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Re: Improved Diagnosis of Diarrhea Using a Molecular Method

In October of 2015, Laboratory Alliance's Microbiology Department replaced its conventional methods for the diagnosis of bacterial diarrheal disease with a molecular-based, multiplex PCR assay. The assay reliably detects the presence of the most common bacteria responsible for infectious diarrhea (*Campylobacter, Salmonella, Shiga* toxin-producing *E. coli,* and *Shigella).* In addition, the molecular assay also routinely screens for the presence of *Yersinia enterocolitica* and *Vibrio cholera/parahaemolyticus,* as well as two viruses: norovirus and rotavirus.

To evaluate the performance of the multiplex PCR assay compared to culture, a two-year retrospective study was conducted to determine isolation or detection rates for the various enteric pathogens. The total numbers of specimens over each of the two time periods were comparable.

As shown in Table 1, the total number of enteric pathogens detected using the molecular assay was 1,135 compared to 382 for culture, which represents an almost 200% increase in positivity rate. Of note, norovirus and rotavirus were detected in 491 and 167 fecal specimens respectively, which accounted for 58% of all enteric pathogens detected during the study period. Importantly, with the exception of *Salmonella*, there was a significant increase in the number of positive specimens detected using the molecular assay compared to the culture method.

More *Salmonella* were detected using culture than by the molecular assay. This higher number was likely due to a foodborne outbreak of *Salmonella* that the Central New York area was experiencing during the July 2013 to June 2015 study culture period.

Table 1. Comparison of Culture and Molecular Assay for Detection of Enteric Pathogens

Diarrheal Pathogen	Routine Culture July 2013 to June 2015	Molecular Assay June 2016 to May 2018	% Change
Norovirus	Not Detected	491	Not applicable
Rotavirus	Not Detected	167	Not applicable
Campylobacter	188	210	+12%
Salmonella	154	139	- 10%
STX – E. coli[a]	32	71	+122%
Shigella	5	34	+580%
Yersinia	2	16	+700%
Vibrio	1	7	+600%
Total	**382**	**1,135**	**+197%**

[a] STX – E.coli = Shiga toxin-producing *E. coli,* also known as enterohemorrhagic *E. coli*

The results of this comparative, two-year retrospective study clearly demonstrate the superiority of the multiplex, PCR assay over routine culture in establishing the rapid and reliable laboratory diagnosis of diarrheal disease caused by commonly occurring viral and bacterial enteric pathogens.

For various reasons, some healthcare providers have been reluctant to adopt the use of the molecular PCR assay as a standard of testing for their patients. It is hoped that the results of this study demonstrate that the molecular assay offered by Laboratory Alliance provides the best diagnostic laboratory test for establishing the infectious cause of a patient's diarrhea, and that the molecular assay will result in improved patient care and management.