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Evaluation of a multiplex nucleic acid test for detection of gastrointestinal pathogens; Utility of Luminex xTAG GPP

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Abstract

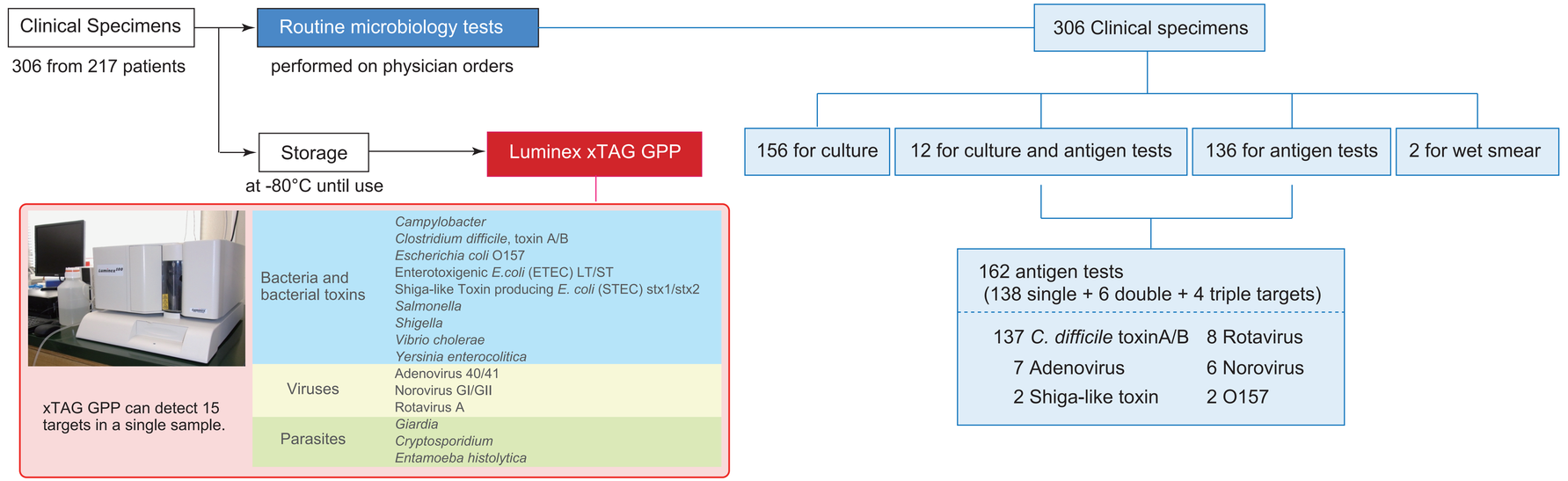
Background: Gastroenteritis is common but sometimes becomes a serious problem for individuals and the community. Because of the variety of pathogens, it is difficult to differentiate among causative pathogens. Here, we evaluated the utility of a qualitative multiplex nucleic acid test, xTAG Gastrointestinal Pathogen Panel (xTAG GPP, Luminex Corp.), in clinical microbiology, comparing with usual diagnostic methods.

Methods: This study was performed at the Nagasaki University Hospital, a tertiary hospital with about 850 beds, and approved by the ethics committee. The fecal specimens that were submitted for the usual microbiological testing were prospectively collected between June 8th and December 31st, 2012. After extraction of nucleic acid from the specimens, 15 targets were analyzed by xTAG GPP. The results were checked against results in the clinical microbiology laboratory database.

Results: Three hundred and six samples collected from 217 patients were enrolled. These samples included 17 (5.6%) with positive results by usual methods ordered by clinicians (*Clostridium difficile*, 15; Norovirus, 1; *Escherichia coli*, 1). In contrast, xTAG GPP showed positive results in 49 (16.0%) samples and detected 54 pathogens. *Shigella*, *Vibrio cholerae*, *Yersinia enterocolitica*, Rotavirus A and *Entamoeba histolytica* were not detected. There were no specimens negative by xTAG GPP but positive by usual testing.

Conclusions: xTAG GPP can comprehensively detect important pathogens that are overlooked in gastroenteritis and may contribute to appropriate antimicrobial therapy selection and enhance infection control practices.

Study Outline



Results

Table 1. A summary of xTAG GPP positives and results of routine laboratory tests among the xTAG GPP positive samples.

	xTAG GPP Positives	Routine laboratory tests: Detected			Not detected			
		Method			Method		Specific order not requested	
		Culture	Antigen		Culture	Antigen		
C. difficile, toxin A/B	31	(9)	(6)	15	(4)	(10)	(2)	16
Campylobacter	3			0			(3)	3
Salmonella	2			0	(2)			2
E. coli O157	2			0			(2)	2
STEC stx1/stx2	2			0			(2)	2
ETEC LT/ST	1	(1)*		1				0
Norovirus GI/GII	9		(1)	1			(8)	8
Adenovirus 40/41	1			0			(1)	1
Cryptosporidium	2			0			(2)	2
Giardia	1			0			(1)	1
Total	54			17				37

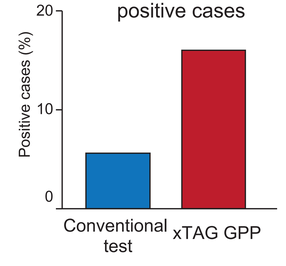
* *E. coli* was identified but not detected the toxin carriage.

From 5 samples, two targes were detected: *C. difficile*, toxin A/B and Adenovirus 40/41 1; *C. difficile*, toxin A/B and Norovirus GI/GII 3; *Cryptosporidium* and Norovirus GI/GII 1.

Table 2. xTAG GPP testing performance in *C. difficile* toxin-required samples.

		C. difficile Ag: Positive	*C. difficile* Ag: Negative	Total
xTAG GPP	Positive	6	12	18
	Negative	0	119	119
Total		6	131	137

Figure 1. Microbiologically-positive cases



Conclusions

- xTAG GPP could detect causative agents in gastroenteritis more effectively than conventional tests.
- xTAG GPP could decrease the subjective uncertainty and increase the detection rate of both suspected and unsuspected pathogens.
- xTAG GPP would contribute to appropriate treatment in patients with gastroenteritis and enhance the infection control practices.
- Multiplex nucleic acid test lead us to recognize the possibility of polymicrobial infection in gastroenteritis.