undiagnosed people. This paper presents the Brazilian strategy for HIVST distribution in the public health system from January 2019.

Methods Throughout 2018 we analyzed guidelines, studies and policies on HIVST worldwide, conducted a two-month international cooperation with France to learn from country's experience, participated and presented in 2 HIVST international Webex led by WHO and PAHO and, in addition to the results of HIVST projects conducted in Brazil since 2015, held regular stakeholders committee meetings and defined HIVST distribution strategies.

Results The strategy consists of actions that allow access to people that are not reached by health services or that should be tested more frequently, taking the test to the sites of sociability of the key populations and using secondary distribution among peers and sexual partners of people at increased risk. The strategies are: to sexual partnerships or peers of PrEP users; at events and places of sociability of key populations by health teams and NGOs; to sexual partners of prisoners and performance of assisted testing and secondary distribution in health services. The MoH developed strategies for communication, user support, referral to diagnostic confirmation and follow-up of PLHIV, as well as strategies for monitoring the distribution and use of tests through a post-test questionnaire. Brazilian MoH launched a dedicated HIVST website, including a FAQ session, and there will be extensive training in February 2019.

Conclusion The Brazilian strategy aims to scale-up access to HIV testing. Quarterly monitoring of the strategy will be of paramount importance in measuring results, making the necessary adjustments and evaluating the expansion of the strategy.

Disclosure No significant relationships.

P058 DESIGN AND PERFORMANCE OF THE ALINITY M STI ASSAY FOR THE DETECTION OF CT, NG, TV, AND MG

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Background The Alinity m STI assay is an *in vitro* assay for the qualitative detection of nucleic acids from *Chlamydia trachomatis* (CT), *Neisseria gonorrhoeae* (NG), *Trichomonas vaginalis*, and *Mycoplasma genitalium* (MG) for use on the automated Alinity m System. For CT, NG, and TV, the assay may be used to test endocervical swabs, clinician-collected and self-collected vaginal swabs, gynecological specimens in PreservCyt, female urine, and male urine from symptomatic and asymptomatic individuals. For MG, the assay may be used to test endocervical swabs from symptomatic and asymptomatic individuals.

Methods The Alinity m STI assay is designed for the Alinity m System, a fully automated continuous access analyzer that utilizes magnetic microparticle sample preparation chemistry, unit-dose lyophilized amplification reagents, and Readiflex™ processing logistics to deliver a time-to-first-result of 115 minutes. The assay can be customized to report any combination of CT, NG, TV, or MG from a single test to allow flexibility in the management of laboratory testing. In addition to 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.

P059 QUANTITATIVE DETECTION OF BACTERIA ASSOCIATED WITH BV IN URINE VERSUS SWAB SAMPLES USING DROPLET DIGITAL PCR

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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 vaginae* 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, whilst *Atopobium vaginae* 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.