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 patients 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.

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


**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.