BACKGROUND: Self-testing for HIV (HIVST), where an individual performs, reads and interprets their own HIV test, offers a simple and private option for people wanting to screen themselves for HIV. HIVST is highly acceptable, increases coverage and frequency of HIV testing, and reaches the time, tests, men, and adolescents. The OraQuick® HIV self-test is an oral fluid test (OFT) available for purchase in two versions: OraQuick In-Home HIV Test (FDA approved), and OraQuick Advance Rapid HIV-1/2 Antibody Test with a double foil packaging containing an illustrated insert providing HIVST instructions for use (IFU). Previous diagnostic evaluation studies have compared OraQuick Advance HIVST with a reference standard of professionally-administered oral- and rapid finger-prick rapid-diagnostics tests (RDTs), used in national algorithms. These have shown some loss of performance, mainly relating to a high frequency of user errors for HIVST, but with sensitivity and specificity remaining within acceptable performance in most populations. As with all RDTs, OraQuick Advance has an inherently limited clinical validity, especially early in the course of HIV infection.

Here we report the clinical performance of OraQuick Advance HIVST, tested in a large cohort of interested users in Zambia using both laboratory and RDT reference standards. After pilot testing the OFT with video recording and cognitive interviewing (See Foster MOPED1178), all participants in the study received the manufacturers IFU and a standardized demonstration of the processes involved in self-testing.

METHODS: The study was conducted in an urban and a rural area in Lusaka, Zambia. Both communities were mapped and divided into smaller zones which were randomly selected. All individuals aged 18 years and above in the randomly selected zones were visited at home and invited to participate in the study. Participants provided written informed consent for inclusion. In the urban area, in addition to the random community sampling, consecutive individuals who attended the health facility for VCT services were also invited to participate.

Researchers demonstrated how to use the OFT and provided manufacturer’s instructions for use (IFU) before participants conducted the test in privacy and recorded their results by themselves on a self-completed questionnaire (SCQ), which included symbols for those with lower literacy level. The participant placed SCQ and the used HIVST in a plastic envelope and returned it to the researcher who repeated the OFT using standard procedure and reviewed the participants test strip. A nurse, blinded to OFT result, performed rapid HIV diagnostic test (RDT) on finger-prick according to the Zambian national HIV testing algorithm. 10 ml venous blood was collected into EDTA bottle, which was sent to the laboratory within 4 hours to prepare plasma aliquots, which were used for all laboratory-based reference testing. The blood was processed in the laboratory and a corresponding amount of plasma harvested and stored at -80 degrees for testing according to the algorithm shown in fig. Demographic data and information on HIV testing prior to HIVST was collected and entered in electronic data capture devices. The study was conducted between 22 June, 2016 – 30 June 2017.

RESULTS: A total of 3,757 participants were recruited, table 1. Overall 58.4% were women and 65.0% had previously tested for HIV. Literacy levels were higher in the urban community and facility-based testers than in the rural community testers.

Is OraQuick® HIV-self-testing valid among intended users? Analysis from a clinical performance study in Lusaka, Zambia. AUTHORS: K.N. Kapaku1, M. Neumann2, K. Marki3, L. Sigande1, M. Nalubamba1, M. Taegtrigem1, E. Corbett1, C. Johnson1, K. Hattori4, B. Kool5, A. Schaub1, A. Mavingha2, A. Aylott1,2

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The flow of participants through the processes of the study is shown in figure 2. There was good agreement of participants contacted and read OFT ST and the researcher reading of the same test as well as between the participant contacted and read OFT ST and researcher conducted OFT. Table 2.

CONCLUSION: This study provides robust evidence of the sensitivity and specificity of the OraQuick® HIV self-test kit, with prior demonstration, in the hands of intended users in urban and rural Zambia, and is likely to be generalizable to other similar settings. Pilot studies of this test led being conducted in communities indicating to us that the testing procedure may also be applicable to other contexts. Further analysis of this dataset on positive OraQuick HIV ST showed that for participants with variable testing history and limited exposure to self-testing in general, additional supports in the form of demonstration will be needed, at least until widespread familiarity with the test develops, in order to obtain robust results. When compared to the standard of care in this testing, the RDT algorithm, the performance of the OFT HIVST provided a reasonable sensitivity (94.2%) and excellent specificity. However, when compared to a laboratory reference standard the sensitivity decreases, though the specificity remains constant. The oral fluid test is inherently less sensitive than the laboratory standard due to being an antibody-alone test and also possibly due to lower levels of antibody in oral fluid. This result may have important implications in the ability of the test, however, as in increasing access to testing and reaching the target of 80% of PLHIV knowing their status, lower sensitivity will need to be weighed against the increased number of individuals who will use the test to lower their HIV status.