

HIV Testing Comparisons

Is it worth the wait?

An Insight Into MSM Testing Preferences

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Disclaimers



Discussion of:

1) Commercial products

2) Off-label and investigational use of products

Background

- 2003: Public Health – Seattle & King County starts pooled NAAT program targeted to MSM
- 2005: first misclassified case of “acute infection”
 - OraQuick (fingerstick): non-reactive
 - HIV RNA: > 1,000,000 copies
 - Vironostika: reactive
 - Western Blot: p24, p51, gp160
- Pooling algorithm changed:

OraQuick (OF or FS) → EIA → pooled NAAT

Background

PHSKC Pooled HIV NAAT Program

MSM screened by POC test (Sep 03-Dec 10), n=16,049

	# HIV-positive	Cumulative HIV-positive	Cumulative "Sensitivity"
OraQuick	314 (2.0%)	314	77%
EIA	40 (0.3%)	354	87%
NAAT	52 (0.3%)	406	100%

Rapid test comparison study:

1. To compare ability of point-of-care HIV tests to detect early HIV infection in real time.
2. To evaluate preferences of HIV-negative MSM for different HIV tests and specimen collection methods.



Methods



Eligibility



HIV Neg MSM or Transgender



Seeking HIV Testing



Not Tested in Last 3 Months

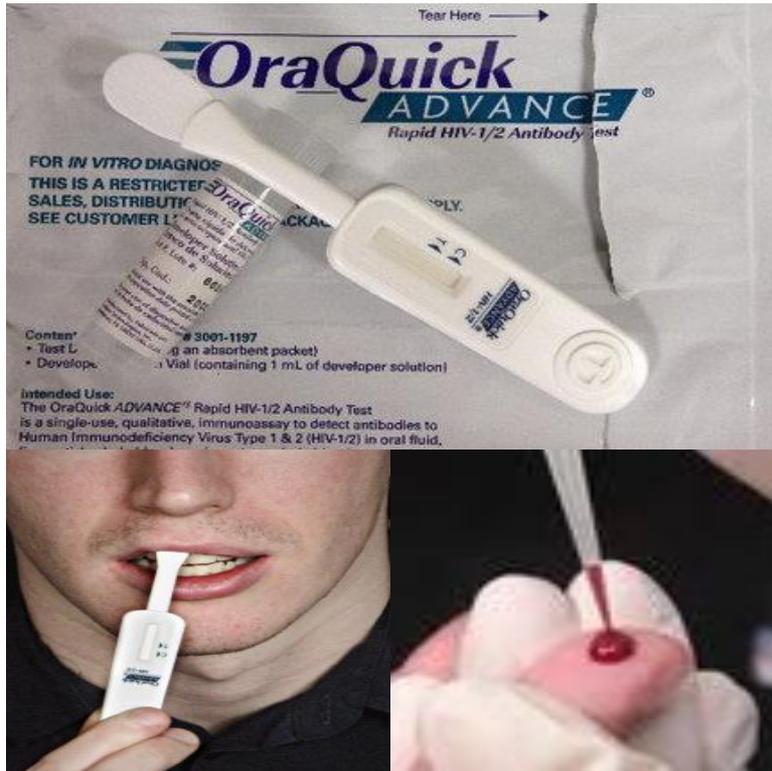


Read & Speak English

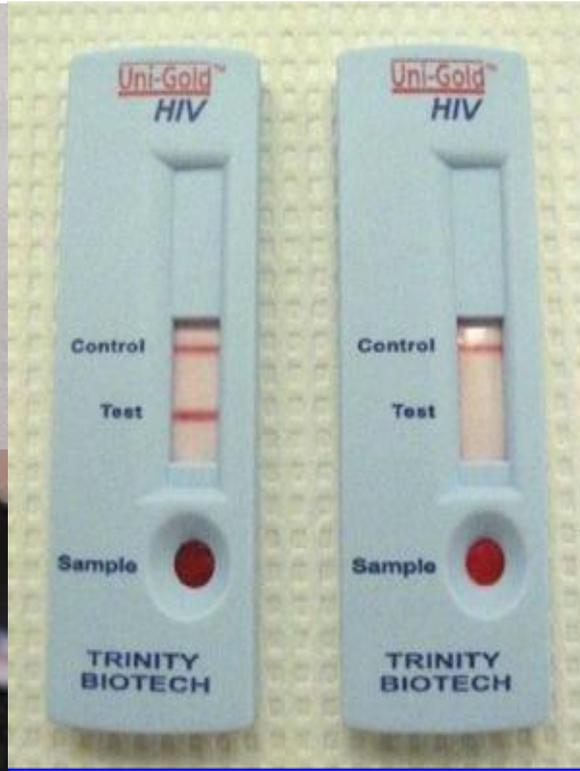
Methods: other key points

- ⦿ Each test on separate fingerstick.
- ⦿ Any positive test except oral fluid only → HIV care.
- ⦿ All subjects get EIA/NAAT → call clinic in 1-2 weeks.
- ⦿ Self-administered survey about test methods.
- ⦿ \$20 compensation.
- ⦿ Quarterly participation allowed.
- ⦿ McNemar's exact tests compare numbers of cases detected.

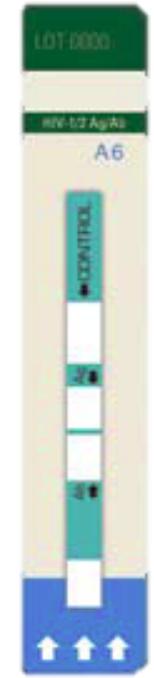
Methods



OraQuick
Oral Fluids & Fingertstick



UniGold



Determine™*
Ab + Ag Combo



* Not Available for sale in the US



ELISA & RNA

- EIA PHSKC: 3rd gen Genetic Systems HIV-1/HIV-2 Plus O EIA
PIC: 4th gen Abbott ARCHITECT HIV Ag/Ab Combo assay
- NAAT PHSKC: 27-specimen master pools (3x3x3 matrix)
Abbott RealTime HIV-1 RNA assay

Methods

Rapid
Tests

- Testing Information Provided

Survey

- Method Preference
- Test Trust
- ONE Test
- Consent
- Counseling

Rapid
Test
Results



Time



Window Period



Specimen
Collection

Results:

Feb 2010 - Nov 2012, n=2144 MSM

	STD Clinic & Gay City n=2127	PIC n=17	Total n=2144
Concordant Positive Rapid Tests	56 (81%)	9	65
Discordant FDA-approved 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

Discordant rapid test results

	OraQuick OF	OraQuick FS	Uni-Gold	Determine Ab/Ag	3 rd or 4 th gen EIA	WB results	HIV RNA (copies/mL)
1	+	+	—	ND	+	24, 31, 40, 55, 120	141,000
2	—	+	+	ND	+	24, 31, 40, 55, 160	128,000
3	—	+	+	ND	+	18, 24, 31, 40, 51, 55, 120, 160	25,000
4	—	—	—	—/+	—	negative	5.7 million
5	—	—	+	ND	+	24, 51, 55, 160	12.8 million
6	—	—	+	+/-	+	24, 40, 55, 160	21,000
7	—	+	—	+/-	+	24, 51, 55	719,000
8	—	+	+	+/-	+	24, 31, 55, 160	436,000
9	—	+	+	+/-	+	24, 55, 160	33,000
10	—	+	+	+/-	+	24, 55, 160	9000
11	—	+	+	+/-	+	18, 24, 55, 160	32,000
		p=0.02	p=0.04				

Discordant rapid test results

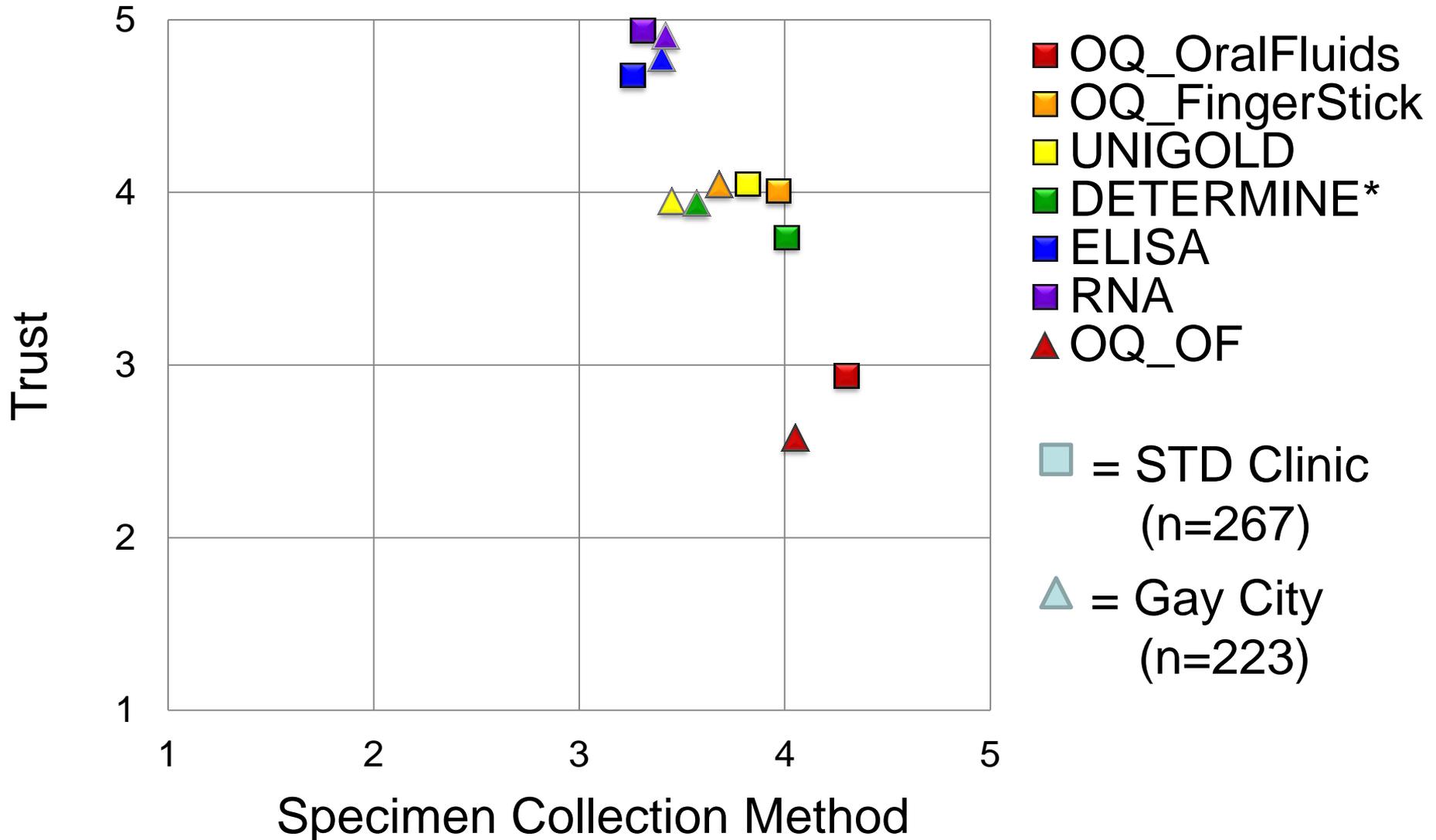
OraQuick OF v
OraQuick FS

		OQ FS	
		-	+
OQ OF	-	2071	7
	+	0	66

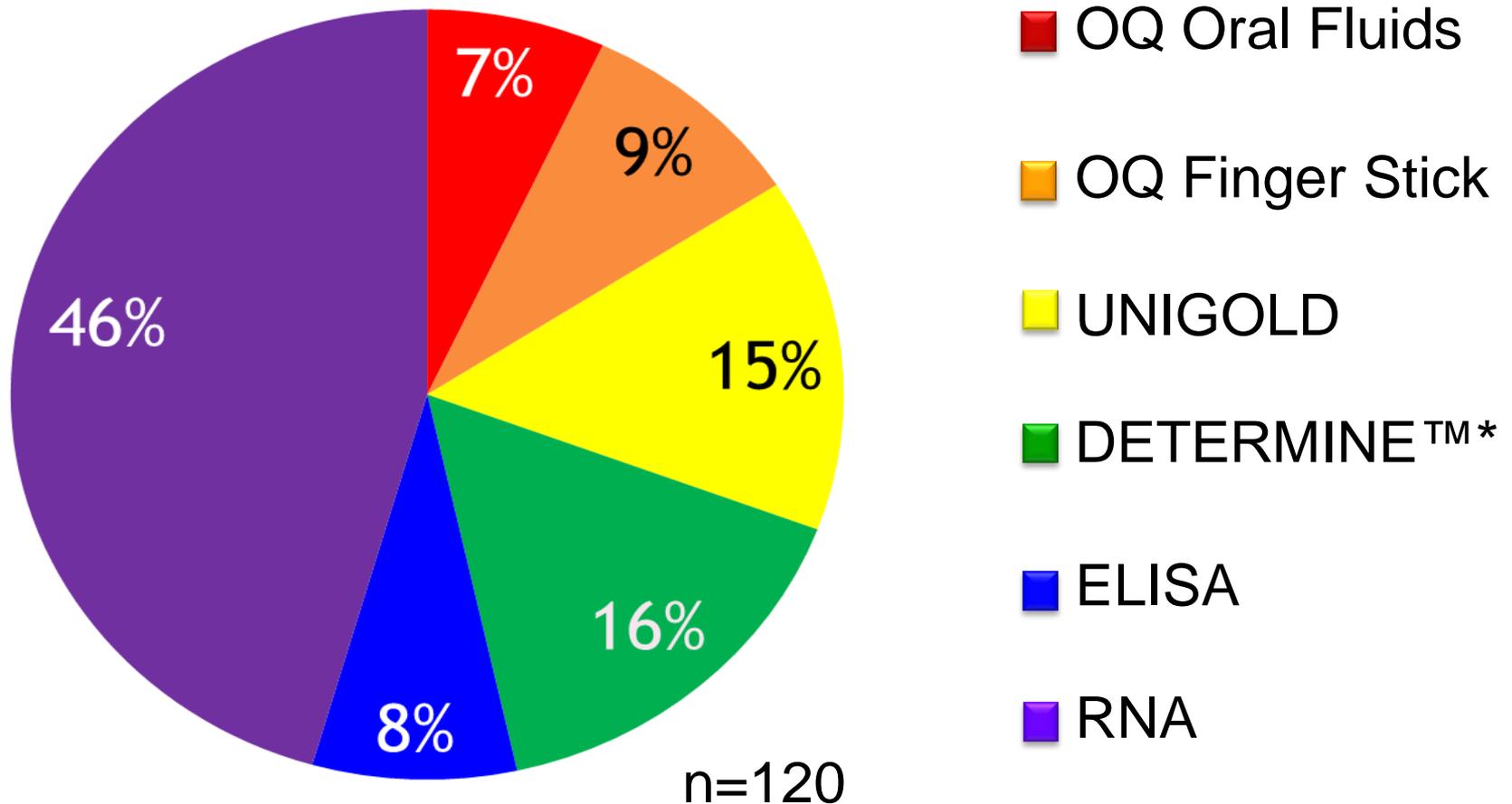
OraQuick OF v
Uni-Gold

		Uni-Gold	
		-	+
OQ OF	-	2070	8
	+	1	65

HIV Testing: Trust VS. Specimen Collection Method



If you could get only one HIV test today, which test would you get?



* Not Available for sale in the US

Summary

- MSM prefer less invasive specimen collection methods
- MSM trust lab based testing more than rapid HIV testing
- RNA testing was the most preferred single test

Discussion

- Important to provide the most preferred types of testing
- Consider integrating RNA testing into rapid testing programs
- Once FDA approved, 4th generation rapid testing may become a more preferable testing option

Limitations

- Testing information provided throughout testing session varied by location/counselor
- Survey conducted after testing
- Not all study participants surveyed (HIV+, time restrictions)
- Findings may not be generalizable to populations with:
 - lower HIV prevalence and incidence
 - less frequent HIV testing
- Tests are not independently read and may overestimate sensitivity. (If one test is +, then others closely examined)

Conclusions

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

Acknowledgments

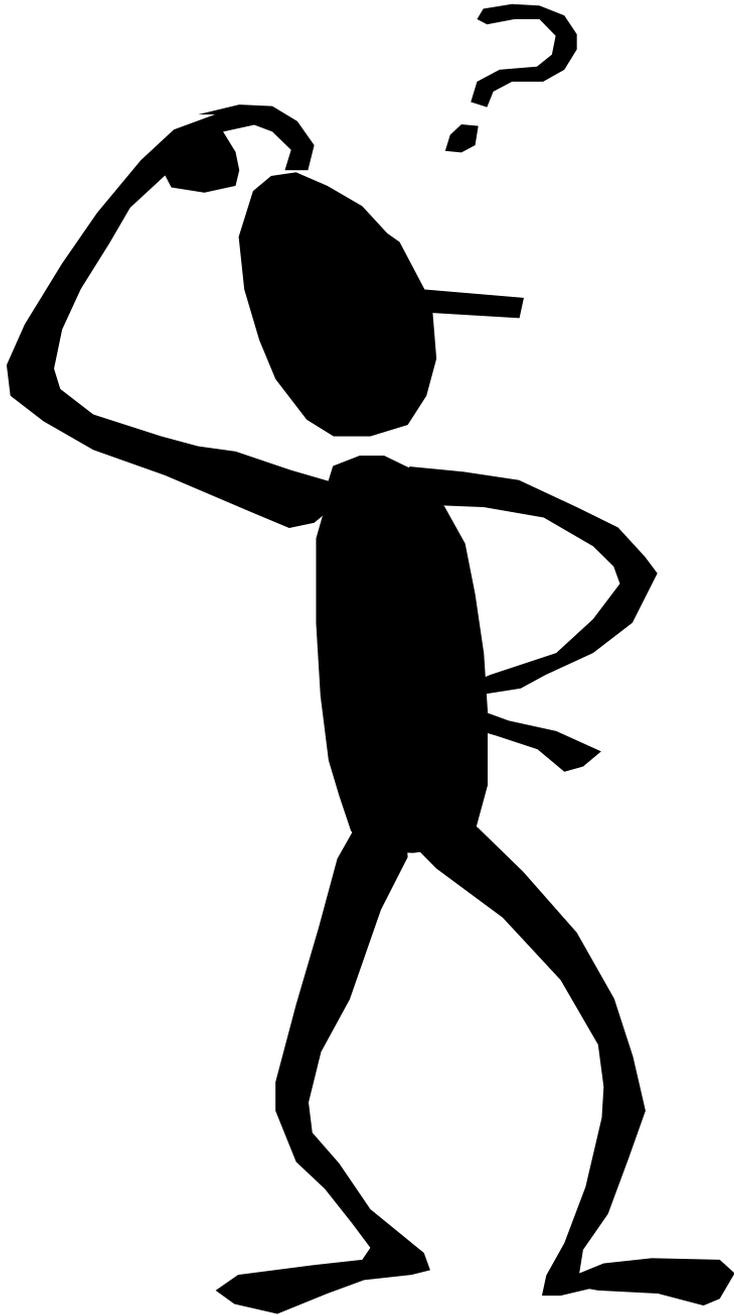
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Questions?