# Oral Fluid is Inferior to Fingerstick Point-of-Care HIV Tests Among Seattle MSM

**Joanne Stekler[1,2], Aric Lane[1], Joshua O'Neal[3], Matthew R. Golden[1,2]**

[1]University of Washington, Seattle, WA, USA [2]Public Health - Seattle & King County, WA, USA [3]San Fransisco State University, Department of Sexuality Studies

Contact Information:
Joanne Stekler, MD, MPH
Box 359931, Harborview Medical Center
325 Ninth Avenue, Seattle, WA 98104
Phone: (206) 731-8312, Fax: (206) 731-5109
Email: jstekler@uw..edu

## ABSTRACT

**Objective:** The Rapid Test Study is an ongoing, real time comparison of four point-of-care (POC) HIV tests designed to determine their relative abilities to detect early HIV infection.

**Methods:** HIV-negative men who have sex with men (MSM) and transgender persons seeking HIV testing were recruited at the Public Health - Seattle & King County (PHSKC) STD Clinic, Gay City Health Project Wellness Center, and University of Washington Primary Infection Clinic (PIC). Study procedures included one POC test performed on oral fluids (OraQuick, Orasure Technologies) and two or three POC tests performed on fingerstick whole blood specimens: OraQuick (5µL), Uni-Gold Recombigen HIV Test (Uni-Gold, Trinity Biotech, 50µL), and Determine HIV-1/2 Ag/Ab Combo (Determine, Alere Inc., 50µL). Serum specimens from subjects with negative POC results were sent for EIA and pooled NAAT. McNemar's exact tests were used to compare the numbers of HIV-infected subjects detected by the different POC HIV antibody tests.

**Results:** Between February 2010 and November 2012, 2144 subjects were enrolled. Of 2127MSM seen at the STD Clinic and Wellness Center, 69 (3.2%) were newly diagnosed with HIV infection. Only 56 (81%) had reactive results on all POC tests, and 4 additional subjects had discordant results with at least one reactive and one non-reactive POC test.

Data comparing test performance were analyzed for these 69 HIV-infected subjects plus 17 HIV-infected men enrolled at the PIC. Of these 86 total subjects, 65 (76%) had concordant reactive POC test results, 4 (5%) had concordant non-reactive POC tests but a reactive 3rd generation EIA, and 7 (8%) of subjects had acute HIV infection. Ten (12%) subjects had discordant POC test results, including one subject with a reactive Determine p24 antigen and an HIV RNA level of 5.7 million copies/mL. OraQuick performed on oral fluids identified fewer men with discordant results compared to both OraQuick performed on fingerstick (0 versus 7, p=.02) and Uni-Gold (1 versus 8, p=.04).

**Conclusion:** Our data show that oral fluid POC testing is inferior to fingerstick and should be the specimen collection method of choice only in rare circumstances. These data also reinforce published data from the PHSKC Pooled HIV NAAT Program that have shown that rapid HIV antibody tests correctly diagnose ~80% of HIV-infected MSM in Seattle. In high HIV incidence populations like ours, currently approved POC tests are inadequate and must be supplemented with pooled NAAT or 4th generation assays.

## BACKGROUND

- 2003: Public Health – Seattle & King County (PHSKC) starts pooled HIV NAAT program for MSM
- 2009: OraQuick detects ~80% of HIV-infected MSM tested
- repeat testing of frozen specimens differs from real time results
- unclear if other point-of-care tests better able to detect early infection

## OBJECTIVE

To compare four point-of-care HIV tests and determine their relative abilities to detect early HIV infection in real time.

## METHODS

**Study population**

HIV-negative MSM recruited when seeking HIV testing at:
- PHSKC STD Clinic
- Gay City Health Project Wellness Center (GC)
- University of Washington Primary Infection Clinic (PIC)

**HIV tests**

Point of care tests
- OraQuick (oral fluids, OraSure Technologies, Inc)
- OraQuick (fingerstick)
- Uni-Gold (fingerstick, Trinity Biotech)
- Determine HIV-1/2 Ag/Ab Combo (fingerstick, Alere Inc.) (This test is not currently FDA-approved/not available for sale in US)

EIA
- PHSKC: 3rd gen Genetic Systems HIV-1/HIV-2 Plus O EIA Bio-Rad
- PIC: 4th gen Abbott ARCHITECT HIV Ag/Ab Combo assay

NAAT
- PHSKC: 27-specimen master pools (3x3x3 matrix)
- Abbott RealTime HIV-1 RNA assay (lower limit detection 40 copies/mL)

## METHODS (continued)

**Data collection and statistical analyses**
- Each test performed on separate fingersticks
- First 1000 participants offered self-administered survey, including:

  "On a scale from 1-5, which HIV test(s) would you prefer, based solely on the specimen collection method(s)?"

  "Among all of the tests that have been done today, on a scale from 1-5, which HIV test(s) do you trust most to correctly tell you whether you are truly HIV-positive or HIV-negative. Answer this question based on today's visit, your recent potential exposures, the test, the test window period, and specimen collection method."

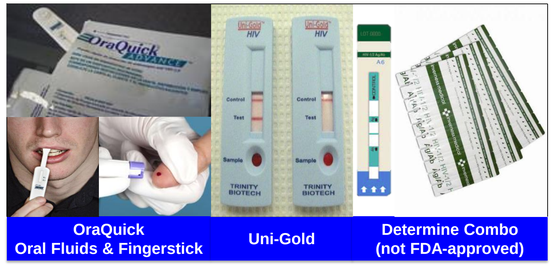
- Quarterly participation allowed
- $20 compensation
- Approved by UW Human Subject Division and all subjects gave verbal informed consent
- McNemar's exact tests used to compare numbers of cases detected

## HIV TEST RESULTS

**HIV Test Results among 2144 MSM enrolled Feb 2010 - Nov 2012**

| | STD Clinic & Gay City n=2127 | PIC n=17 | Total n=2144 |
|---|---|---|---|
| Concordant Rapid Positive Tests | 56 (81%) | 9 | 65 |
| Discordant FDA-approved Rapid Tests | 3 (4%) | 7 | 10 |
| All Rapids Negative / EIA Positive | 3 (4%) | 1 | 4 |
| Acute (EIA Neg / NAAT Pos) | 7 (10%) | 0 | 7* |
| Total HIV Positive | 69 (3.2%) | 17 | 86 |

*Includes one person with reactive p24 Ag on Determine (#4 below)




Photos obtained from the following websites:
http://www.netneon.com
http://www.vtcares.org/prevention/
http://www.cdc.gov/hiv/topics/testing/resources/factsheets
http://irise.com.ge
http://www.liu.edu/Brooklyn/Academics/Schools/SON/
http://www.pressreleasepoint.com

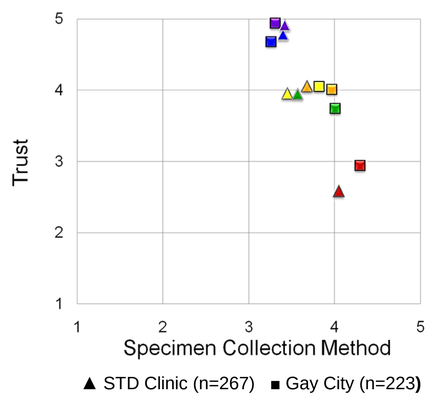
**Results of study HIV tests among 11 HIV+ MSM with discordant results**

| | OraQuick Oral Fluid | OraQuick Fingerstick | Uni-Gold | Determine | EIA or 4th gen | HIV RNA (copies/mL) |
|---|---|---|---|---|---|---|
| 1 | + | + | — | ND | + | 140,000 |
| 2 | — | + | + | ND | + | |
| 3 | — | + | + | ND | + | 128,000 |
| 4 | — | — | — | —/+ | — | 5.7 million |
| 5 | — | — | + | ND | + | 12.8 million |
| 6 | — | — | + | +/— | + | 21,000 |
| 7 | — | + | — | +/— | + | 719,000 |
| 8 | — | + | + | +/— | + | 436,000 |
| 9 | — | + | + | +/— | + | 33,000 |
| 10 | — | + | + | +/— | + | |
| 11 | — | + | + | +/— | + | 32,000 |
| | | p=0.02* | p=0.04* | | | |

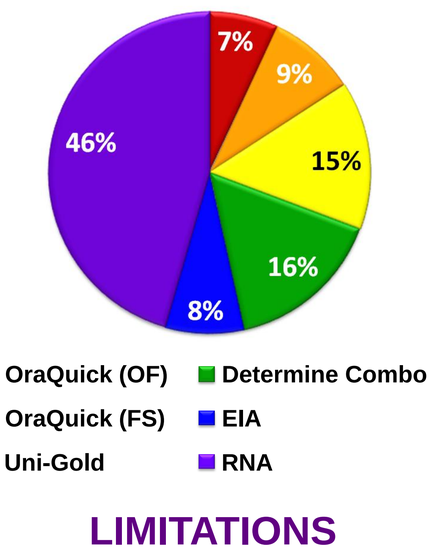
ND: not done *Compared to OraQuick performed on oral fluids

## SURVEY RESULTS

**Preference for specimen collection method and trust in tests are inversely related among Seattle MSM (n=490)**




**"Taking all factors into account, if you could get only one HIV test today, which test would you get?" (n=120)**




## LIMITATIONS

- Findings may not be generalizable to populations with lower HIV prevalence and incidence and less frequent HIV testing.
- Tests are not independently read and may overestimate sensitivity.

## CONCLUSIONS

1) Oral fluid testing, although preferred as a specimen collection method, is less trusted among tested MSM, is significantly less sensitive than fingerstick tests, and should be the test method of choice only in rare circumstances.
2) These data reinforce published data showing rapid HIV antibody tests correctly diagnose ~80% of HIV-infected MSM in Seattle.
3) This study has not yet identified a point-of-care test that is significantly better than others in detecting HIV infection.
4) In high HIV incidence populations like ours, currently approved point-of-care tests are not sufficient and must be supplemented with pooled NAAT or 4th generation assays, which are preferred.

## REFERENCES

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O'Neal JD, Golden MR, Branson BM, Stekler JD. HIV nucleic acid amplification testing versus rapid testing: it is worth the wait. Testing preferences of men who have sex with men. *J Acquir Immune Defic Syndr*. 2012 Aug 1;60(4):e117-20.

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