with a rapid test and a second test using an enzyme immunoassay (EIA) was developed (average turnaround time of 2 weeks). Given the changes in the market since 2003, we present results of a second rapid test validation to update the Guatemalan algorithm.

Methods Validation was performed in 2012–2013, evaluating a total of 10 rapid tests in two phases: 1) with serum, HIV-negative samples were obtained from blood banks, and positive samples from HIV care units; 2) with whole blood, negative samples were obtained from antenatal care services and positive samples from HIV care units. We tested 452 serum samples [244 HIV+, 208 HIV-] and 432 whole blood samples (10 HIV positive, 422 HIV negative) using two EIA (Roche ELECSYS HIV Combi and Abbott AXSYM HIV Ag/Ab Combo). Discordant results were evaluated with HIV-1 Western Blot. For fourth generation rapid tests, only antibody was evaluated. Data was analysed using OpenEpi.

Results Six HIV rapid tests were included for both phases. All tests (except Double Check Gold) reported sensitivity higher than 99% and specificity higher than 95%. Determine HIV 1/2 and HIV Ag/Ab reported the highest results for sensitivity (100%). Hexagon HIV (100%) and Accu-Tell (99.5%) reported the highest results for specificity. All rapid tests that also included HIV-2 detection, showed cross-reactivity, ranging from 37% of HIV cases for Anarapid HIV 1/2/O Tri-line to 15% for Rapid HIV 1/2/O Tri-Line.

Conclusion Our results show that Determine HIV½ and HIV Ag/Ab should be recommended as a screening test while Hexagon HIV and Accu-Tell should be recommended as second test. Rapid test validation provides valuable information for on-site confirmation of reactive results improving diagnosis turnaround time.

Disclosure of interest statement We declare that we have no conflicts of interest.

P17 - HIV testing, treatment and care

P17.01 PERFORMANCE EVALUATION OF THE GENEXPERT HIV-1 QUANT ASSAY FOR DETECTION OF HIV-1 IN PLASMA

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Introduction The HIV-1 Quant Assay performed on the GeneXpert® Instrument Systems, is designed for the rapid quantitation of HIV-1 in human plasma with an analytical range of 40 to 10,000,000 copies/mL for HIV-1 Group M subtypes A, C, D, AE, F, G, H, AB, AG, J, K and Groups N and O. Testing is performed in a single-use disposable GeneXpert cartridges that hold the real-time reverse transcriptase polymerase chain reaction (RT-PCR) reagents and host the RT-PCR processes. This study assessed the performance of the system in routine plasma.

Methods To date, a total of 130 plasma samples have been tested over the analytical range and compared to a benchmark real time PCR system. Seventy four samples (56.9%) were of a known subtype comprising of subtype B (37.6%), AE (7.7%), C (4.6%) AG (1.5%) and mixed (4.6%). Additional samples consisting of an external quality control samples run over multiple days, and samples with HIV-1 RNA not detected or below the lower limit of were also tested to assess performance.

Results Overall the HIV-1 Quant Assay performed on the GeneXpert® Instrument Systems correlated with the routine analytical platform (r2 = 0.9333). Samples ranged undetectable (16, 8.8%), below the benchmark test lower limit of detection (<20 cpy/ml) (10, 7.9%), low range (20–5,000) (43, 33.1%), medium (5,000–50,000) (24, 18.5%) and high range (>50,000 cpy/ml) (29, 22.3%). Thirteen samples (10%) were invalid as a result of insufficient sample. Samples in the lower analytical range <1,000 cpy/ml showed little variance when compared with the Roche (CAP/CTM) assay using Bland-Altman correlation analysis. Reproducibility was assessed in the high, medium and low range within 1–2SD of mean. Sixteen replicates of a commercial external control showed very good reproducibility.

Conclusion The HIV-1 Quant Assay performed on the GeneXpert® Instrument Systems correlated with a commonly used HIV RNA test in plasma and offered significant workflow advantages. The system has a small footprint and requires no further consumables other that the single-use test cartridges. Further studies are planned to fully assess the assay performance.

Disclosure of interest statement No conflict of interest to declare.

P17.02 ORAQUICK® IN-HOME HIV TEST KIT IN PERU: AVAILABILITY AND ACCEPTABILITY AMONG MEN WHO HAVE SEX WITH MEN AND TRANSGENDER WOMEN

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Background In Peru an estimated 70% of people who are HIV positive do not know their status. Knowing one's HIV status is critical in HIV prevention. Oraquick® in-home HIV test is the first rapid HIV self-test U. S FDA-approved for home use. We aimed to assess its availability and the willingness of men who have sex with men (MSM) and transgender women (TW) to use it in Peru.

Methods Four Pharmacy chains in Peru were surveyed to ascertain commercial availability of the Oraquick® in-home HIV test kits. High-risk MSM and TW who attended either of two STI clinics in Lima from June 2013 to May 2014 were surveyed. Data on demographics and willingness to use Oraquick® IN HOME HIV TEST kit were collected using an interviewer administered computer-based questionnaire.

Results The Oraquick® Rapid HIV-1/2 test kit was available for purchase for home use by 4 (100%) pharmacy chains, 3 in Lima and one in northern Peru. The average test kit cost was 54 soles (18 USD); kits were available to clients 18 years or older for over-the-counter purchase. Of the 137 interviewed survey participants, 85% (n = 117) reported they would use a rapid home HIV self-test at least twice yearly. Respondents reported willingness to pay up to 21 soles (approximately 7 USD) for the test and in the event of positive results, to do the confirmatory blood test in a clinic. Also, 78% (n = 117) of participants reported being comfortable getting an HIV self-test kit by mail or for home use from a clinic.

Conclusion Our findings show the potential utility for home HIV self-testing to enhance HIV serostatus awareness in Peru.