Evaluation of Nanosphere Verigene RT-PCR and Microarray Assay Versus Culture in the Detection of Enteric Pathogens

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Introduction

With gastroenteritis as the second leading cause of morbidity and mortality worldwide (Guerrant et al. 2001), it is imperative to have a laboratory method which is highly rapid, sensitive, and cost-effective to aid in the diagnosis and treatment of affected patients. This validation study seeks to evaluate the Nanosphere Verigene real-time PCR and microarray assay as a potential replacement for the current culture-based methods of testing stool samples for enteric pathogens in the Bridgeport Hospital microbiology lab.

Objectives

- To perform a validation of the sensitivity of the Verigene assay in comparison to current culture methods for enteric pathogens in stool samples.
- To perform a correlation study between the two sample processor modules of the instrument to ensure assay accuracy.
- To perform a CAP-required 20 day validation of the internal controls for the Verigene assay against commercially-prepared external controls
- To prepare a cost analysis for insurance reimbursement of the Verigene assay versus culture based methods for detecting enteric pathogens in stool samples.

Molecular Diagnostics versus Culture

- Higher sensitivity to detect pathogens at lower concentrations
- Reportable results obtained within 2.5 hours of receiving specimen.
- Tests for multiple pathogen targets simultaneously.
- Some species unable to be detected due to being fastidious and unculturable.
- Results typically take 48-72 hours to obtain.
- Multiple successive tests necessary to identify pathogen.

Verigene Enteric Pathogens Target	Percent Agreement, 95% CI	
	Positive	Negative
Campylobacter group	97.0	99.0
Salmonella spp.	97.3	99.5
Shigella spp.	98.4	99.0
Vibrio group	91.5	99.9
Yersinia enterocolitica	100	100
Shiga toxin 1	100	99.6
Shiga toxin 2	97.3	99.8
Norovirus G1 and G2	94.8	99.7
Rotavirus A	96.3	99.9

Figure 1. Comparison of Verigene EP assay to culture and enzyme immunoassay reference methods. Adapted from the Nanosphere Verigene EP Performance Overview (2014).

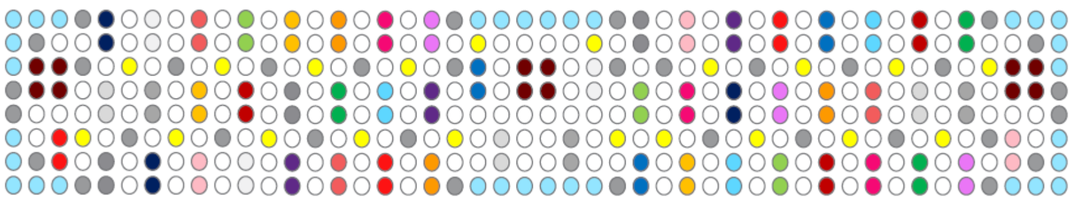

Figure 2. Verigene microarray design for detection of multiple enteric pathogens from a single stool sample (Nanosphere, 2014).

Figure 3. Verigene Processor SP drawer assembly. Pictured from top to bottom is the test cartridge, amplification tray, tip holder assembly, and extraction tray.

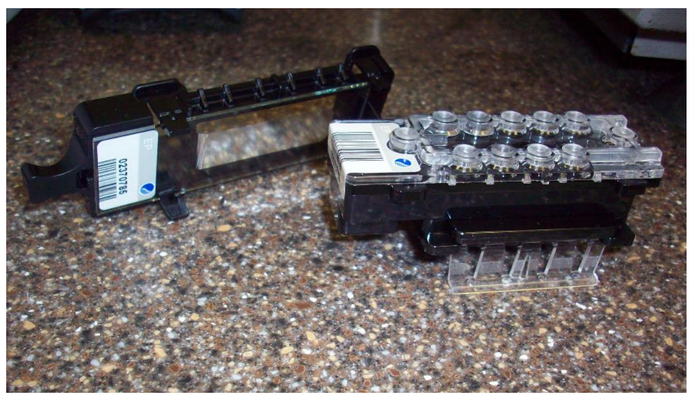

Figure 4. The Nanosphere Verigene test cartridge (top) contains the substrate holder (bottom left) and reagent pack (bottom right). After completion of the automated extraction, amplification, and hybridization procedure, the substrate holder is separated from the reagent pack and interpreted on the Verigene reader.

References

Guerrant, Richard L., et al. "Practice guidelines for the management of infectious diarrhea." *Clinical infectious diseases* 32.3 (2001): 331-351.

Nanosphere, Inc. *Verigene Enteric Pathogens Customer Training Presentation*. Northbrook, 2014.

Nanosphere, Inc. *Verigene Enteric Pathogens Nucleic Acid Test Package Insert*. Northbrook, 2014.