

Rapid HIV Testing: 2005 Update

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Awareness of Serostatus among Persons with HIV, United States

Number HIV infected	850,000 - 950,000
Number unaware of their HIV infection	180,000 - 280,000

Advancing HIV Prevention: New Strategies for a Changing Epidemic

■ Four priorities:

1. Make voluntary HIV testing a routine part of medical care
2. Implement new models for diagnosing HIV infections outside medical settings
3. Prevent new infections by working with persons diagnosed with HIV and their partners
4. Further decrease perinatal HIV transmission

MMWR April 18, 2003

Four FDA-approved Rapid HIV Tests

Sensitivity
(95% C.I.)

Specificity
(95% C.I.)

OraQuick Advance

- whole blood

99.6 (98.5 - 99.9)

100 (99.7-100)

- oral fluid

99.3 (98.4 - 99.7)

99.8 (99.6 - 99.9)

- plasma

99.6 (98.5 - 99.9)

99.9 (99.6 - 99.9)

Uni-Gold Recombigen

- whole blood

100 (99.5 - 100)

99.7 (99.0 - 100)

- serum/plasma

100 (99.5 - 100)

99.8 (99.3 - 100)

Four FDA-approved Rapid HIV Tests

	Sensitivity (95% C.I.)	Specificity (95% C.I.)
Reveal G2		
- serum	99.8 (99.2 – 100)	99.1 (98.8 – 99.4)
- plasma	99.8 (99.0 – 100)	98.6 (98.4 – 98.8)
Multispot		
- serum/plasma	100 (99.9 – 100)	99.9 (99.8 – 100)
- HIV-2	100 (99.7 – 100)	

OraQuick Advance HIV-1/2



- CLIA-waived for finger stick, whole blood, oral fluid; moderate complexity with plasma
- Store at room temperature
- Screens for HIV-1 and 2
- Results in 20 minutes



Obtain finger stick specimen...



Insert loop into vial and stir

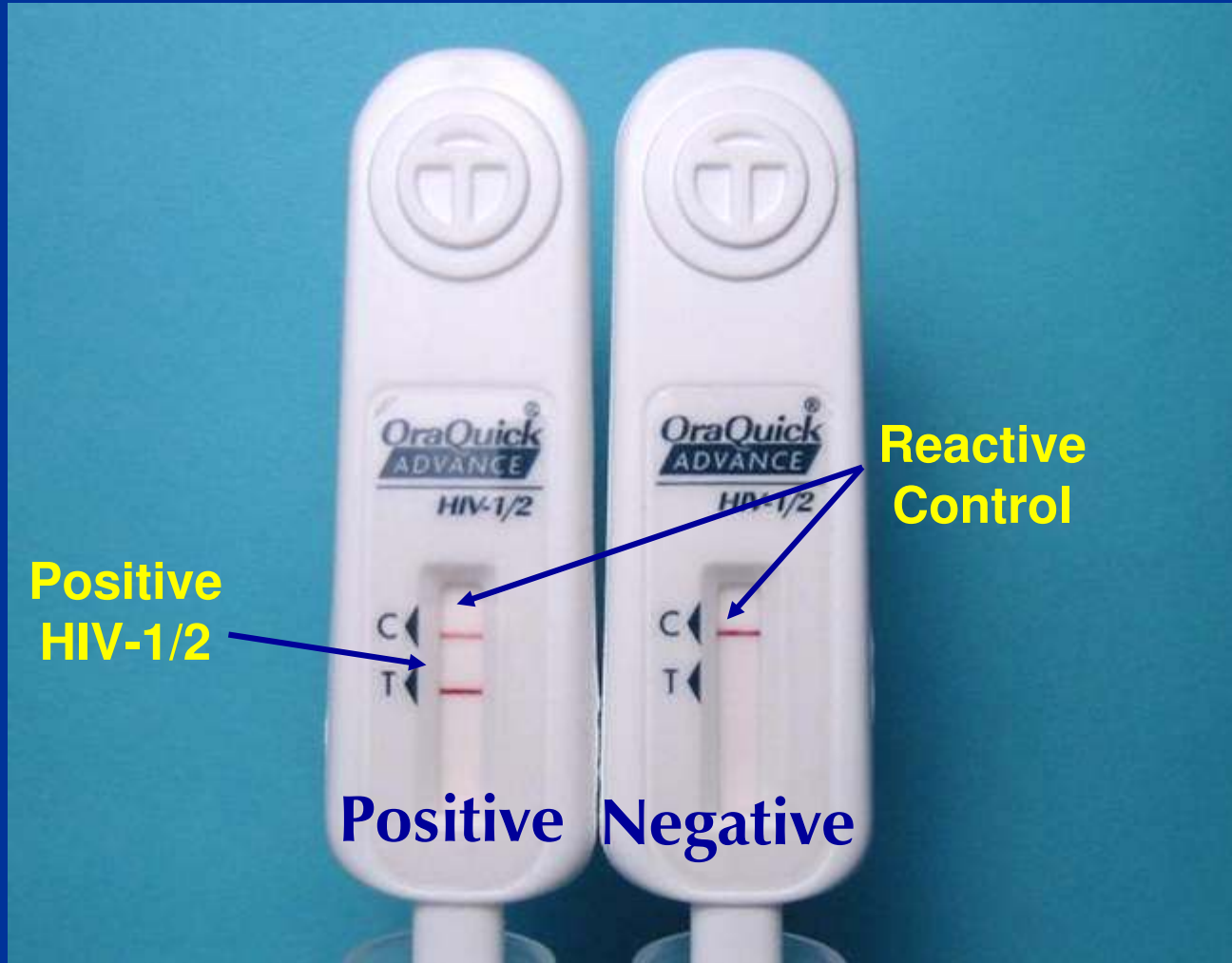


**Collect oral fluid specimens by swabbing gums
with test device.**

Gloves optional; waste not biohazardous



Insert device; test develops in 20 minutes



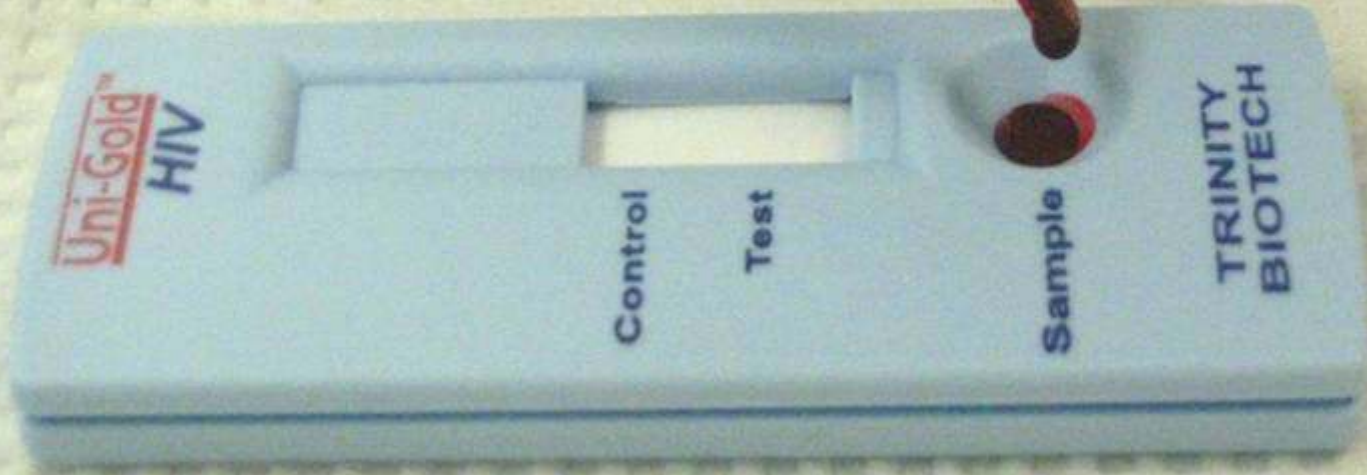
Read results in 20 – 40 minutes

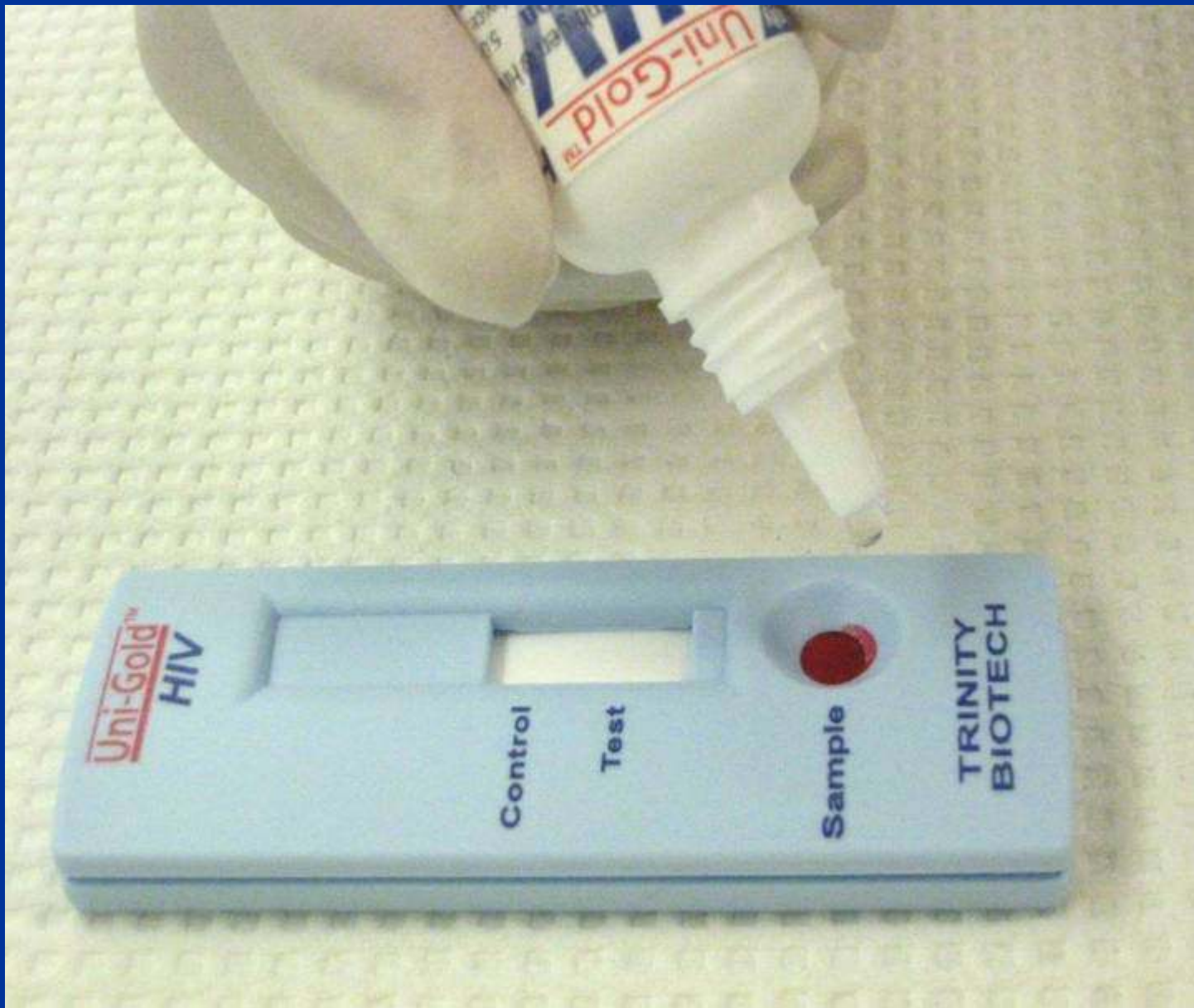
Uni-Gold Recombigen



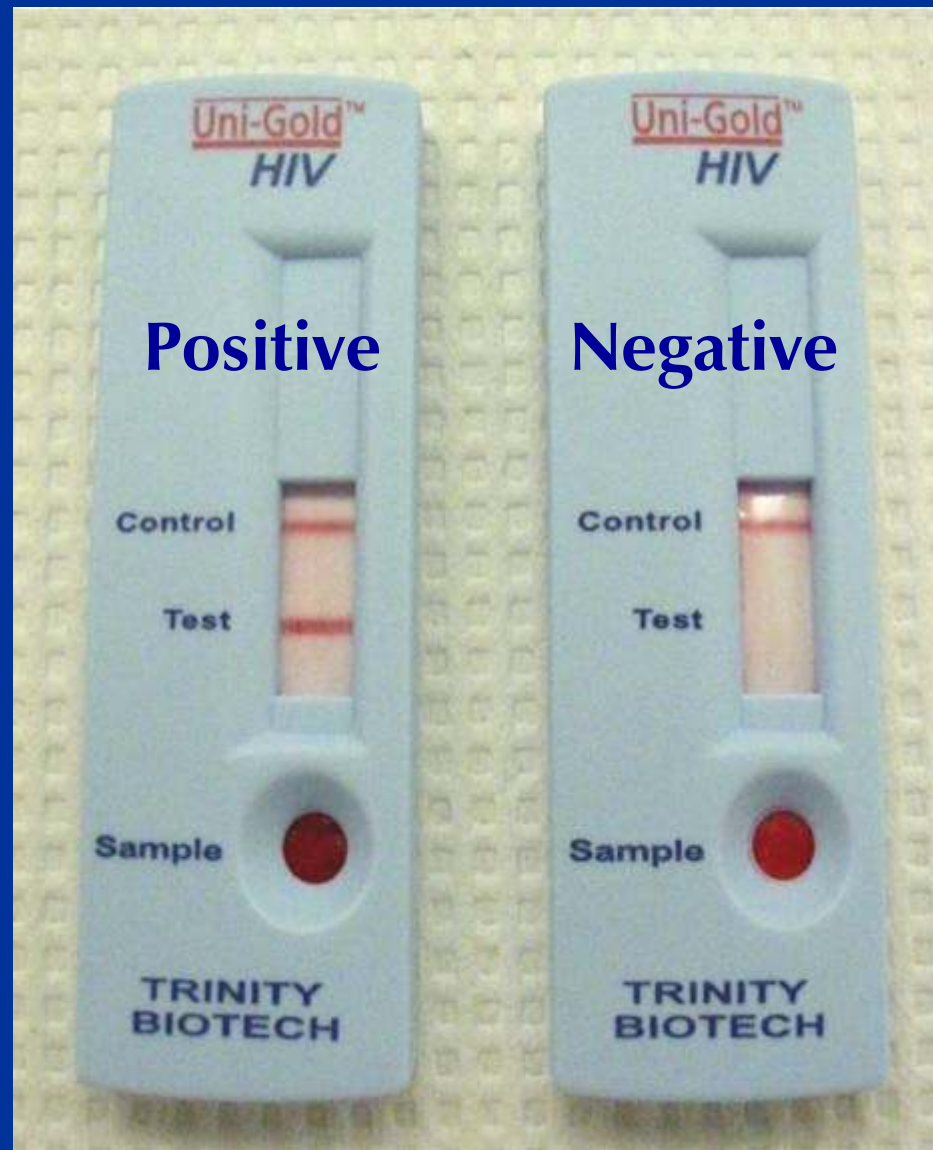
- CLIA-waived for finger stick, whole blood; moderate complexity with serum, plasma
- Store at room temperature
- Screens for HIV-1
- Results in 10 minutes

Add 1 drop
specimen to well





Add 4 drops of wash solution



Read results in 10 -12 minutes

Reveal G2



- CLIA moderate complexity with serum, plasma
- Reconstitute and refrigerate reagents
- Screens for HIV-1
- Perform test in 5 minutes



Centrifuge to obtain serum or plasma



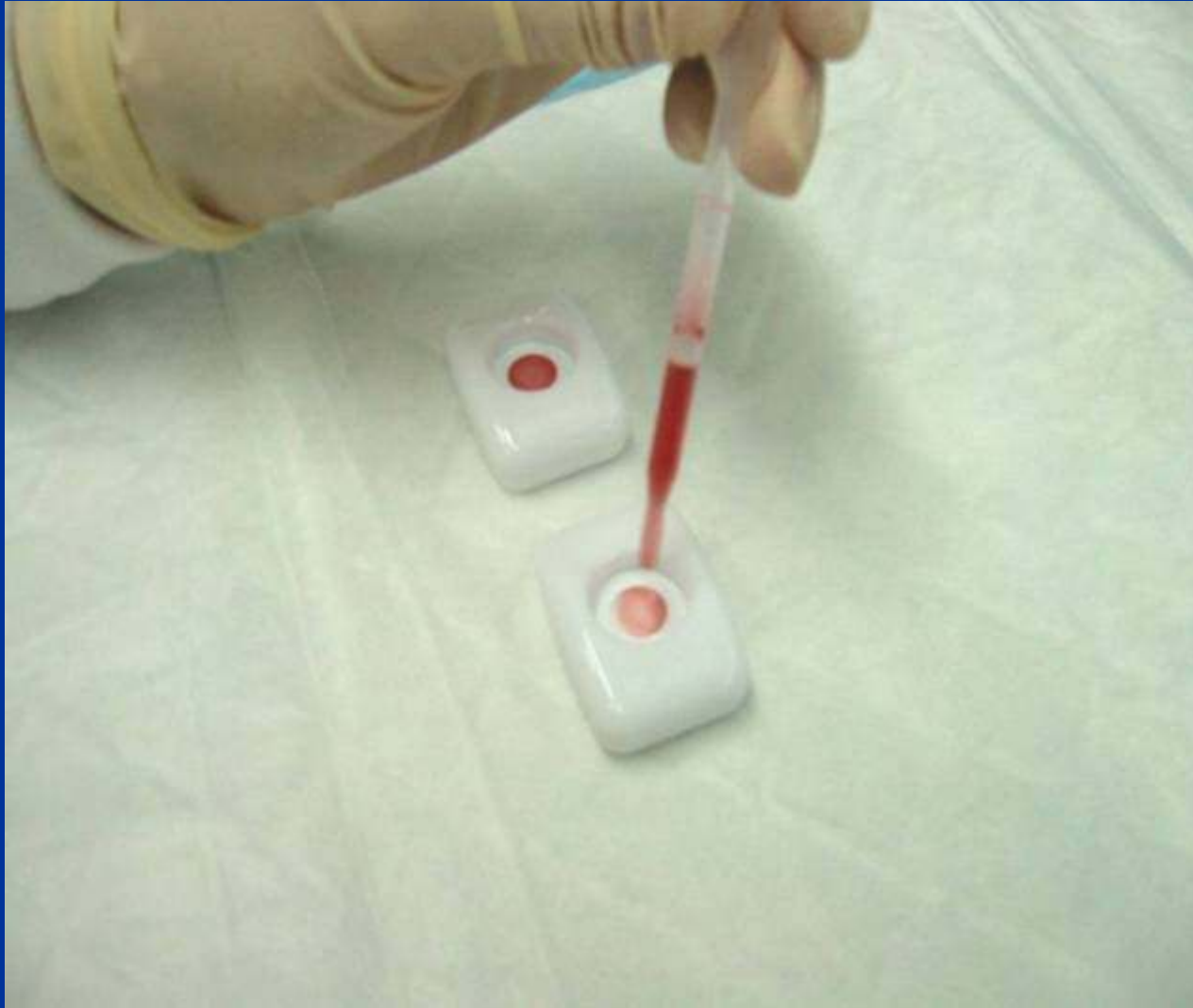
**Add buffer to reconstitute conjugate.
(Sufficient for 15 tests; Refrigerate to store)**



Add 3 drops buffer to moisten membrane



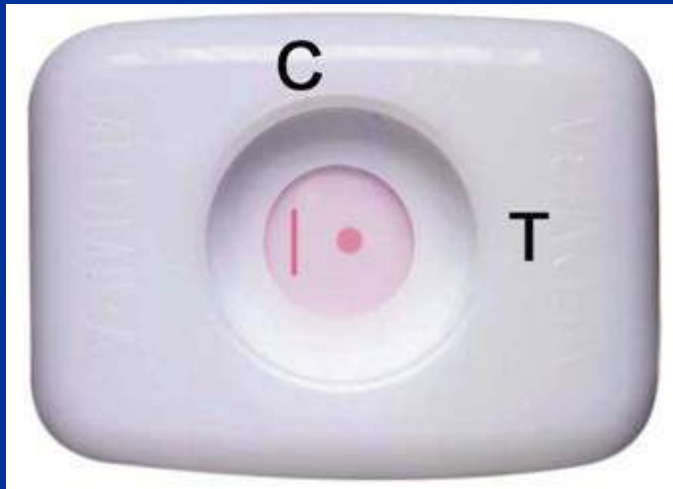
**Add one drop of serum or plasma,
followed by 3 drops of buffer.**



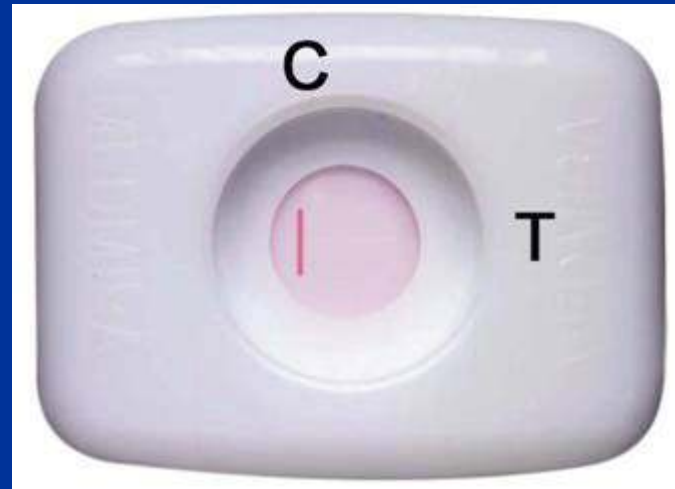
Add 4 drops of Colorimetric Detection Agent



Add 3 drops of buffer to wash



Reactive



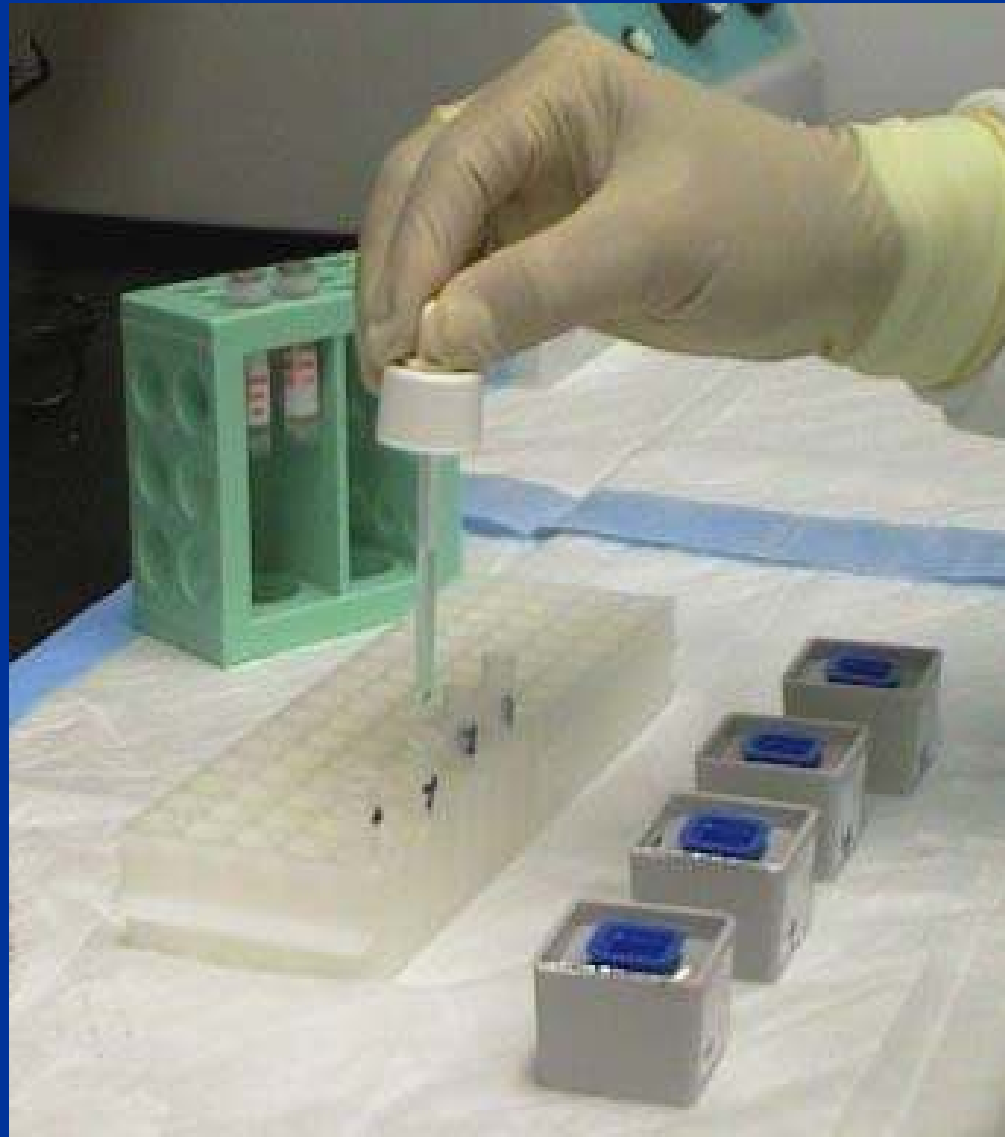
Negative

Read results immediately

Multispot HIV-1/HIV-2



- CLIA moderate complexity with serum, plasma
- Refrigerate reagents
- Distinguishes HIV-1 from HIV-2
- Perform test in 15 minutes



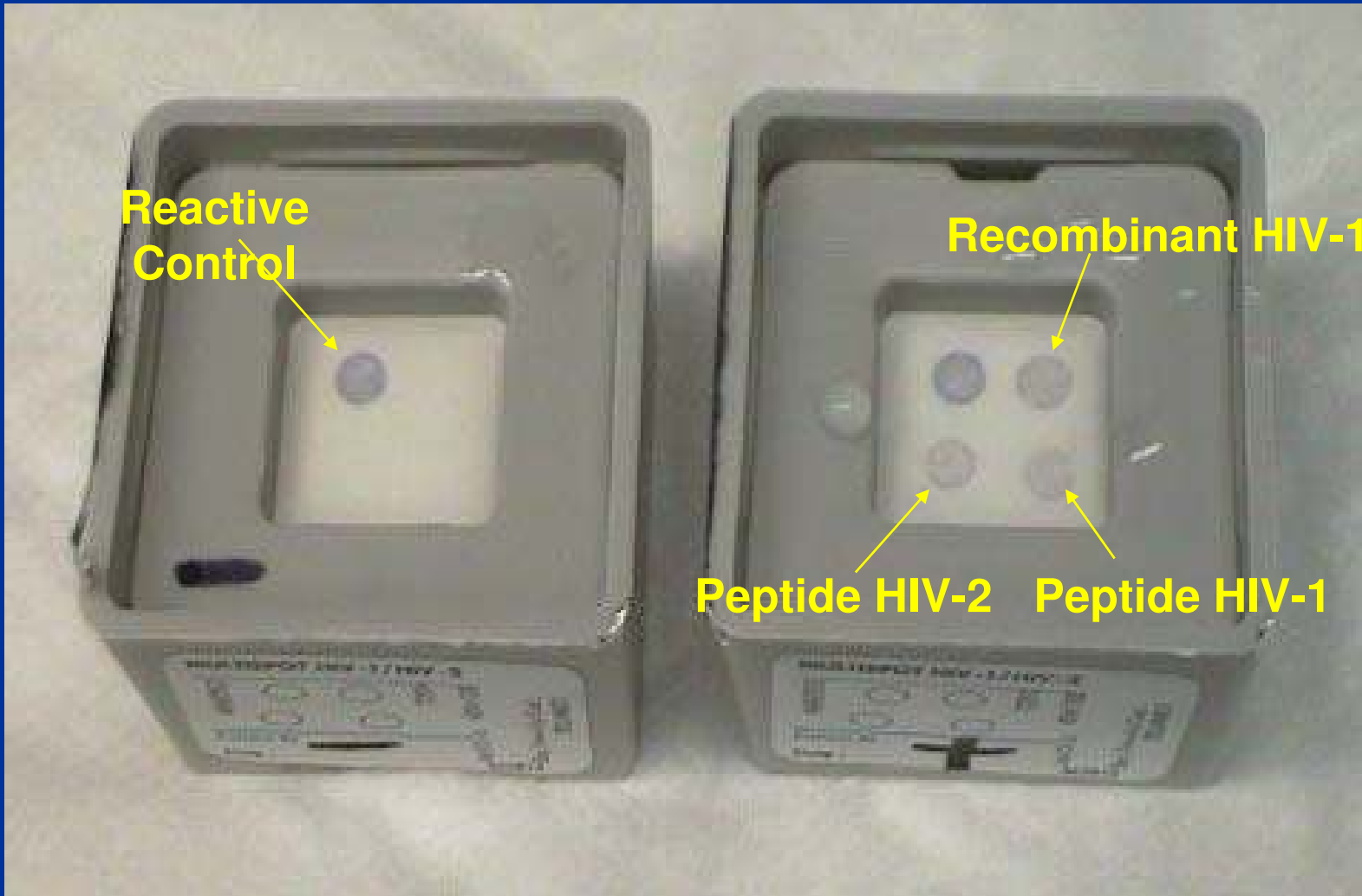
Dilution of plasma or serum



Remove and discard pre-filter



Several timed reagent & wash steps



Negative

**HIV-1 & HIV-2
Positive**

Remember the tradeoffs...

- Good News: More HIV-positive people receive their test results.
- Bad News: Some people will receive a false-positive result before confirmatory testing.

Interpreting Rapid Test Results

For a laboratory test:

Sensitivity: Probability test=positive if patient=positive

Specificity: Probability test=negative if patient=negative

Predictive value:

Probability patient=positive if test=positive

Probability patient=negative if test=negative

Example: Test 1,000 persons
Test Specificity = 99.6% (4/1000)

HIV prevalence = 10%

True positive: 100 False positive: 4

Positive predictive value: $100/104 = 96\%$

Example: Test 1,000 persons

Test Specificity = 99.6% (4/1000)

HIV prevalence = 10%

True positive: 100

False positive: 4

Positive predictive value: $100/104 = 96\%$

HIV prevalence = 0.4%

True positive: 4

False positive: 4

Positive predictive value: $4/8 = 50\%$

Positive Predictive Value of a Single Test Depends on Specificity & Varies with Prevalence

Predictive Value, Positive Test

<u>HIV Prevalence</u>	<u>OraQuick</u>	<u>Reveal</u>	<u>Uni-Gold</u>	<u>Single EIA</u>
10%	99%	92%	97%	98%
5%	98%	85%	95%	96%
2%	95%	69%	87%	91%
1%	91%	53%	77%	83%
0.5%	83%	36%	63%	71%
0.3%	75%	25%	50%	60%
0.1%	50%	10%	25%	33%
Test Specificity	99.9%	99.1%	99.7%	99.8%

Routine HIV Screening for Emergency Department Patients



Cook County Hospital, Chicago

- OraQuick testing since October 2002
 - 60% accept HIV testing
 - 98% receive test results
 - 2.5% new HIV positive
 - 80% entered HIV care
- 4 new demonstration projects (*Wisconsin, Massachusetts, Los Angeles, New York*)

Characteristics Rapid Test Positive Patients

	<i>N=82</i>
No previous test	47 (57%)
Risk Factors	
MSM	29 (34%)
IDU	8 (10%)
Sex Partner IDU	3 (4%)
No identified risk	42 (51%)

HIV Screening in Acute Care Settings

New HIV+

- Cook County ED, Chicago 2.5%
- Grady ED, Atlanta 2.7%
- Johns Hopkins ED, Baltimore 3.2%
- Massachusetts (4 hospitals) 2.0%

HIV testing sites 1.2%

HIV Screening with OraQuick in Labor and Delivery: the MIRIAD Study

- Testing of pregnant women in labor for whom no HIV test results are available; 12 hospitals in 5 cities: Atlanta, Chicago, Miami, New Orleans, New York
- To date
 - 4894 women screened
 - 34 (0.7%) new HIV infections identified
 - 4 false positive OraQuick tests, no false negatives
 - 11 false-positive EIAs: 5 p24 only, 6 WB negative
- Positive Predictive value: OraQuick 90%; EIA 76%

Turnaround Times for Rapid Test Results, Point-of-Care vs Lab Testing

- Point-of-care testing: median 45 min
 - (range 30 min – 2.5 hours)

- Same test in Laboratory: median 3.5 hours
 - (range 94 min – 16 hours)

MMWR 52:36, Sept 16, 2003

OraQuick Outreach Testing for High-risk Persons: El Paso

- On-site testing at community sites:
Old Plantation night club and mobile van
- Individual counseling and testing
- El Paso Gay Community Center and Centro de Salud Familiar la Fe

OraQuick Fingertstick Results:

N = 1275

- Preliminary positive 18 (1.4%)
- True positives 17 (1.3%)
- False Positives 1 (0.07%)
- Specificity 1256/1257 (99.9%)

- Positive Predictive Value 17/18 (94%)
- All clients received their test results

OraQuick Outreach to High-risk Persons of Color

- On-site testing at sites throughout the community
- Group pretest counseling.
- Individual testing and post-test counseling.

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Outreach Testing Sites

- Chemical Dependency Programs
- Homeless shelters
- Sex worker support program
- Drop-in center for gay youth
- Teen clinic
- Gay bars
- Sex offender groups
- “Johns” programs
- Half-way houses
- Health fairs
- Strip club workers
- African-born groups
- Drug court support groups

OraQuick Fingertstick Results:

N = 1021

■ Preliminary positive	5 (0.5%)
■ True positives	4 (0.4%)
■ False Positives	1 (0.1%)
■ Sensitivity	4/4 (100%)
■ Specificity	1016/1017 (99.9%)
■ Positive Predictive Value	4/5 (80%)

Results

- 99.7% of clients received their test results and post-test counseling.
- The average time between fingerstick and learning test result was 28 minutes.

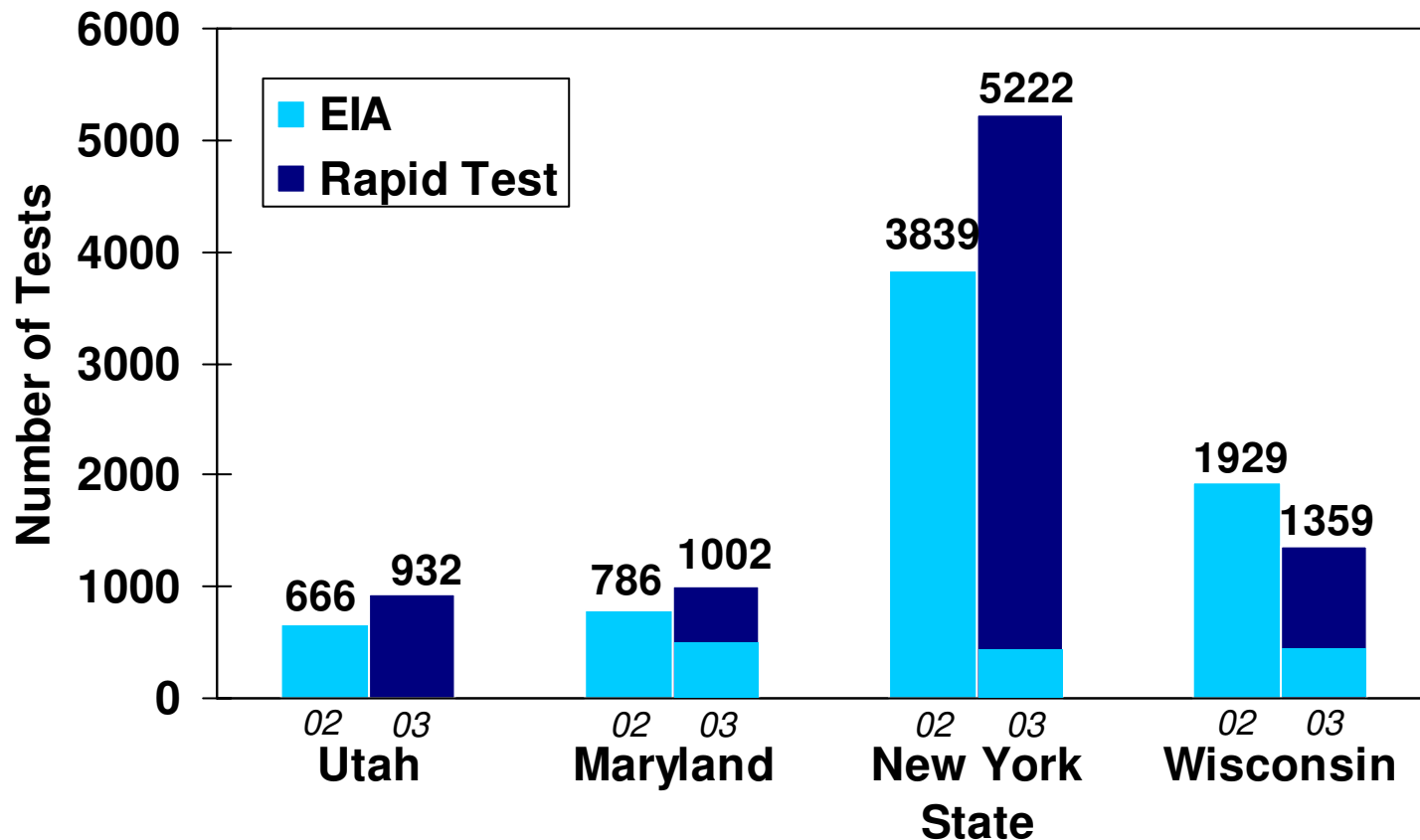
CDC's OraQuick Procurement & Distribution

527,775 test kits shipped in 2003 and 2004
—137 health depts and CBOs in 36 states

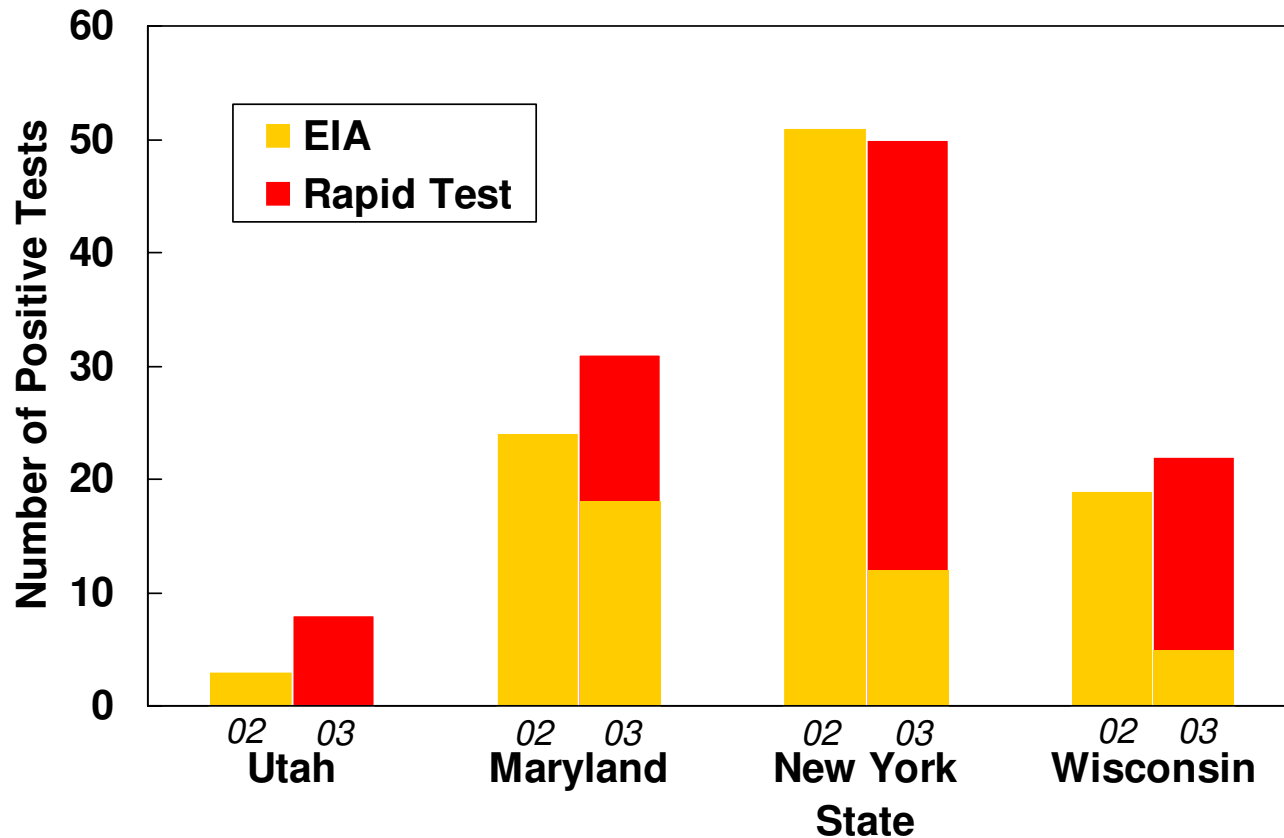
Utilization September 2003 – September 2004:

- 173,003 persons tested
- 2,741 (1.6%) HIV positive
- 17,266 devices used for training
- 25,926 devices use to run external controls

Changes in HIV Testing at Same Sites After Rapid Testing Introduced



Changes in Positive Tests at Same Sites After Rapid Testing Introduced



Results of Confirmatory Testing

Initial specimen			Follow-up specimen		
EIA*	Confirmatory test		EIA	Supplemental test	
ND†	IFA	neg [§]	neg	IFA¶	pos**
neg	—	ND	ND	Viral load	>750,000 copies
neg	WB††.§§	Indeterm¶¶	pos	WB	Pos
neg	WB§§	pos	ND	ND	—
neg	WB§§	pos	ND	ND	—
pos	IFA	indeterm	pos	WB	Pos
pos	WB	indeterm	pos	WB	Pos
pos	WB	indeterm	ND	Viral load	>750,000 copies
pos	WB	indeterm	pos	WB	Pos
neg	WB	neg	ND	Viral load	neg
neg	WB	indeterm	ND	WB	neg
neg	WB	neg	neg	WB	neg
neg	WB	neg	neg	WB	neg

MMWR March 19, 2004

Results of Confirmatory Testing

OraQuick	Initial specimen			Follow-up specimen		
	EIA†	Confirmatory test		EIA	Supplemental test	
Reactive	ND†	IFA	neg§	neg	IFA¶	pos**
Reactive	neg	—	ND	ND	Viralload	>750,000 copies
Reactive	neg	WB††§§	Indeterm¶¶	pos	WB	Pos
Reactive	neg	WB§§	pos	ND	ND	—
Reactive	neg	WB§§	pos	ND	ND	—

5 patients:

- Initial EIA or confirmatory test negative
- Some labs did only EIA
- HIV-positive on follow-up specimen

Results of Confirmatory Testing

OraQuick	Initial specimen			Follow-up specimen		
	EIA*	Confirmatory test		EIA	Supplemental test	
Reactive	pos	IFA	indeterm	pos	WB	Pos
Reactive	pos	WB	indeterm	pos	WB	Pos
Reactive	pos	WB	indeterm	ND	Viral load	>750,000 copies
Reactive	pos	WB	indeterm	pos	WB	Pos

4 patients:

- Initial confirmatory test indeterminate
- Early infection, evolving Western blot
- HIV-positive on follow-up specimen

Results of Confirmatory Testing

OraQuick	Initial specimen			Follow-up specimen		
	EIA*	Confirmatory test		EIA	Supplemental test	
Reactive	neg	WB	neg	ND	Viral load	neg
Reactive	neg	WB	indeterm	ND	WB	neg
Reactive	neg	WB	neg	neg	WB	neg
Reactive	neg	WB	neg	neg	WB	neg

4 patients:

- Initial and follow-up tests negative
- False-positive OraQuick rapid test

Results of Confirmatory Testing

OraQuick	Initial specimen			Follow-up specimen		
	EIA*	Confirmatory test		EIA	Supplemental test	
Reactive	pos	WB	neg	—	—	—
Reactive	neg	WB	indeterm	—	—	—
Reactive	neg	WB	indeterm	—	—	—
Reactive	neg	WB	neg	—	—	—
Reactive	neg	WB	neg	—	—	—
Reactive	neg	WB	neg	—	—	—
Reactive	neg	WB	neg	—	—	—
Reactive	neg	WB	neg	—	—	—

8 patients:

- Unsuccessful follow-up
- HIV status unconfirmed

Confirmatory Testing

- Confirmatory test essential (not just EIA!)
- For Western blot:
 - Venipuncture for whole blood
 - Oral fluid specimen
- Follow-up testing of persons with negative or indeterminate Western blot results after 4 weeks

Additional Resources

General and technical information (updated frequently):

www.cdc.gov/hiv/rapid_testing