#0967

Evaluation of Viral Suppression on Rapid HIV Test Reactivity among MSM, NHBS, 2017

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Background

- National HIV Behavioral Surveillance (NHBS) monitors HIV infection and HIV-associated behaviors among key populations at highest risk of acquiring HIV.
- Men who have sex with men (MSM) are recruited every three years using venue-based, time-space sampling.
- Participants are offered HIV counseling and voluntary, anonymous HIV testing via finger-stick or venous whole blood.
- Participants on antiretroviral therapy (ART) may experience seroreversion due to sustained viral suppression (VS).
- The impact of sustained VS on the ability of rapid tests (RTs) to identify HIV infection has not extensively been reported.

Objective

- To evaluate and assess the impact of ART and VS on RT performance among MSM who self-reported being HIV-positive (SRP) in 23 U.S. cities.

Methods and Testing

- An anonymous standardized questionnaire was used to collect information on MSM who reported having previously received a positive HIV test result and includes questions about their receipt of HIV care and if they are currently using ART.
- Participants were offered anonymous HIV testing on finger-stick or venous whole blood using RT chosen by project areas (1).
- Dried blood spot (DBS) cards were collected after rapid testing and stored at ambient temperature with desiccants and humidity indicator cards for up to a week before being sent to CDC and/or local lab (1).
- All DBS were tested with a modified protocol for Abbott RealTime m2000 HIV-1 Viral load (VL) kit (2) to measure VL.
- DBS from SRP participants with discrepant RT results (non-reactive, RT-NR) were tested locally using either HIV-1 Western Blot (WB) only or Abbott ARCHITECT HIV Ag/Ab Combo Assay (ARCHITECT) and Geenius HIV-1/2 supplemental assay (Geenius), or at CDC lab using modified Bio-Rad GS HIV Combo Ag/Ab EIA (BRC) and Geenius (3) on BRC reactive samples.

Analysis



- The analysis was limited to participants who self-reported HIV-positive (SRP) and had at least one RT with a valid test result.
- These participants were considered HIV-positive for the purpose of this study.

Results

Figure 1. False-negative rate among SRP

- **Overall, false-negative rate was 2.3% (45/1936)**

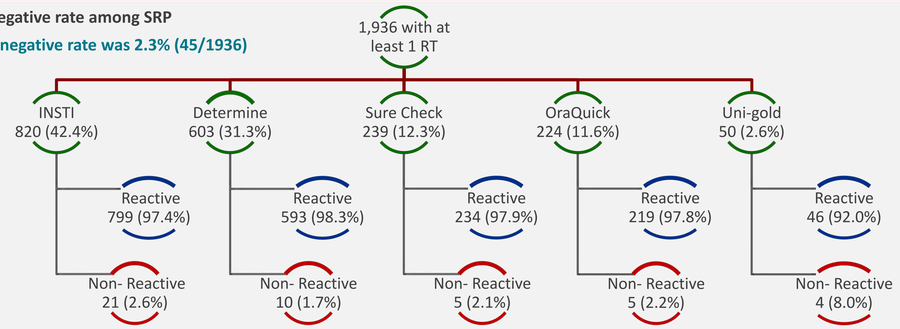


Table 1. Reactivity of FDA-approved rapid HIV tests using whole blood among MSM by viral load results and self-reported ART use

Of 1,936 eligible participants with RT results, 1673 had VL and ARV results and data on current ART use while 255 were missing VL results either because the participants did not consent to storage of specimens or they consented to storage but had no specimen sent, there was not enough remnant specimen for laboratory testing, or there were errors when specimens were tested. Eight participants were missing data on current ART use.

		INSTI (N=820)		Determine (N=603)		SureCheck (N=239)		OraQuick (N=224)		Uni-Gold (N=50)		Total (N=1936)	
	N	**R**	**NR**	**R**	**NR**	**R**	**NR**	**R**	**NR**	**R**	**NR**	**R**	**NR**
Overall	1936	799	21	593	10	234	5	219	5	46	4	1891	45
By VL and ART use	1673											**1655**	**18**
VL undetectable	1172	497	7	351	2	153	3	121	4	33	1	**1155**	**17**
Currently on ART	1128	479	7	340	2	147	2	117	4	29	1	**1112**	**16**
VL detectable <2.92log$_{10}$(cop/mL)	156	79	0	40	0	10	0	26	0	1	0	**156**	**0**
Currently on ART	151	77	0	38	0	10	0	25	0	1	0	**151**	**0**
VL detectable ≥2.92log$_{10}$(cop/mL)	345	129	1	115	0	62	0	32	0	6	0	**344**	**1**
Currently on ART	284	104	0	98	0	50	0	27	0	5	0	**284**	**0**

- **Of the 1655 RT-R participants with VL and ART use results, 1311 (79.2%) had undetectable VL or detected <2.92 log10 (cop/mL) of whom 1263 (96.3%) reported ART use.**
- **Of the 18 RT-NR participants with VL and ART use results, 17 (94.4%) had undetectable VL of whom 16 (94.1%) reported being on ART.**

Table 2. Diagnostic and supplemental test results for SRP MSM with non-reactive RTs tested at local laboratories

Total Observations	Rapid Test	Specimen submitted	Screening Ag/Ab assay	Ag/Ab Result	Supplemental antibody test	Result	ARV-Yes	ARV-No	Final Interpretation
2	INSTI	Plasma	ARCHITECT	Reactive	Geenius	HIV-1 Positive	2	0	HIV-1 Positive^
2	Sure Check	DBS	Not done	-	WB	HIV-1 Positive	1	1	HIV-1 Positive*
1	Sure Check	DBS	Not done	-	WB	Indeterminate	1	0	Not confirmed*

*VL undetectable; ^remaining specimens were not tested for VL

Table 3. Diagnostic and supplemental test results for SRP MSM with non-reactive RTs tested at CDC using assays modified for DBS use

Total Observations	Rapid Test	BRC Ag/Ab Result	Geenius HIV-1/2 antibody assay result	Total DBS VL undetectable, ARV-Yes	Total DBS VL detectable, ARV-No	Final Interpretation
1	OraQuick	Reactive	HIV-1 Indeterminate	1	0	Not confirmed
1	Uni-Gold	Reactive	HIV-1 Indeterminate	1	0	Not confirmed
2	Determine	Non-Reactive	Not done	2	0	Not confirmed**
1	INSTI	Non-Reactive	Not done	1	0	Not confirmed
7	INSTI	Reactive	HIV-1 Positive	6	1	HIV-1 Positive
3	OraQuick	Reactive	HIV-1 Positive	3	0	HIV-1 Positive

** One participant reported date of diagnosis as 6 months prior to the time of interview.

Abbreviations: INSTI: BioLytical INSTI HIV -1/ HIV-2 Antibody Test, Determine: Alere Determine HIV-1/2 Ag/Ab Combo Rapid Test, SureCheck: Chembio SureCheck HIV-1/2 Assay, OQ: OraQuick ADVANCE Rapid HIV-1/2 Antibody Test, Unigold: Trinity Biotech Uni-gold Recombigen HIV-1/2, R: Rapid Test Reactive, NR: Rapid Test Nonreactive, VL: viral load, ART: antiretroviral therapy.

Results Summary

- One participant with RT-NR result had detectable VL (3.58 log$_{10}$(cop/mL)) and did not report current ART use.
- Of 45 participants with RT-NR results, 20 provided specimens for confirmatory testing either locally or at the CDC laboratory; of which 14 of 20 were confirmed HIV-1 positive.
- Six of twenty participants with RT-NR results were not confirmed HIV-1 positive using laboratory based testing.
  - Five participants reported time since diagnosis which ranged from 2 to 13 years, thus seroreversion may have occurred.
  - The remaining participant reported time since diagnosis as 6 months prior to the interview, thus early treatment in infection may have delayed seroconversion.

Conclusions

- False-negative HIV RTs results occurred among SRP but were rare (~2%) and consistent across most RTs types.
- For small number of participants, VS was associated with non-reactivity possibly due to seroreversion. However, the percent of participants virally suppressed on ART was similar among those with RT-R and RT-NR results.
- Use of RTs to assess HIV infection status in the presence of current ARV use for HIV treatment or prevention may result in misclassification.
- Lab-based testing may be needed to verify HIV infection status with PrEP monitoring and prevalence of HIV in communities with high ARV use.

References

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Acknowledgements

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