881. Comparison of Reproducibility of VERSANT® HIV-1 RNA 3.0 Assay (bDNA) and COBAS AMPLICOR HIV-1 Monitor® Test, version 1.5 (UltraSensitive), on Samples with Low HIV-1 Viral Load

*Session: Poster Session: HIV: Diagnostics  
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*Room: Exhibit Hall A

**Background:** Accurate assays with good reproducibility are essential for measuring low HIV-1 RNA titers in plasma specimens of HIV-infected patients. We compared the VERSANT HIV-1 RNA 3.0 Assay (bDNA; Bayer HealthCare LLC, Tarrytown, NY) and COBAS AMPLICOR HIV-1 Monitor, v 1.5 (CAM; Roche Diagnostics, Branchburg, NJ) on samples with low HIV-1 viral load.

**Methods:** Multiple replicates of a test panel consisting of 5 dilutions (ranging from 150 to 5,000 copies/mL), prepared from a HIV-1 RNA-positive specimen (ProMedDx LLC, Norton, MA), were tested by both bDNA and CAM in 5 separate assay runs to assess assay reproducibility. In addition, reproducibility and failure rates of the 2 assays were evaluated by testing replicates of 21 clinical plasma samples with HIV-1 RNA levels <5,000 copies/mL.

**Results:** While both assays yielded a titer for each replicate of the HIV-1 test panel members ranging from 500 to 5,000 copies/mL, bDNA and CAM reported a titer in 92.5% (37/40) and 55.0% (22/40), respectively, of replicates at 150 copies/mL (P<0.001, Fisher’s exact test). Inter-assay precision was similar for both assays, but CAM had greater intra-assay variability (28.4% to 40.1%) than bDNA (13.7% to 27.8%). For test panel members, total %CV ranged from 14.9% to 40.1% for bDNA and from 33.5% to 51.1% for CAM. Among the clinical samples, total %CV for bDNA and CAM was 36.6% and 58.3%, respectively. Inter- and intra-assay %CV were 17.4% and 31.7% for bDNA and 0% and 58.3% for CAM, respectively. CAM had a test failure rate of 1.9% (“Invalid QS” in 4/210 tests) during initial testing of clinical samples, whereas bDNA showed no test failures with 3 results of “<75 copies/mL”. Bland-Altman plotting of intra-assay data showed greater variability for CAM than for bDNA as shown by the narrower ±2 S.D. limits for bDNA.

**Conclusions:** bDNA achieved a significantly higher success rate for quantification of HIV-1 RNA at level of 150 copies/mL, with lower variability at HIV-1 RNA levels ranging up to 5,000 copies/mL. With lower overall variability, bDNA appears to be a more robust assay than CAM for testing low HIV-1 viral load samples.

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