NATIONAL CENTER FOR HIV, VIRAL HEPATITIS, STD, AND TB PREVENTION

OVERCOMING ACCESS BARRIERS TO VIRAL SUPPRESSION TESTING BY SELF-MICROCOLLECTED BLOOD

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BACKGROUND

- Structural, socio-behavioral barriers and public health measures, such as mandated shutdowns, can limit access to traditional care services and are major hurdles to HIV medication adherence. Rural areas can be particularly challenging.
- Current FDA-approved assays for viral suppression (VS) testing require venipuncture blood collected in a healthcare setting and may not be accessible due to stigma and economic hurdles.
- VS testing using self-collected blood could facilitate engagement and retention in care for persons with HIV (PWH).
- While self-collected dried blood spots have been extensively used, test sensitivity is limited due to the small sample size and potential DNA contamination in whole blood.
- Micro-collection devices, such as microtainers (MCT), are an option to provide a plasma sample for gold-standard testing.

METHODS

- We developed a fingerstick self-collection protocol and kit with written and video instructions using EDTA-preservative MCTs for ambient temperature shipping.
- Participants, most who were not familiar with self-fingerstick, were mailed kits, collected a MCT sample of blood, packaged, and shipped the samples within 24 hours of collection.
- Acceptable shipping times were ≤4 days at ≤35°C with a whole blood volume of ≥250 µL.
- MCT samples were processed for plasma separation for semi-quantitative testing using a 1:7 dilution protocol with a LOQ sensitivity of 210 cp/mL, 99% quantified at 350 cp/mL.
- 28 participants had a same-day venipuncture specimen collected at a local clinic for comparison with traditional viral load (VL) testing.

RESULTS

- Of 90 participants who made a collection, 81% shipped a suitable sample.
- Seventy-two persons who reported to be on PrEP or who were virally suppressed had no viral target detected in the MCT samples.
- The participants with a quantitated venipuncture VL ≥30 copies also had RNA quantitated in MCT (VL range 273 - 11,918 cp/mL). Results from the MCT samples were within 0.31 log10 cp/mL of the VL provided by venipuncture.

CONCLUSIONS

- Untrained individuals were able to self-collect blood and ship a sufficient volume using MCTs.
- In a separate analysis, MCT self-collections were also found to support antiretroviral drug level testing.
- Offering remote VS testing to persons willing to self-collect could overcome recognized socio-economic and infrastructure barriers to clinic access, support HIV telemedicine, and empower PWH to remain in care.



Self-collected specimen process

MCT collection and shipping materials



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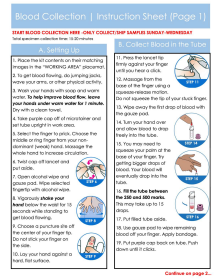
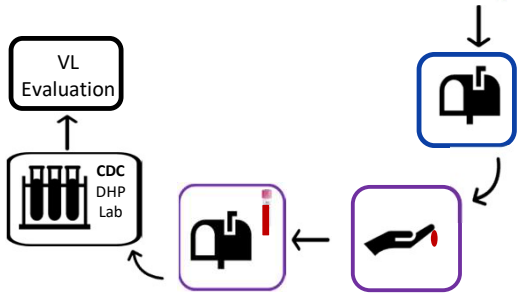
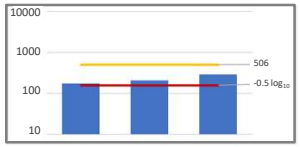




Low-copy HIV-1 assessment (cp/mL) after 5 days at 35°C: Initial concentration 506 cp/mL



In triplicate

Concordance of venipuncture and self-collected, mailed MCT viral loads

Venipuncture undiluted (cp/mL)	MCT 1:7 (cp/mL*7)
605	385
1554	1939
608	273
<30	TND
TND	TND
<30	TND
TND	TND

REFERENCES

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