

PLB46C

Paper Poster Session

Late breaker session: Other

Development of a semi-quantitative, real-time PCR-based diagnostic test for bacterial vaginosis

Jami Elliott¹, Doug Rains^{*1}

¹*Quantigen Genomics, Fishers, United States*

Background: Bacterial vaginosis (BV) is a common syndrome in women, whereby typically dominant *Lactobacillus* species are overtaken by anaerobic commensal bacteria. Signs and symptoms, when present, typically overlap with those for other, unrelated infections. As a result, diagnoses based strictly on presentation can prove challenging for even experienced practitioners. Several independent groups have attempted to develop clinically accurate qPCR-based tests for BV. The most successful of these groups have employed large patient training sets to formulate PCR-based interpretive algorithms, based on the relative concentrations of both *Lactobacillus* and BV-associated bacterial species in these same patients. Unfortunately, many of these algorithms employ a normalization scheme that is highly dependent on sample collection; specifically, they calculate “copies of each bacteria/uL of fluid,” a ratio that can vary wildly from collection to collection. Quantigen Laboratory, in partnership with Thermo-Fisher, has developed a novel real-time PCR diagnostic test for BV using Thermo’s OpenArray™ Real-Time PCR System that seeks to overcome this limitation. Quantigen’s BV test measures relative quantities of each BV-related bacteria by normalizing to total bacterial load, as measured by a broad-range 16s TaqMan® assay. Quantigen here demonstrates that its testing panel and associated interpretive algorithm correlate highly to BV status in 400 patients, as independently determined by a combination of Amsel and Nugent scoring. In addition, we show that our test produces consistent results in multiple swabs from the same patient, regardless of inevitable inconsistencies in sample collection. We show that the OpenArray™ system allows for the simultaneous detection of microorganisms that can produce similar symptoms to BV (e.g., *Candida*), as well as co-infections (e.g., all common STDs) that would otherwise be missed by traditional testing methodologies. Finally, Quantigen demonstrates how the OpenArray® system permits the analysis of dozens to hundreds of samples simultaneously (depending upon how many targets and replicates the end users chooses to employ), making it a choice worth considering for medium- to high-throughput testing laboratories.

Material/methods: Please copy and paste the corresponding text here

Results: Please copy and paste the corresponding text here

Conclusions: Please copy and paste the corresponding text here