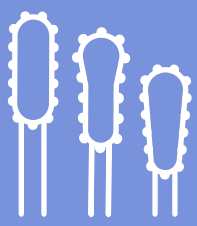
Scientific Booklet

Gastrointestinal Diseases



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Acknowledgments:

We would like to express our gratitude to the authors whose works have been arranged in this booklet: their insights and expertise greatly assisted this prime selection.

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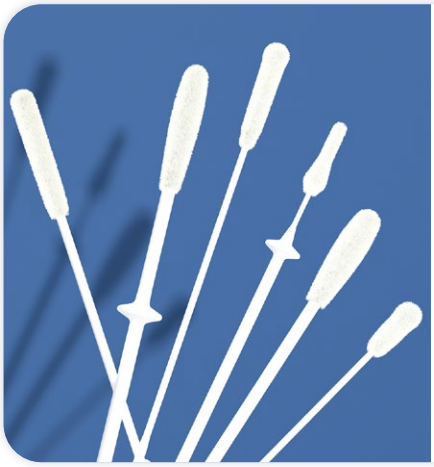

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Gastrointestinal Diseases

Pigment Visibility on Rectal Swabs Used to Detect Enteropathogens: a Prospective Cohort Study

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Keywords

FLOQSwabs®	Rectal Swab	Visible Pigment	Children Infection

Abstract

Data are lacking regarding the impact of visible pigment on rectal swab diagnostic accuracy. We describe the test characteristics of rectal swabs with and without pigment in children with gastroenteritis. Between December 2014 and September 2017, children (age, 18 years) with 3 episodes of vomiting and/or diarrhea in a 24-h period and symptoms for 7 days were enrolled through two pediatric emergency departments and from a province-wide nursing telephone advice line in Alberta, Canada. Copan FLOQSwabs® were analyzed by employing nucleic acid amplification panels. The primary outcomes were the sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) for the rectal swabs, with stool specimen results being used as the reference standard. An enteropathogen was detected in 76.0% (1,399/1,841) of the paired specimens. A total of 54.4% (1,001/1841) of the swabs had visible pigment. The respective enteropathogen detection characteristics of swabs with and without visible pigment were as follows: 92.2% (95% confidence interval [CI], 90.0%, 94.0%) versus 83.7% (95% CI, 80.5%, 86.4%) for sensitivity, 94.3% (95% CI, 90.5%, 96.6%) versus 91.2% (95% CI, 86.3%, 94.5%) for specificity, 97.9% (95% CI, 96.4%, 98.8%) versus 96.5% (95% CI, 94.5%, 97.8%) for PPV, and 80.9% (95% CI, 76.0%, 85.1%) versus 65.8% (95% CI, 60.0%, 71.1%) for NPV. Processing of swabs without visible pigment would increase the rate of identification of positive swabs from 50.0% (682/1,365) to 88.3% (1,205/1,365). There is a modest decrease in the reliability of a negative test on swabs without evidence of pigment, but the overall yield is significantly greater when they are not excluded from testing. Hence, rectal swabs without visible feces should not be routinely rejected from testing.

Diagn Microbiol Infect Dis. 2020 Aug;97(4):115055

Gastrointestinal Diseases

Evaluation of Copan FecalSwab™ Preserved Stool Specimens with the BD MAX™ Enteric Bacterial Panel and the BD MAX™ Extended Enteric Bacterial Panel

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Keywords

FecalSwab™	BD Max	Stool	Gastrintestinal Panel

Abstract

The objectives of this study were to assess the ideal volume of Copan FecalSwab™ (FS) preserved stool sample to use with the BD MAX™ Enteric Bacterial Panel and the Extended Enteric Bacterial Panel (BDM GIP) and to compare the performance of FS to the recommended Meridian Para-Pak Cary-Blair medium (PP) for the BDM GIP. Three different input volumes (10, 25, and 50 µL) of stool inoculated with American Type Culture Collection strains representing the targets detected by BDM GIP were tested. Additionally, 144 unpreserved stool samples submitted for gastrointestinal (GI) testing were transferred to PP and FS media and tested by the BDM GIP using 10 µL of PP and 50 µL of FS media. A 100% agreement was observed between PP and FS results. The performance of 50 µL of FS stool preserved sample was equivalent to 10 µL of traditional Cary-Blair PP preserved specimens for GI pathogens detection using the BDM GIP.

J Clin Microbiol. 2017 Oct;55(10):3123-3129

Gastrointestinal Diseases

Evaluation of Copan FecalSwab™ as Specimen Type for Use in Xpert *C. difficile* Assay

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Keywords

FecalSwab™	*C.difficile*	Xpert Assay	LBM®

Abstract

Liquid-based microbiology™ (LBM®) devices incorporating flocked swabs and preservation medium ease transport of specimens and improve specimen yield compared to traditional fiber wound swabs; however, the performance of LBM® collection devices has not been evaluated in many molecular assays. It is unclear how the differences in matrix and specimen loading with an LBM® device will affect test performance compared to traditional collection devices. The purpose of this study was to evaluate the performance of specimens collected in FecalSwab™ transport medium (Copan) compared to unpreserved stool using the Cepheid Xpert *C. difficile* assay (Cepheid, Sunnyvale, CA). Results equivalent to unpreserved stool samples were obtained when 400 l of FecalSwab™ preserved stool was employed in the Xpert assay. The positive and negative percent agreement of specimens inoculated with FecalSwab™ medium (n 281) was 97.0% (95% confidence interval [CI], 90.9 to 96.4%) and 99.4% (95% CI, 96.4 to 99.9%), respectively, compared to reference results obtained using unpreserved stool. Throughout this study, only four discrepant results occurred when comparing preserved specimens to unpreserved stool specimens in the Xpert *C. difficile* PCR assay. Post discrepant analysis, using the BD MAX Cdiff assay, the specificity and sensitivity both increased to 100%. The high positive and negative percent agreements observed in this study suggest that stool preserved in FecalSwab media yields equivalent results to using unpreserved stool when tested on the Xpert *C. difficile* assay, allowing laboratories to adopt this liquid-based microbiology collection device.

Clin Microbiol Infect. 2019 Apr;25(4):454-461

Gastrointestinal Diseases

Relationship Between Enteric Pathogens and Acute Gastroenteritis Disease Severity: a Prospective Cohort Study

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Keywords

FLOQSwabs®	Acute Gastroenteritis	Virus Infection	Salmonella

Abstract

Objectives: To evaluate the relationship between individual bacterial and viral pathogens and disease severity.
Methods: Children <18 years with three or more episodes of vomiting and/or diarrhoea were enrolled in two Canadian paediatric emergency departments between December 2014 and August 2016. Stool specimens collected with Copan FLOQSwabs® were analysed employing molecular panels, and outcome data were collected 14 days after enrolment. The primary outcome was severe disease over the entire illness (symptom onset until 14-day follow-up), quantified employing the Modified Vesikari Scale (MVS) score. The score was additionally analysed in two other time periods: index (symptom onset until enrolment) and follow-up (enrolment until 14-day follow-up).
Results: Median participant age was 20.7 (IQR: 11.3, 44.2) months; 47.4% (518/1093) and 73.4% (802/1093) of participants had index and total MVS scores ≥11, respectively. The most identified pathogens were rotavirus (289/1093; 26.4%) and norovirus (258/1093; 23.6%). In multivariable analysis, severe disease over the entire illness was associated with

rotavirus (OR = 9.60; 95%CI: 5.69, 16.19), *Salmonella* (OR = 6.61; 95%CI: 1.50, 29.17), adenovirus (OR = 2.53; 95%CI: 1.62, 3.97), and norovirus (OR = 1.43; 95%CI: 1.01, 2.01). Pathogens associated with severe disease at the index visit were: rotavirus only (OR = 6.13; 95%CI: 4.29, 8.75), *Salmonella* (OR = 4.59; 95%CI: 1.71, 12.29), adenovirus only (OR = 2.06; 95%CI: 1.41, 3.00), rotavirus plus adenovirus (OR = 3.15; 95%CI: 1.35, 7.37), and norovirus (OR = 0.68; 95%CI: 0.49, 0.94). During the follow-up period, rotavirus (OR = 2.21; 95%CI: 1.50, 3.25) and adenovirus (OR = 2.10; 95%CI: 1.39, 3.18) were associated with severe disease.
Conclusions: In children presenting for emergency department care with acute gastroenteritis, pathogens identified were predominantly viruses, and several of which were associated with severe disease. *Salmonella* was the sole bacterium independently associated with severe disease.

PLoS One. 2018 Jun 26;13(6):e0199766

Gastrointestinal Diseases

Nonaplex PCR Using Cliffhanger Primers to Identify Diarrhoeagenic *Escherichia coli* from Crude Lysates of Human Faecal Samples

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Keywords

FecalSwab™	*Escherichia coli*	Sanger Sequencing	Fecal Samples

Abstract

Sensitive, probe-based detection of multiple DNA targets is limited by the competitive reannealing of the antiparallel duplex DNA helix with the complementary DNA strand. To address this, we developed Cliffhanger primers, which create single-stranded DNA overhangs on PCR amplicons while simultaneously increasing the multiplex PCR efficacy and allowing PCR amplification using crude lysates of human faecal samples. A multiplex PCR that targeted eight genes from diarrhoeagenic *Escherichia coli* plus an internal control was performed and compared to a routine method that consisted of culture followed by multiplex PCR with fragment length separation. A total of 2515 clinical faecal samples, collected with Copan FecalSwabs™, from patients with diarrhoea were tested using both methods, and there was a significant increase in clinical sensitivity and negative predictive value with the Cliffhanger method for seven out of eight genes. All Cliffhanger-only positive samples were confirmed by Sanger sequencing of the PCR amplicon. Notably, the Cliffhanger method reduced the total sample turn-around time in the laboratory from 20 hours to 6 hours. Hence, use of Cliffhanger primers increased assay robustness, decreased turn-around time and increased PCR efficacy. This increased the overall clinical sensitivity without the loss of specificity for a heavily multiplexed PCR assay.

J Clin Microbiol. 2019 Nov 22;57(12):e00962-19

Gastrointestinal Diseases

Evaluation of Anatomically Designed Flocked Rectal Swabs for Use with the BioFire FilmArray Gastrointestinal Panel for Detection of Enteric Pathogens in Children Admitted to Hospital with Severe Gastroenteritis

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Keywords

FecalSwab™	Enteric Pathogens	Childern	Shigella

Abstract

Diagnosing diarrheal disease is difficult in part due to challenges in obtaining and transporting a bulk stool specimen, particularly in resource-limited settings. We compared the performance of Copan FecalSwab™ flocked rectal swabs to that of traditional bulk stool samples for enteric pathogen detection using the BioFire FilmArray gastrointestinal panel in children admitted to four hospitals in Botswana with community onset severe gastroenteritis. Of the 117-matched flocked rectal swab/stool pairs, we found no significant difference in pathogen detection rates between the flocked rectal swab samples and traditional bulk stool sampling methods for any bacterial (168 versus 167, respectively), viral (94 versus 92, respectively), or protozoan (18 versus 18, respectively) targets. The combination of flocked rectal swab samples with FilmArray testing allows for the rapid diagnosis of infectious gastroenteritis, facilitating a test-and-treat approach for infections that are lifethreatening in many resource-limited settings. The culture recovery rates for bacterial pathogens utilizing this approach need to be assessed.

Diagn Microbiol Infect Dis. 2020 Mar;96(3):114895

Gastrointestinal Diseases

Impact of Freeze/Thaw Cycles and Single Freezing at -80 °C on the Viability of Aerobic Bacteria from Rectal Swabs Performed with the eSwab® System

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Keywords

eSwab®	*Escherichia coli*	Freezing Thawing	Rectal

Abstract

The testing of bacterial preservation should be included in preliminary studies to epidemiological studies. In the case of multidrug-resistant organism (MDRO) studies, quantifications of the bacteria make it possible to understand their emergence. The purpose of this preliminary study was to evaluate the performance of Copan eSwab® on survival of *Escherichia coli, Klebsiella pneumoniae, and Enterococcus faecalis*, based on the number of freezing and thawing (F/T) cycles at -80 °C and freezing time. A first experiment with 9 samples showed that multiple F/T cycles drastically affected Enterobacteriaceae viabilities and less E. faecalis one. A single freezing maintained the three species viabilities during three weeks. A second experiment showed that *E. coli* survival was maintained with a 3-month single freezing. This study which used a limited number of bacterial isolates is however a proof of concept establishing the utility of eSwab® samples when frozen once in quantitative studies of bacteria.

J Clin Microbiol. 2020 Sep 22;58(10):e01033-20

Gastrointestinal Diseases

Performance Evaluation of the Novodiag Bacterial GE Multiplex PCR Assay

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Keywords

eNAT®	FLOQSwabs®	Digestive Infections	Novodiag Bacterial GE+

Abstract

The bacteriological diagnosis of intestinal bacterial infections has historically been based on culture on agar plates. However, culture may lack sensitivity, and some enteropathogens, such as pathovars of *Escherichia coli*, may escape routine diagnosis. Our goal was to evaluate the analytical performance of the Novodiag Bacterial GE kit for the detection of enteropathogenic bacteria in acute community diarrhea. We included 251 stools in this study (198 retrospective and 53 prospective) collected with Copan FLOQSwabs® and Copan eNAT® medium. The analytical performance was calculated using a composite reference standard (CRS) in the absence of a perfect gold standard (lack of sensitivity of culture). The CRS was defined as positive if culture was positive or, in case of a negative culture, if the BD Max extended enteric bacterial panel and/or other real-time PCR (RTPCR) tests were positive. Of the 251 samples, 200 were positive, and 51 were negative. Overall sensitivities of the Novodiag Bacterial GE kit for *Campylobacter sp., Salmonella sp., Shigella* sp./enteroinvasive *E. coli* (EIEC), *Yersinia enterocolitica*, enterohemorrhagic *E. coli* (EHEC), and enterotoxigenic E. coli (ETEC) ranged from 98.98 to 100%, specificities ranged from 98.08 to 100%, positive predictive values (PPVs) ranged from 88.24 to 100%, and negative predictive values (NVPs) ranged from 99.36 to 100%. The analytical performance of the Novodiag Bacterial GE kit is excellent. It can be used as a routine tool in the rapid diagnosis of bacterial gastroenteritis. Despite the eNAT® tube dilution of the primary sample, the detection of Salmonella sp. and EHEC was perfect. The kit has the advantage of only detecting pathogenic Y. enterocolitica. Its performance for Campylobacter is very satisfactory.

J Clin Microbiol. 2020 Mar 25;58(4):e01787-19

Gastrointestinal Diseases

Diagnostic Accuracy of a Noninvasive Test for Detection of *Helicobacter pylori* and Resistance to Clarithromycin in Stool by the Amplidiag *H. pylori*+ClariR Real-Time PCR Assay

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Keywords

eNAT®	*Helicobacter pylori*	Stool	*H. Pylori*+ClariR Assay

Abstract

The noninvasive detection of *Helicobacter pylori* and its resistance to clarithromycin could revolutionize the management of *H. pylori*-infected patients by tailoring eradication treatment without any need for endoscopy when histology is not necessary. Several real-time PCR tests performed on stools have been proposed, but their performances were either poor or they were tested on too few patients to be properly evaluated. We conducted a prospective, multicenter study including 1,200 adult patients who were addressed for gastroduodenal endoscopy with gastric biopsies and who were naive for eradication treatment in order to evaluate the performance of the Amplidiag *H. pylori*+ClariR assay recently developed by Mobidiag (Espoo, Finland). Stool specimens were collected with Copan FLOQSwabs® and Copan eNAT® medium. The results of the Amplidiag *H. pylori*+ClariR assay performed on DNA from stools (automatic extraction with the EasyMag system [bioMérieux]) were compared with those of culture/Etest and quadruplex real-time PCRs performed on two gastric biopsy samples (from the antrum and corpus) to detect the *H. pylori glmM* gene and mutations in the 23S rRNA genes conferring clarithromycin resistance. The sensitivity and specificity of the detection of *H. pylori* were 96.3% (95% confidence interval [CI], 92 to 98%) and 98.7% (95% CI, 97 to 99%), respectively. The positive and negative predictive values were evaluated to be 92.2% (95% CI, 92 to 98%) and 99.3% (95% CI, 98 to 99%), respectively. In this cohort, 160 patients (14.7%) were found to be infected (positive by culture and/or PCR). The sensitivity and specificity for detecting resistance to clarithromycin were 100% (95% CI, 88 to 100%) and 98.4% (95% CI, 94 to 99%), respectively.

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Gastrointestinal Diseases

Evaluating the Preservation and Isolation of Stool Pathogens Using the COPAN FecalSwab™ Transport System and Walk-Away Specimen Processor

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Keywords

WASP®	FecalSwab™	Stool Culture	Isolation & Preservation

Abstract

The isolation of stool pathogens is difficult due to their fastidious nature and the rapid overgrowth of fecal flora. In this study, we evaluate the preservation and isolation of enteric pathogens from stool using the automated COPAN Walk-Away Specimen Processor™ (WASP®) in conjunction with FecalSwab™ and selenite media. Pathogen viability and fecal commensal abundance were stable in FecalSwab™ media under both room-temperature and refrigerated incubation conditions, resulting in a significantly increased number of well-isolated pathogen colonies observed when compared to samples incubated in modified Cary-Blair media. Isolation of individual pathogen colonies was improved via WASP® planting compared to those planted using the Isoplater system. Furthermore, preincubation using the newly formulated COPAN selenite media significantly enhanced the yield of *Salmonella enterica* serovar Typhimurium. Together, the automated WASP® system combined with FecalSwab™ and selenite media represents a rapid and efficient approach for the processing of stool specimens compared to standard methods.

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Gastrointestinal Diseases

Recovery of Aerobic Gram-Negative Bacteria from the Copan eSwab® Transport System after Long-Term Storage

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Keywords

eSwab®	Gram-Negative Bacteria	Long-Termo Storage	Stool

Abstract

We evaluated the Copan eSwab® transport system for the quantitative recovery of E*scherichia coli, Klebsiella pneumoniae, and Pseudomonas aeruginosa* after 1, 2, 3, 5, and 7 days of storage at room and refrigerator temperatures, and 7 and 30 days of storage at–80 °C and–20 °C using mono- and polymicrobial samples. The study was based on Clinical and Laboratory Standards Institute (CLSI) M40-A2 standard procedures on the quality control of microbiological transport systems. Copan eSwab® met the CLSI standards at room and refrigerator temperatures for all (combinations of) bacterial strains tested. At room temperature, after 24 h, bacterial growth was observed. At –80 °C, bacterial viability was maintained in monomicrobial samples; however, in polymicrobial samples, *P. aeruginosa* recovery was compromised. Storage at–20 °C was unsuitable. We conclude that specimens collected using Eswab should be transported to the laboratory as soon as possible. If transport or processing is delayed, specimens should preferably be stored at refrigerator temperatures.

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Gastrointestinal Diseases

Rapid and accurate eXDR screening: use Xpert Carba-R® with FecalSwab™

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Keywords

Xpert Carba	FecalSwab™	Carbapenemase-producing Enterobacterales

Abstract

The FecalSwab™ displays high performances for stool culture, but it was not assessed for carbapenemase-producing Enterobacterales (CPE) screening. We assess the performances of the Xpert Carba-R v2® with the Copan FecalSwab™. Using a collection of 12 CPE strains, the limit of detection was assessed at 158 CFU/swab [interquartile range 93–589]. In 2019, 1540 swabs were included by 4 hospital laboratories, of which 39 (2.5%) yield an invalid result. Among the 1501 valid, 87 (5.8%) were positives by culture and PCR and 25 (1.7%) were discrepant: 7 PCR-negative culture-positive, and 18 PCR-positive culture-negative. Two PCR-positive culture-negative results involved non-Enterobacterales strains: a KPC-producing *Acinetobacter baumannii* and a KPC-producing *Aeromonas spp*. The overall percent agreement was 98.3% and the Kappa value was 0.88. FecalSwab™ is an accurate sampling device for CPE screening. It allows performing all eXDR screening using a single swab, simplifying the sample collection, and improving the patient comfort. Regarding discrepant, we suggest combining a CPE screening by both culture and Xpert Carba-R v2® methods.

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Gastrointestinal Diseases

Differences in Illness Severity among Circulating Norovirus Genotypes in a Large Pediatric Cohort with Acute Gastroenteritis

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Keywords

FecalSwab™	Norovirus	Pediatric	Sanger Sequencing

Abstract

Norovirus is a major pathogen identified in children with acute gastroenteritis (AGE), little is known about the strain's diversity and their clinical severity. Stool and/or rectal swabs were collected with Copan FecalSwabs™ from children ≤18 years of age recruited at emergency departments (ED), and a provincial nursing advice phone line due to AGE symptoms in the province of Alberta, Canada between December 2014 and August 2018. Specimens were tested using a reverse transcription real time PCR and genotyped by Sanger sequencing. The Modified Vesikari Scale score (MVS) was used to evaluate the disease severity. The objectives are to identify the Genogroup and Genotype distribution and to compare illness severity between the GI and GII genogroups and to complete further analyses comparing the GII genotypes identified. GII.4 was the genotype most commonly identified. Children with GII.4 had higher MVS scores (12.0 (10.0, 14.0; $p = 0.002$)) and more prolonged diarrheal (5 days (3.0, 7.8)) and vomiting (3.2 days (1.7, 5.3; $p < 0.001$)) durations compared to other non GII.4 strains. The predominant strain varied by year with GII.4 Sydney[P31] predominant in 2014/15, GII.4 Sydney[P16] in 2015/16 and 2017/18, and GII.3[P12] in 2016/17. Genogroup II norovirus strains predominated in children with AGE with variance between years; clinical severity associated with different strains varied with episodes being most severe among GII.4 infected children.

Microorganisms. 2020 Nov 8;8(11):1755

Gastrointestinal Diseases

Limited Genetic Diversity of blaCMY-2-Containing IncI1-pST12 Plasmids from *Enterobacteriaceae* of Human and Broiler Chicken Origin in The Netherlands

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Keywords

AmpC B-lactamase	FecalSwab™	IncI1–pST12 plasmids

Abstract

Distinguishing epidemiologically related and unrelated plasmids is essential to confirm plasmid transmission. We compared IncI1–pST12 plasmids from both human and livestock origin and explored the degree of sequence similarity between plasmids from Enterobacteriaceae with different epidemiological links. Short-read sequence data of *Enterobacteriaceae* cultured from humans and broilers were screened for the presence of both a blaCMY-2 gene and an IncI1–pST12 replicon. Isolates were long-read sequenced on a MinION sequencer (OxfordNanopore Technologies). After plasmid reconstruction using hybrid assembly, pairwise single nucleotide polymorphisms (SNPs) were determined. The plasmids were annotated, and a pan-genome was constructed to compare genes variably present between the different plasmids. Nine *Escherichia coli* sequences of broiler origin, four *Escherichia coli* sequences, and one *Salmonella enterica* sequence of human origin were selected for the current analysis. A circular contig with the IncI1–pST12 replicon and blaCMY-2 gene was extracted from the assembly graph of all fourteen isolates. Analysis of the IncI1–pST12 plasmids revealed a low number of SNP differences (range of 0–9 SNPs). The range of SNP differences overlapped in isolates with different epidemiological links. One-hundred and twelve from a total of 113 genes of the pan-genome were present in all plasmid constructs. Next generation sequencing analysis of blaCMY-2-containing IncI1–pST12 plasmids isolated from *Enterobacteriaceae* with different epidemiological links show a high degree of sequence similarity in terms of SNP differences and the number of shared genes. Therefore, statements on the horizontal transfer of these plasmids based on genetic identity should be made with caution.

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Gastrointestinal Diseases

Prospective Evaluation of the mariPOC Test for Detection of *Clostridioides difficile* Glutamate Dehydrogenase and Toxins A/B

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Keywords

FecalSwab™	Stool	mariPOC CDI	*Clostridioides difficile*

Abstract

The objective of this study was to evaluate a novel automated randomaccess test, mariPOC CDI (ArcDia Ltd., Finland), for the detection of *Clostridioides difficile* glutamate dehydrogenase (GDH) and toxins A and B directly from fecal specimens. The mariPOC test was compared with both the GenomEra *C. difficile* PCR assay (Abacus Diagnostica Oy, Finland) and the TechLab *C. diff* Quik Chek Complete (Alere Inc.; now Abbot) membrane enzyme immunoassay (MEIA). Culture and the Xpert *C. difficile* assay (Cepheid Inc., USA) were used to resolve discrepant results. In total, 337 specimens collected with Copan FecalSwab™ were tested with the mariPOC CDI test and GenomEra PCR. Of these specimens, 157 were also tested with the TechLab MEIA. The sensitivity of the mariPOC test for GDH was slightly lower (95.2%) than that obtained with the TechLab assay (100.0%), but no toxin-positive cases were missed. The sensitivity of the mariPOC test for the detection of toxigenic *C. difficile* by analyzing toxin expression was better (81.6%) than that of the TechLab assay (71.1%). The analytical specificities for the mariPOC and the TechLab tests were 98.3% and 100.0% for GDH and 100.0% and 99.2% for toxin A/B, respectively. The analytical specificity of the GenomEra method was 100.0%. The mariPOC and TechLab GDH tests and GenomEra PCR had high negative predictive values of 99.3%, 98.3%, and 99.7%, respectively, in excluding infection with toxigenic *C. difficile*. The mariPOC toxin A/B test and GenomEra PCR had an identical analytical positive predictive value of 100%, providing highly reliable information about toxin expression and the presence of toxin genes, respectively.

Note

Note

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