The Alinity m STI assay is designed for the Alinity System. For CT, NG, TV, and MG, the assay detects an endogenous human DNA sequence and an exogenous internal control as validity controls for sample adequacy, extraction, and amplification efficiency.

Results Performance characteristics of the Alinity m STI assay were evaluated in a clinical study. Endocervical swabs, vaginal swabs, gynecological specimens in PreservCyt, and urine were collected from 398 females. Urine was collected from 411 males. For each subject, the Alinity specimen type was compared to a matched specimen tested with CE marked assays for CT, NG, TV, and MG. For all analytes, the overall positive percent agreement ranged from 91.4% to 98.2% and the overall negative percent agreement ranged from 99.7% to 100%.

Conclusion The Alinity m STI assay is a sensitive and specific assay for the detection and differentiation of CT, NG, TV, and MG on a state-of-the-art instrument.

Disclosure No significant relationships.

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Background Bacterial vaginosis is the most common vaginal condition found in women of reproductive age. The lack of published data on the detection of BV-associated pathogens from urine, a non-invasive sample, lends novelty to the present study. This study aimed to detect and quantify Gardnerella vaginalis, Prevotella bivia, Atopobium vaginale and Lactobacillus crispatus from urine, as an alternative non-invasive method to vaginal swabs from pregnant women using droplet digital PCR (ddPCR).

Methods A total of n=100 DNA samples (50 paired urine and swabs) were tested. The samples were stratified as BV negative and positive using the BD MAX Vaginal panel assay (Becton Dickinson). Total DNA was extracted from urine and swabs using the PureLink Microbiome Kit (ThermoFisher Scientific). Droplet digital PCR was used to determine the absolute quantification of the pathogens using commercially available primer and probe sets. Differences in bacterial load between urine and swab samples were evaluated using Spearman’s correlation.

Results In BV positive women, the average copies of Gardnerella quantified was 241598 and 441655 copies/μl in the urine and swab, respectively. Prevotella bivia had a mean of 3459 and 6005 copies/μl. Atopobium vaginale was present at a mean of 51055 and 38454 copies/μl in urine and swab samples, respectively. The Lactobacillus species was present in the urine at a mean level of 1057 copies/μl DNA and 241385 copies/μl in swabs within BV negative women. A positive correlation between urine and swab samples for all the above mentioned microorganisms was observed (p<0.0001).

Conclusion We observed that urine has the potential to serve as an alternative sample collection method to detect BV-associated bacteria. The data obtained from this pilot study can be used as preliminary data to develop larger studies on this technology. Our future research direction will be to develop ddPCR using urine as a diagnostic test for BV.

Disclosure No significant relationships.