



## Bacteriology

Evaluation of the rapid RIDAQUICK *Campylobacter*® test in a general hospital

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## ABSTRACT

The study objective was to evaluate the effectiveness of the new rapid immunochromatographic test RIDAQUICK *Campylobacter*® (r-biopharm AG, Darmstadt, Germany) for the qualitative detection of *Campylobacter* antigens in pathologic feces from primary and specialist care patients. Three hundred feces samples were studied from patients with diarrhea, 50.6% from adults and 49.4% from children, which were received by our microbiology laboratory for coproculture. *Campylobacter* culture results, with or without PCR data, served as reference values for the comparative evaluation of RIDAQUICK *Campylobacter*® findings. *Campylobacter* was detected in 12.3% of samples. The diagnostic accuracy values of the RidaQuick *Campylobacter*® versus culture were: sensitivity of 87%, specificity of 97%, and positive and negative predictive values of 77% and 98%, respectively. RIDAQUICK *Campylobacter*® is a rapid test for the diagnosis of enteritis due to *Campylobacter* and could be an option for the clinical diagnosis of one of the main causes of bacterial enteritis in resource-limited settings.

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## 1. Introduction

The genus *Campylobacter* belongs to the family Campylobacteriaceae (Hindiyeh et al., 2000) and contains 18 species, including *Campylobacter jejuni*, the cause of around 90% of acute *Campylobacter* enteritis cases in humans (Hindiyeh et al., 2000; Kawatsu et al., 2008; Granato et al., 2010). This zoonotic disease is prevalent worldwide and transmitted via water and food (Friedman et al., 2000; Granato et al., 2010).

*C. jejuni* and *Campylobacter coli* colonize the digestive tract of numerous animals, especially birds, and most infections are produced by the consumption of their undercooked meat (Granato et al., 2010). The incubation period of the enteritis ranges from 1 to 7 days, and its signs and symptoms are non-specific. These infections are generally self-limiting (Skirrow and Titus, 2000) and only rarely give rise to extra-intestinal disease (e.g., bacteremia, reactive arthritis, or Guillain-Barré syndrome) (Hannu et al., 2002; Granato et al., 2010; Floch et al., 2012). Hence, antibiotic treatment is not usually indicated for diagnosed patients (Giltner et al., 2013). Nevertheless, detection of this etiologic agent is important for the differential diagnosis with other potential causes of diarrhea (Tissari and Rautelin, 2007) and because the infection may persist. Furthermore, specific antibiotic treatment may be indicated in immunodepressed patients and in children and the elderly, showing an appreciable rate of resistance to

fluoroquinolones (Hindiyeh et al., 2000; Tolcin et al., 2000; Granato et al., 2008; Arsenault et al., 2011). For these reasons, rapid etiologic detection is vital in the aforementioned populations.

The diagnosis of enteritis due to *Campylobacter* was traditionally performed using culture, visualization by Gram staining (fuchsin), and conventional biochemical identification methods such as API-systems (bioMérieux Vitek, Inc, Hazelwood, MO, USA). *Campylobacter* is a curved Gram-negative rod that requires microaerophilic incubation for up to 48 h at 42 °C using selective media (Bessède et al., 2011a). More recent diagnostic techniques include the detection of antigens (enzyme-linked immunosorbent assay or immunochromatography) or DNA in feces and matrix-assisted laser desorption ionization–time of flight (MALDI-TOF) mass spectrometry of the colonies (Bessède et al., 2011b; Martiny et al., 2013). The antigen detection methods are of particular interest because they yield results within hours or minutes and are easy to apply, especially using the immunochromatographic approach (Floch et al., 2012). In addition, *Campylobacter* antigens can persist in the clinical sample in the absence of viable microorganisms, allowing primary infections to be detected by this method when the bacteria are not viable, which is a major potential clinical advantage. However, highly variable results have been obtained using commercialized kits (Table 1), and further knowledge is required on the functioning of these kits in clinical samples to establish their usefulness in the diagnosis of this infectious enteritis.

The objective of this study was to evaluate the behavior of the new rapid immunochromatographic test RIDAQUICK *Campylobacter*®

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**Table 1**  
Results of tests for detection of *Campylobacter* antigen.

Study	Test	Results	No. of samples
Tolcin et al., 2000	ProSpecT <i>Campylobacter</i> ® (Alexon-Trend, Ramsey, MN, USA): EIA microplate assay.	Se = 96%; Sp = 99%	164; GS: culture
Endtz et al., 2000 Hindiye et al., 2000		Se = 80%; Sp = 100% Se = 89%; Sp = 99%; PPV = 80%; NPV = 99%	30; GS: culture 631; GS: culture
Dediste et al., 2003		Se = 89.1%; Sp = 97.7%; PPV = 78.3%; NPV = 99%	1205; GS: culture
Tissari and Rautelin, 2007 (R-biopharm AG, Darmstadt, Germany): EIA microplate assay	RidaScreen <i>Campylobacter</i> ® Se = 69%; Sp = 87%		1050; GS: culture
Kawatsu et al., 2008	Campy in-house: immunochromatographic assay	Se = 84.8%; Sp = 100%	222; GS: culture
Bessède et al., 2011a	In-house PCR	Se = 80%; PPV = 85%	242; GS: Culture or PCR + EIA
	Multiplex PCR Seeplex Diarrhea ACE Detection®	Se = 89%; PPV = 85%	
(R-biopharm AG, Darmstadt, Germany): EIA microplate assay.	RidaScreen <i>Campylobacter</i> ® Se = 91%; PPV = 85%		
	Premier CAMPY® (Meridian Bioscience, Inc. Cincinnati, OH, USA): EIA microplate assay.	Se = 95%; PPV = 80%	
	ImmunoCard STAT! Campy® (Meridian Bioscience, Inc.): immunochromatographic assay.	Se = 90%; PPV = 70%	
Dey et al., 2012		Se = 86%; Sp = 100%; GS: culture	Se = 90%; Sp = 100%; GS: PCR 463
Floch et al., 2012 Couturier et al., 2013 Granato et al., 2010		PPV = 80.6% Se = 80%; Sp = 98% Se = 98.4%; Sp = 94.2%; PPV = 92.6%; NPV = 98.8%; GS: culture	609; GS: culture 500; GS: culture 300
		Se = 98.5%; Sp = 98.2%; PPV = 97.8%; NPV = 98.8%; GS: culture + PCR (discordant)	
Giltner et al., 2013	Premier CAMPY® (Meridian Bioscience, Inc.): EIA microplate assay.	Se = 100%; Sp = 98%; PPV = 91%; NPV = 100%	60; GS: culture
		Se = 75%; Sp = 96.5%; PPV = 42.9%; NPV = 99%	119; GS: culture

EIA = enzyme immunoassay; Se = Sensitivity; Sp = Specificity; PPV = Positive predictive value; NPV = Negative predictive value; GS = Gold standard.

(r-biopharm AG, Darmstadt, Germany) in the detection of *Campylobacter* antigen in feces samples from patients with diarrhea.

## 2. Materials and methods

Between March and May 2013, 300 consecutive samples of fresh feces samples were studied from patients diagnosed with diarrhea in primary (57.6%) and specialist (42.4%) care; 50.6% were from adults and 49.4% from children under 14 years of age (Table 2). The samples were received by the Microbiology Laboratory of University Hospital Virgen de las Nieves, Granada (Spain), for coproculture and were simultaneously studied with the RIDAQUICK *Campylobacter*® test to detect the presence of *Campylobacter* antigens. This hospital is a reference center in Andalusia (southern Spain) serving a population of around 440,000 individuals.

Samples were gathered in sterile containers with no transport media and delivered to our laboratory under refrigeration (4 °C), with a maximum delay of 2 hours before their processing. They were processed for coproculture immediately on their reception by culture in CampyBAP® medium with 10% blood (Becton Dickinson, BD, Franklin Lakes, NJ, USA) using a 30-µg cefoxitin disk (BD BBL®) and incubated for 48 h at 42 °C in microaerophilic atmosphere (Campygen®, Oxoid, Basingstoke, UK). Suspicious colonies were identified by means of oxidase cytochrome tests (Difco, Detroit, MI, USA), Gram staining, and mass spectrometry using the Biotyper® system (Bruker

Daltonics, Coventry, UK) (He et al., 2010). The samples were also seeded in the usual culture media for enteropathogens for 48 h (XLD® agar [BD] at 37 °C for recovery of *Salmonella*, *Shigella*, and *Plesiomonas*, and CIN® agar [BD] at 30 °C for recovery of *Yersinia* and *Aeromonas*) or 24 h (Selenito® broth [Difco] for recovery of *Salmonella*, followed by a subculture in Hektoen® agar [BD] at 37 °C). Colonies suspected of being enteropathogenic were identified by means of the Biotyper® system (Bruker Daltonics) and the usual biochemical tests (MicroScan; Siemens Healthcare, Rockville, MD, USA). Colonies identified as *Salmonella* were subjected to the agglutination test to determine the serogroup (Difco).

The RIDAQUICK *Campylobacter*® was used according to the manufacturer's instructions, mixing well 50 mg or 50 µL of the feces in a tube containing 0.5 mL of reagent A and 0.5 mL of reagent B. The mixture was incubated at room temperature for 5 min, and 150 µL of the supernatant was then placed in the sampling port of the device. After a 15-min interval at room temperature, the reading was made by 2 researchers using simple visual observation, and the result was accepted for evaluation when their readings coincided. The result was considered positive when violet red lines could be seen in the control (C) and test (T) bands, negative when the control line alone appeared, and invalid when no line could be observed.

All samples tested were kept at –80 °C in aliquots. In samples with discrepant culture and immunochromatography results, the presence of *Campylobacter* DNA was also investigated using RIDAGENE

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