

**Abstract:**

**Topic:** New technologies for diagnosis of HIV or co-infections

**Keyword(s):** feasibility- diagnosis-

**Abstract title:**

Can single sample test devices for infant HIV handle current test volumes in Ugandan health facilities?

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**Abstract text:**

**Background:** Infant HIV diagnosis in resource-limited settings employs a centralized laboratory framework whereby dried blood spot (DBS) samples are sent from health facilities to reference laboratories for DNA PCR testing. While DBS DNA PCR testing can accommodate a high sample throughput (92 samples per run), delays in result availability increase the likelihood of infants being lost to follow-up and subsequent failure to receive critical treatment and support measures. Northwestern University researchers are currently developing single sample testing devices that will enable result availability in approximately 30 minutes. Providing a health facility with one device could enable same-day result availability albeit reduced sample throughput. Assuming a 7 hour working day and a test volume threshold of 5 tests per day, we evaluate whether the devices can accommodate current daily test volumes at the decentralized level in Ugandan health facilities.

**Material & Methods:** We analyzed test records from a centralized laboratory in Kampala for tests performed between September 2007 and July 2008. We calculated descriptive statistics on the daily test volume (number of tests performed) per health facility and turnaround times (TAT) between date of sample collection and laboratory result availability. We assessed whether daily test volume varied by health facility type. A Kruskal-Willis test was used to assess for a difference in median test volumes. Health facilities were classified as: national/regional referral, district, county, private and other (dispensaries, military hospitals). The data was analyzed using Statistical Analysis Software.

**Results:** We analyzed a total of 2043 test records from 74 health facilities. The health facilities comprised 6(8%) national and regional referral hospitals, 14(19%) district hospitals, 29(39%) county hospitals, 20(27%) private hospitals and 5(7%) other. National and regional referral hospitals accounted for 29% of the test volume with tests performed between Nov 2007 and Jun 2008. District hospitals accounted for 22% (Jul 2007 \* Jun 2008), county hospitals for 19% (Sep 2007 \* Jun 2008), and private hospitals for 26% (Oct 2007 to Jul 2008) of the test volume. Overall, the health facilities had a median test volume of 1 test per day (IQR:1, 2) with a range of

1 to 14 tests per day and a median TAT of 24 days (IQR:17, 38). While the difference in median test volumes among health facilities was found to be statistically significant ( $p < 0.001$ ), this finding probably reflects a slightly higher median test volume of 2 tests per day (IQR: 1, 3) observed among national and regional referral hospitals and therefore may not be operationally significant.

**Conclusion:** Test volume analysis suggests that a single sample test device is sufficient to meet the current testing demand at the majority of clinics and potentially address the long TATs associated with centralized laboratory testing.