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## INTRODUCTION:

### Revised abstract:

Proper diagnosis of diarrheal diseases can be complex due to the variety of pathogens that can cause gastro-enteric infections. A specimen collection and transportation device that allows efficient nucleic acid extraction, Multiplex Real-Time PCR systems and culture confirmation is essential. Copan FecalSwab™ is an LBM device, consisting of a FLOQswabs™ and a tube with 2ml Cary-Blair medium, compatible with manual and WASP™ automated plating for culture, antigen and toxin detection and nucleic acids amplification assays. Nimbus (Hamilton) is an instrument for nucleic acid extraction and PCR set-up. Allplex™ GI-Bacteria (I) (Seegene) is a multiplex Real-Time PCR that detects 7 pathogens from stool.

## OBJECTIVE:

The objective of this study was to compare original stools to stool samples in FecalSwab™, extracted with the Nimbus and tested with Allplex™ GI-Bacterial (I) assay for the detection of enteric pathogens.

## METHODS:

Fifty two stools, tested in duplicate, were used for this validation. Two equal aliquots of each stool were weighted: one was added to a FecalSwab™ and another to a microtube with 1 ml of ASL buffer (Qiagen). The FS tube was loaded on Nimbus, while the fresh stool required other preparation steps: 10 minutes incubation at RT, 2 minutes centrifugation prior DNA extraction and PCR reaction set up on the Nimbus and run on the CFX96 Real Time PCR (Bio-Rad). Stool preparation time for nucleic acids extraction was also calculated.



## MATERIALS:

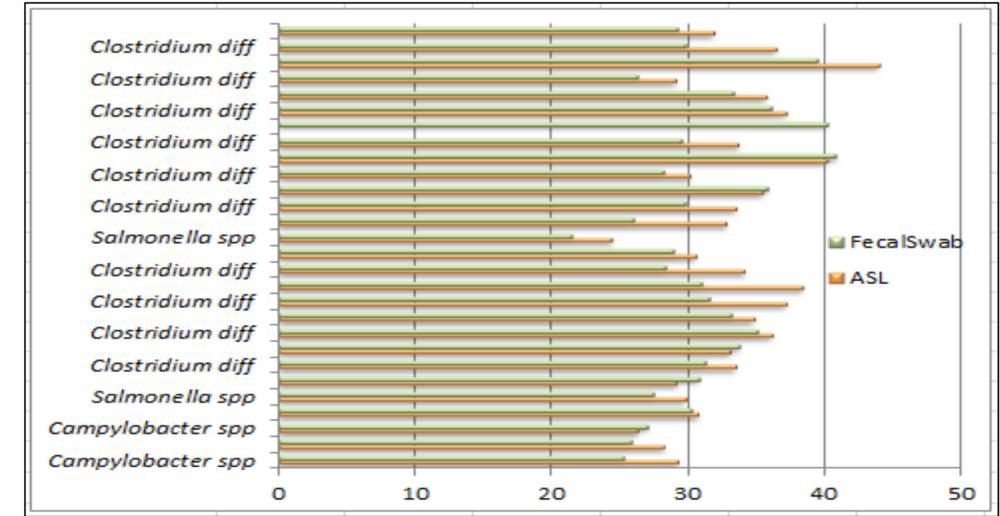
## RESULTS:

Among the positive samples, 4 *Salmonella spp.*, 19 *C. diff* toxin B and 5 *Campylobacter spp.* were detected. Concordant results were obtained with all the negative samples with both nucleic acids extractions (24/24), 28/28 positive were detected with the FecalSwab™ samples and 27/28 positive and 1 discordant with the samples in ASL buffer, which was previously positive by TOX A/B QUIK CHECK (Alere).

		Stools in ASL Buffer	
		+	-
Stools in FecalSwab	+	27	1
	-	0	24



## RESULTS:



The Cts analysis confirms that 23/28 cases, positive samples in **FecalSwab™ amplified as average 3 Cts before the original stools** in ASL buffer, in 5/28 FecalSwab™ samples amplified after original stools and the difference had an average not higher than 1 Ct. The samples preparation time was also compared: **FecalSwab™ preparation time was 5 seconds** versus 15 minutes for the original stools. The amplification with Allplex GI-Bacterial kit also allowed to observe the presence of two co-infections: one sample was positive for *C. diff* and *Aeromonas spp* (both FecalSwab™ and original stool were positive); one sample, positive for *Campylobacter spp* and *Yersinia enterocolitica*, was detected only in the FecalSwab sample.

## CONCLUSIONS:

The results obtained in this study demonstrated that the Copan FecalSwab™ in combination with Nimbus extraction system and Allplex™ GI-Bacterial (I) assay improved the positivity rate of gastro enteric pathogens and shorten the preparation time.