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Protocol

Short Communication: Validation of the Asante HIV-1 Rapid Recency Assay for Detection of Recent HIV-1 Infections in Uganda

ANALYTICAL TESTING INFECTIOUS DISEASES

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Abstract

Point of care rapid recency testing for HIV-1 may be a cost-effective tool to identify recently infected individuals for incidence estimation, and focused HIV prevention through intensified contact tracing. We validated the Asante™ HIV-1 rapid recency® assay for use in Uganda. Archived specimens (serum/plasma), collected from longitudinally observed HIV-1 recently and long-term infected participants, were tested with the Asante HIV-1 rapid recency assay per manufacturer's instructions. Previously identified antiretroviral therapy (ART)-naive samples with known seroconversions within 6 months of follow-up were tested in independent laboratories: the Rakai Health Sciences Program (RHSP) and the Uganda Virus Research Institute HIV Reference Laboratory (UVRI-HRL). In addition, samples from participants who seroconverted within 6–18 months and samples from individuals with chronic HIV-1 infection of at least 18 months duration were classified into three categories: ART naive, ART exposed with suppressed viral loads, and ART exposed with detectable viremia. Of the 85 samples seroconverting in ≤6 months, 27 and 42 samples were identified as "recent" by the Asante HIV-1 rapid recency test at the RHSP laboratory and UVRI-HRL, corresponding to sensitivities of 32% and 49%, respectively. There was 72% agreement between the laboratories (Cohen's kappa = 0.481, 95% CI = 0.317–0.646, $p < .0001$). Specificity was 100% (200/200) among chronically infected ART-naive samples. The Asante HIV-1 rapid recency assay had low sensitivity for detection of recent HIV-1 infections in Uganda, with substantial interlaboratory variability due to differential interpretation of the test strip bands. Specificity was excellent. Assessment of assay performance in other settings is needed to guide decisions on test utility.