluation of the Bioline Standard Diagnostics SD immunochromatographic norovirus detection kit using fecal specimens from Australian gastroenteritis incidents

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ARTICLE INFO

Article history:
Received 15 November 2012
Received in revised form 4 February 2013
Accepted 19 February 2013
Available online 23 March 2013

Keywords:
Norovirus
Immunochromatography
Sensitivity
Specificity
Genotypes
Detection
Point-of-care testing

ABSTRACT

Human norovirus is a major cause of both sporadic cases and outbreaks of gastroenteritis and comprises two main genogroups (GI and GII) which, in turn, comprise a variety of genotypes. The current study examined the efficacy of the Bioline SD kit using fecal material from Australian gastroenteritis incidents. At best, the SD kit had a sensitivity of 62%. Freezing and thawing specimens before testing significantly improved sensitivity. The SD kit had a specificity of 98.6%. Genotype analysis (Open Reading Frame 2) indicated the SD kit could detect a range of genotypes and genotype variants including GI.1, GI.3, GI.4, GII.1, GII.3, GII.4 (unclassified), GII.4 (2006b), GII.4 (2009), GII.4 (2012) and GII.6 but the kit failed to detect GI.2 and GII.2 norovirus. The kit did not cross-react with a number of common fecal viruses including astrovirus, sapovirus, rotavirus or adenovirus. The kit was very easy to use and would be valuable in point-of-care testing.

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1. Introduction

The noroviruses, which are now recognized as a major cause of both sporadic cases and outbreaks of gastroenteritis (Marshall and Bruggink, 2006), are single-stranded positive-sense RNA viruses classified as the genus *Norovirus* within the family *Caliciviridae* (Clarke et al., 2012). The norovirus genome includes three open reading frames (ORFs) (Clarke et al., 2012). ORF 1 encodes the non-structural polyprotein, ORF 2 encodes the major structural capsid protein and ORF 3 encodes a structural protein (Clarke et al., 2012).

Noroviruses are classified into a number of genogroups (Vinje et al., 2004) and three of these, genogroups I, II, and IV (GI, GII and GIV), occur in human infections (Vinje et al., 2004). Most noroviruses affecting humans belong to GI or GII (Burton-MacLeod et al., 2004). Norovirus classification at the next level has been referred to as classification at the genotype level (Vinje et al., 2004). The GII.4 genotype appears to be the most common in humans (Bull et al., 2006; Gallimore et al., 2004; Kirkwood, 2004) and has been further subdivided into "variants" (Siebenga et al., 2008).

A diverse range of laboratory methods are now available for the detection of noroviruses (Marshall and Bruggink, 2006). These include electron microscopy, reverse transcription-polymerase chain reaction (RT-PCR) methods, real time RT-PCR methods and enzyme immunoassay methods (Marshall and Bruggink, 2006). All these methods generally involve relatively sophisticated laboratory equipment.

"Point-of-care" testing is an emerging area in medical diagnosis, and requires a generally rapid, easy to carry out procedure that does not involve sophisticated laboratory equipment. Point-of-care testing commonly utilizes immunochromatographic methods (Sturenburg and Junker, 2009), and a range of commercial immunochromatographic kits for norovirus detection have been released onto the market. These include the RIDAQUICK kit (Bruggink et al., 2011; Derrington et al., 2009), the Denka Seiken Quick Ex-Norovirus kit (Mutoh et al., 2009), the Immuno-Probe IP-NoV kit (Khamrin et al., 2008; Thongprachum et al., 2010), the Immuno-Probe NV IC-1 stick kit (Nguyen et al., 2007), and the Morinaga Milk Industry Co., Ltd kit (Khamrin et al., 2009). Probably most attention has focused on the internationally available RIDAQUICK kit (Battaglioli et al., 2012; Bruggink et al., 2011; Bruins et al., 2010; Derrington et al., 2009; Geginat et al., 2011; Kirby et al., 2010; Pombubpa and Kittigul, 2012) which generally gives excellent specificity and reasonable sensitivity. The RIDAQUICK kit appears to have particular value as a backup in a testing laboratory (Derrington et al., 2009).

Recently, a new immunochromatographic kit for norovirus detection, the Bioline Standard Diagnostics norovirus antigen kit (SD kit), was released onto the market in Australia and elsewhere and, according to the manufacturer's instructions, the SD kit only requires one major procedural step, all necessary consumables are provided

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0732-8893/$ – see front matter © 2013 Elsevier Inc. All rights reserved.
http://dx.doi.org/10.1016/j.diagmicrobio.2013.02.018

with the kit and the kit does not require refrigeration for storage. The SD kit has so far received little attention in the literature (Kim et al., 2012; Park et al., 2012) but its apparent ease of usage invites more detailed evaluation, particularly in view of its potential value in point-of-care testing for norovirus. The current study represents one of the first independent studies of the sensitivity and specificity of the SD kit and uses fecal material from sporadic and outbreak gastroenteritis incidents collected in Victoria, Australia. Further, the study examines, for the first time, the effects of freezing and thawing of fecal specimens and the effect of longer term storage of fecal specimens prior to testing by the SD kit. The findings are reviewed in relation to the value of the kit for point-of-care and laboratory testing.

2. Materials and methods

2.1. The Bioline Standard Diagnostics immunochromatographic norovirus detection assay

The Bioline Standard Diagnostics norovirus immunochromatographic detection assay (SD kit) is marketed by Standard Diagnostics, Inc. (Kyonggi-do, Korea) as a quick qualitative assay for GI and GII noroviruses. The kit is marketed as a "one step" norovirus antigen test. The manufacturer advises that the kit be stored at 1–30 °C and that fecal specimens for testing be kept at 2–8 °C for no more than 72 h. Thereafter specimens should be at under −20 °C prior to thawing and testing. The kit and fecal specimens to be tested are brought to room temperature before testing.

The SD kit comes supplied with all required consumables and was used following the manufacturer's instructions. Briefly, a set volume of sample diluent was added to a collection tube and a small portion of feces then added and mixed thoroughly. The supplied dropping cap was then applied to the collection tube and 4–5 drops of the fecal mixture added to the sample well of the test device (Fig. 1). This latter step is the "one step" referred to by the manufacturer. The test device was then allowed to stand for 15 min. A positive result was identified by the presence of both the control line and the test line (Fig 1. A) in the test device and a negative result was identified by the presence of only the control line (Fig. 1 B) in the test device. The absence of a control line indicated the test was invalid and required repeating.

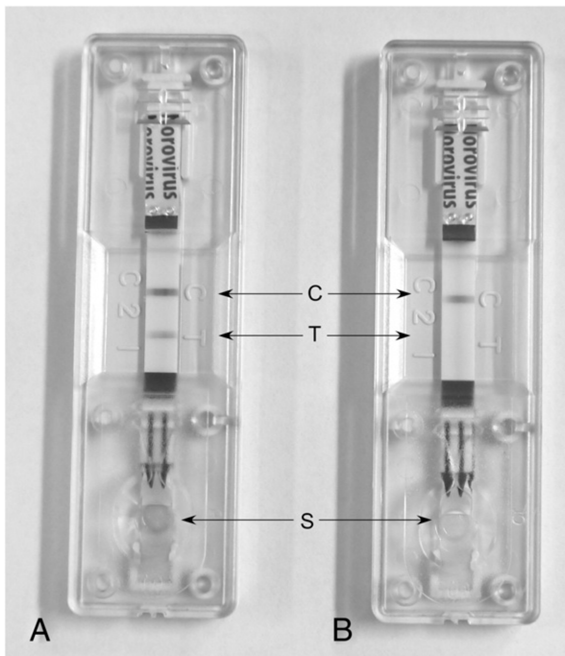

Fig. 1. The SD kit test device showing a norovirus positive result (A) and a norovirus negative result (B). C = control line; T = test line; S = sample well.

2.2. Fecal specimens

All fecal specimens included in this study were sent to the Victorian Infectious Diseases Reference Laboratory for testing for norovirus. All fecal specimens were collected in the State of Victoria, Australia and were derived from sporadic cases or outbreaks of gastroenteritis. Only one fecal specimen per person was used in this study.

Fecal specimens used for the evaluation of the SD kit comprised six groups. Details of these six groups follow.

2.3. Group 1 fecal specimens

This group comprised 50 fecal specimens positive for norovirus by RT-PCR protocol 1 (Table 1) and these specimens were tested by the SD kit within 72 h of specimen collection. These specimens were not subjected to freezing and thawing.

2.4. Group 2 fecal specimens

This group comprised 217 fecal specimens negative for norovirus by RT-PCR protocol 1 (Table 1) and these specimens were tested by the SD kit within 72 h of specimen collection. These specimens were not subjected to freezing and thawing.

2.5. Group 3 fecal specimens

This group comprised 100 fecal specimens positive for norovirus by RT-PCR protocol 1 (Table 1). These specimens were tested by the SD kit more than 3 days after specimen collection both before freezing and after freezing and thawing. Freezing involved putting the fecal specimen at −20 °C for at least 24 h.

2.6. Group 4 fecal specimens

This group comprised 100 fecal specimens negative for norovirus by RT-PCR protocol 1 (Table 1). These specimens were tested by the SD kit more than 3 days after specimen collection both before freezing and after freezing and thawing. Freezing involved putting the fecal specimen at −20 °C for at least 24 h.

2.7. Group 5 fecal specimens

This group comprised 13 fecal specimens and were selected as a specificity control to evaluate the SD kit for cross-reactivity to common fecal viruses other than norovirus. Of these 13 specimens, negative staining electron microscope studies indicated two were positive for sapovirus, two were positive for astrovirus, two were positive for adenovirus and seven were positive for rotavirus. All 13 specimens were negative for norovirus by RT-PCR protocol 1 (Table 1). The group 5 fecal specimens were stored at −20 °C prior to being thawed for testing in the current study.

2.8. Group 6 fecal specimens

The study involved SD kits corresponding to two batch numbers: batch 1("189001") and batch 2 ("189002"). The experiment involving group 6 specimens was designed to test whether kits corresponding to different batch numbers had the same sensitivity and specificity. Group 6 comprised 50 fecal specimens that had been shown to be norovirus positive by RT-PCR protocol 1 (Table 1). The specimens were frozen and then thawed prior to testing, in tandem, by SD kits corresponding to batches 1 and 2.

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