Rapid HIV Testing: 2003 Update

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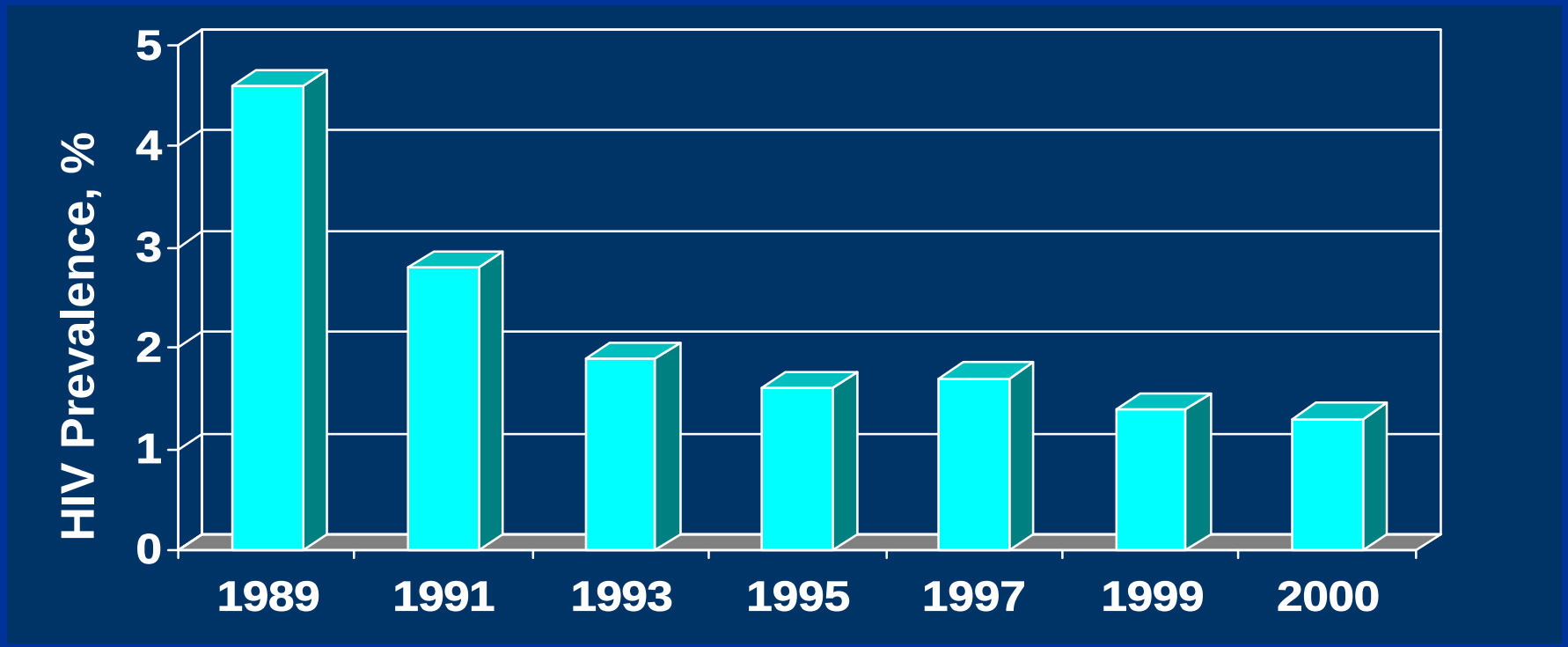
Why do we need rapid HIV tests?

- 180,000 – 280,000 persons don't know they are infected
- 40,000 new HIV infections per year

- 27,000 – 30,000 HIV positive tests each year at publicly-funded testing sites
- 31% of those who test positive do not receive their results

HIV Prevalence, 1989-2000
Publicly-funded Counseling & Testing Sites

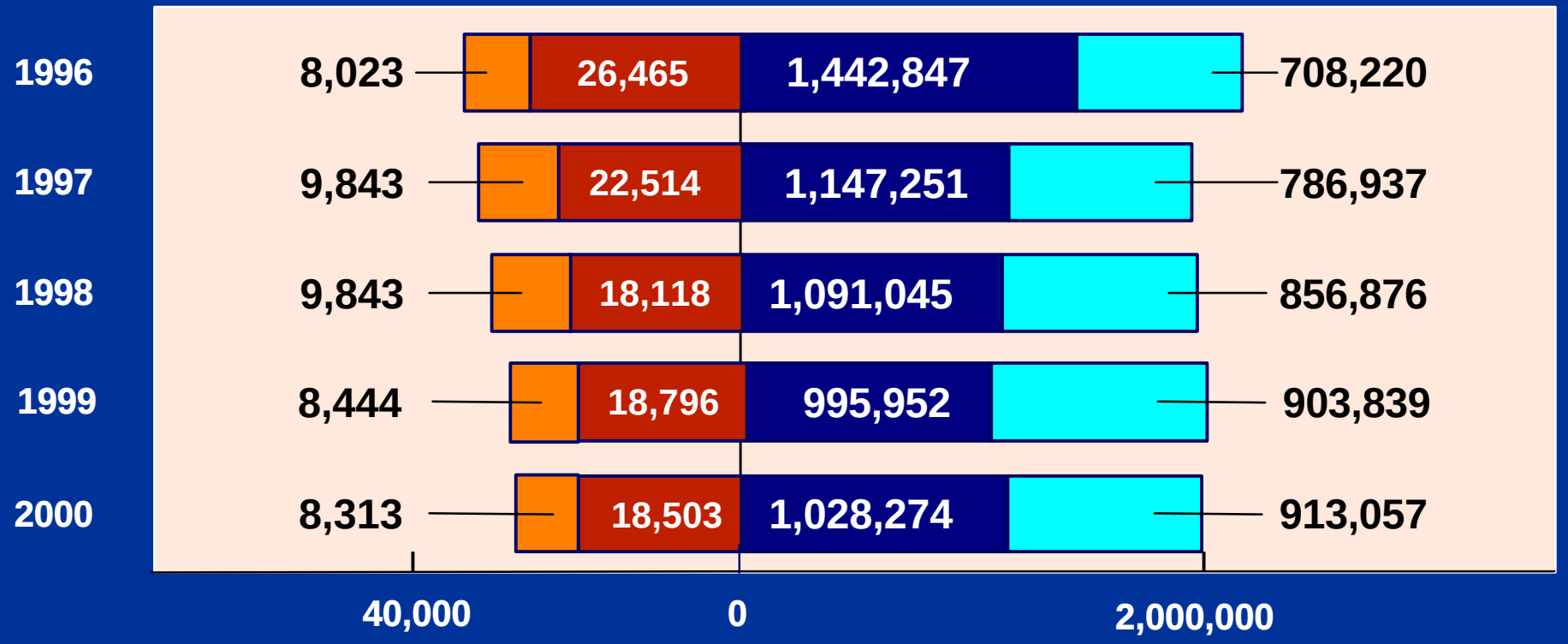


What if rapid HIV tests were used in all public testing sites?

Site	Prevalence	Return for Results	
		HIV+	HIV-
HIV C/T sites	1.9%	82.1%	**84.3%**
STD Clinics	1.6%	67.8%	**48.1%**
Drug Treatment	2.9%	73.6%	70.8%
Family Planning	0.4%	76.9%	63.0%
Other testing sites	2.1%	73.2%	64.6%
Rapid test		97.0%	93.0%

Source: CDC Client Record Database, 1995

What if rapid HIV tests were used in all public testing sites?



1998: PHS Recommendation Changed

- Provide preliminary positive HIV test results before confirmatory results are available in situations where tested persons benefit.

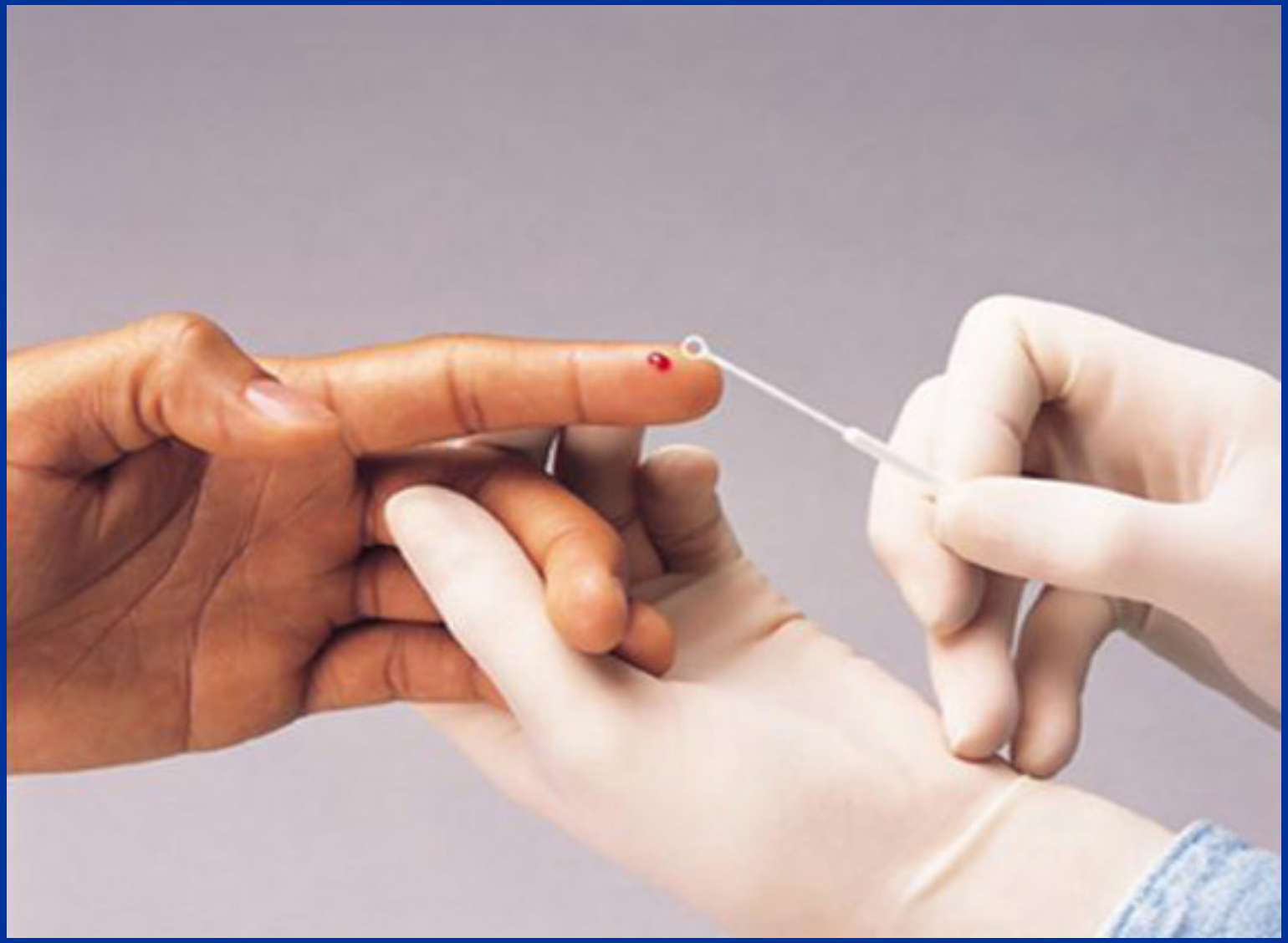
MMWR 47:211-15, 1998

OraQuick Rapid HIV-1 Antibody Test

- Easy to use: untrained first-time users report 98.5% of results correctly
- Read test results in 20-60 minutes
- Sensitivity = 99.6% / Specificity = 100%
- CLIA-waived

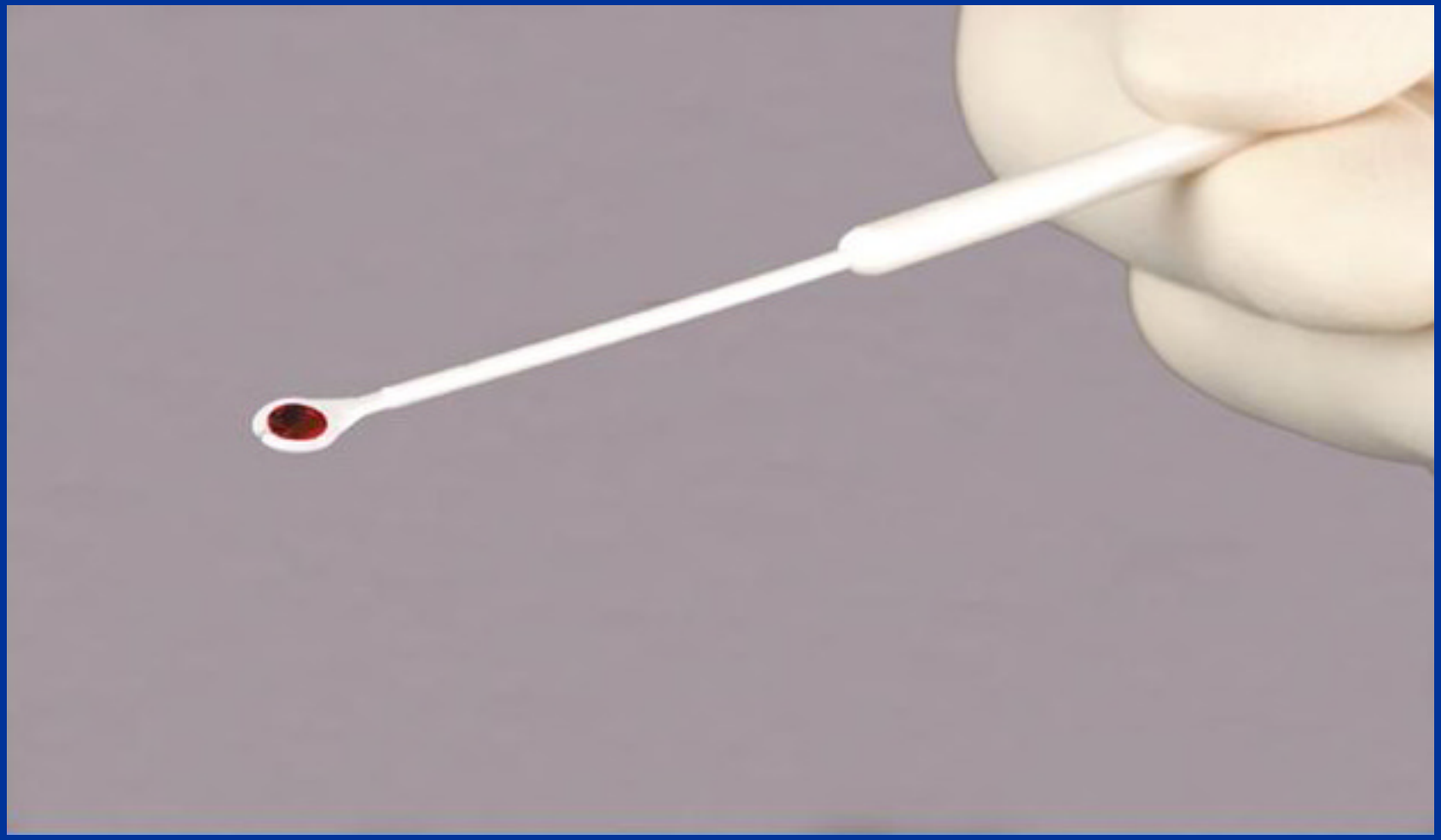
OraQuick: Oral fluid, serum, whole blood

FDA-approved for use with whole blood; granted CLIA waiver.



Obtain finger stick specimen…

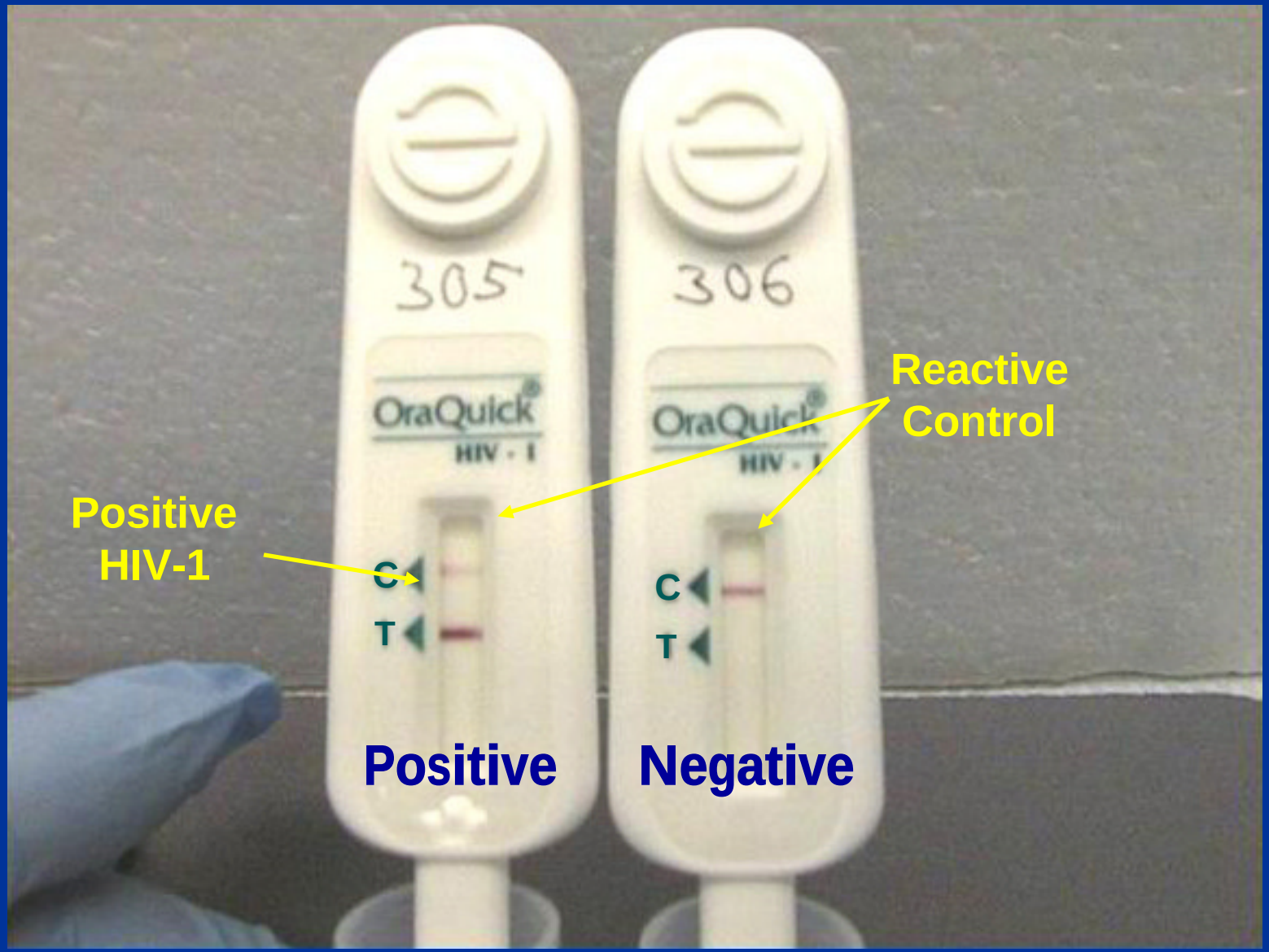
Or whole blood



Loop collects 5 microliters of whole blood

Insert loop into vial and stir

Insert device; test develops in 20 minutes



Read results

Requirements for OraQuick Testing

- Sold only to “clinical laboratories”

- To perform CLIA-waived tests, entities must:
  1) Enroll in CLIA program
  2) Obtain a Certificate of Waiver
  3) Pay a biennial fee
  4) Follow manufacturers’ instructions
  5) Meet state requirements

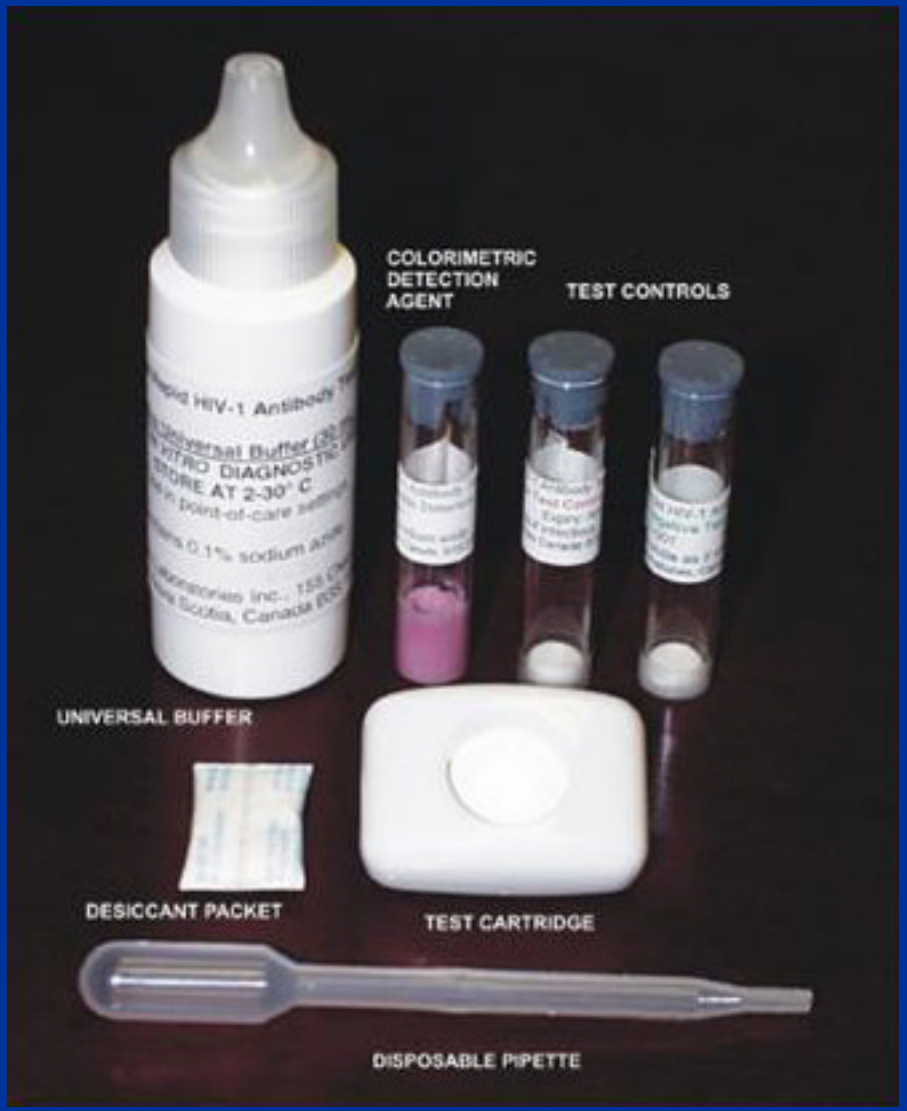
Requirements for OraQuick Testing

- Have an adequate quality assurance program
- Assurance that operators will receive and use instructional materials
- QA guidelines for OraQuick testing and sample forms:

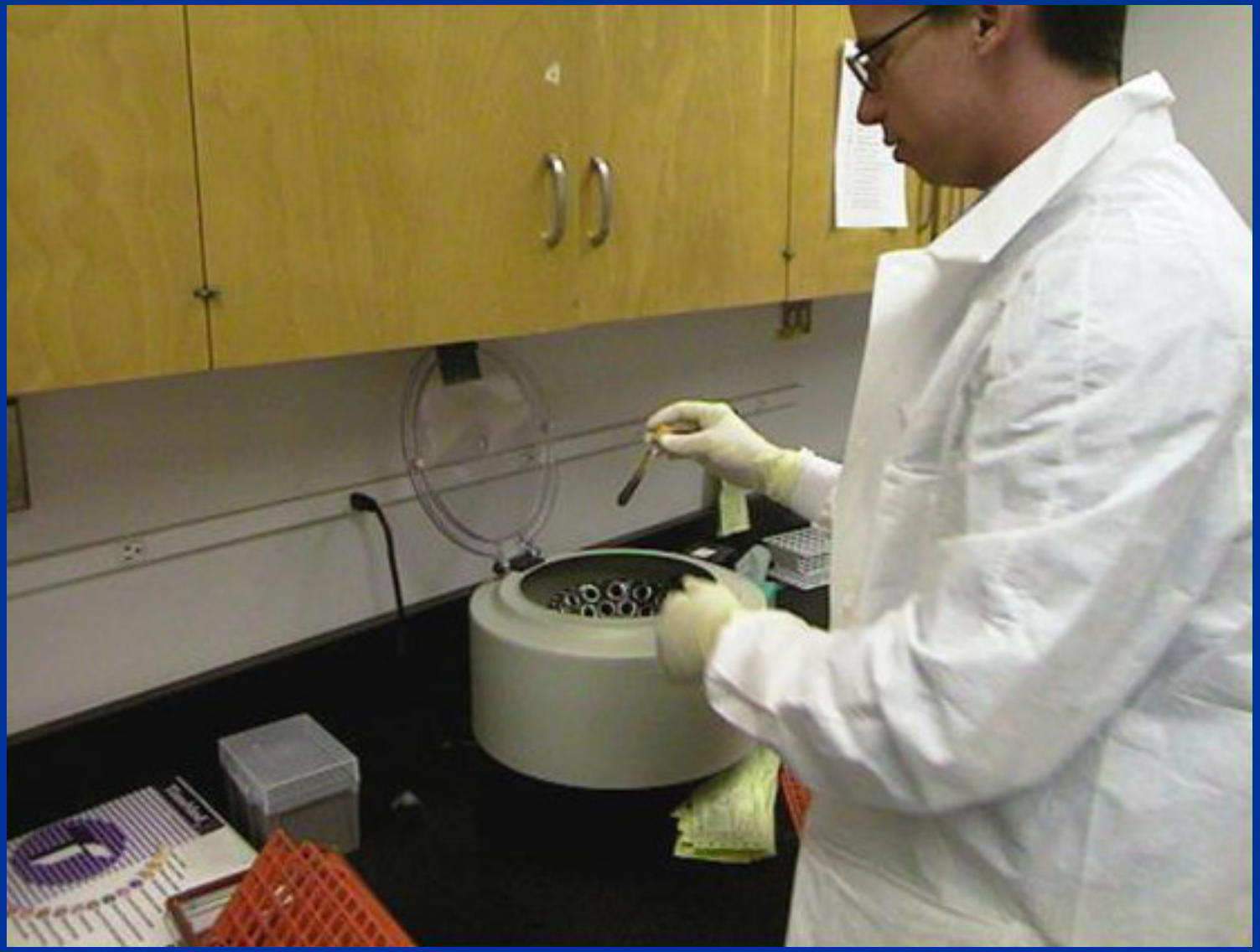
www.cdc.gov/hiv/testing.htm

Reveal HIV-1 Antibody Test

- Requires serum or plasma, more dependent on laboratory
- CLIA: moderate complexity
- Read results within minutes
- Sensitivity 99.8%
- Specificity: serum 99.1% plasma 98.6%
- Run controls with each test



Reveal HIV-1 Rapid Antibody Test for serum, plasma
CLIA Category - Moderate Complexity

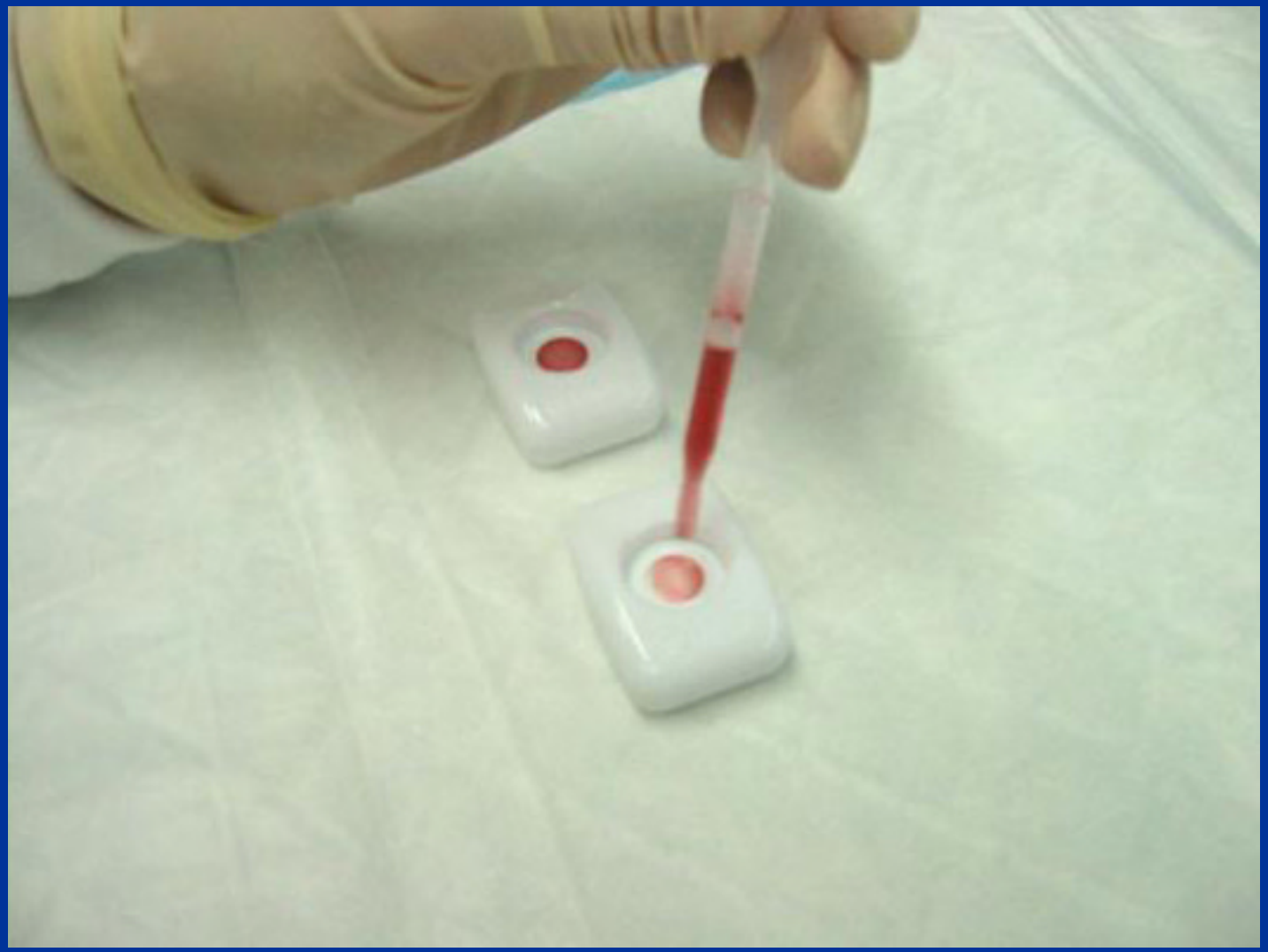


Centrifuge to obtain serum or plasma

Add 20 drops of buffer to reconstitute conjugate. (Refrigerate to store)

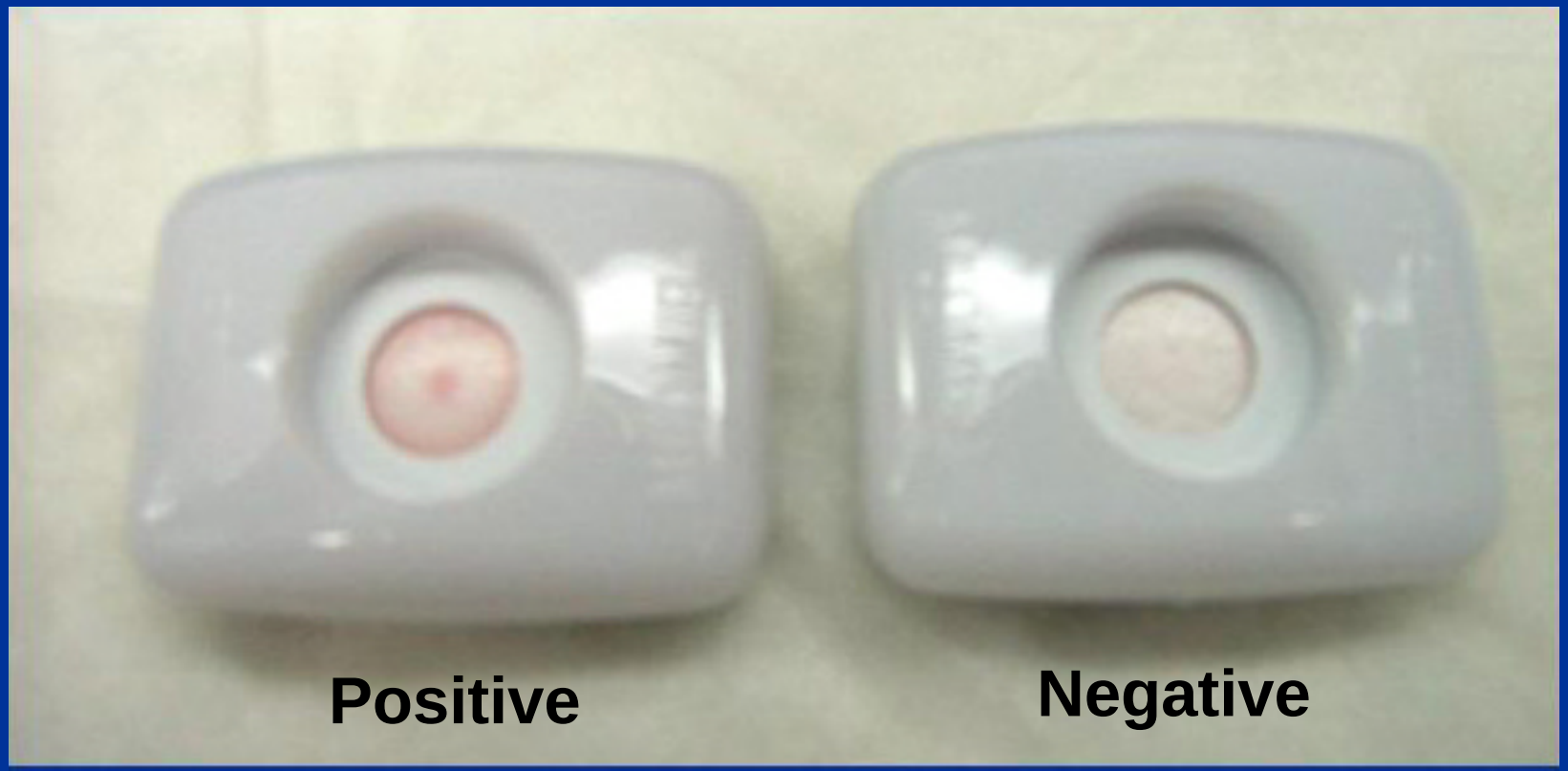
Add 3 drops buffer to moisten membrane

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



Add 4 drops of conjugate solution

Add 3 drops of buffer to wash



Read results immediately

Rapid Test Performance: Serum

	Sensitivity	Specificity
OraQuick	100%	100%
Reveal	99%	100%
SUDS	97.9%	94.5%
HIV 1-2 EIA	-	95.1%

206 HIV+, 194 HIV- stored sera

Point-of-Care Testing

- To expand testing in non-clinical settings:
  - Fingerstick or whole blood specimen
  - One-step
  - Easy to interpret
  - Internal control

Example: Three possible OraQuick test results

- Non-reactive
- Reactive
- Invalid

Non-reactive

Reactive

Invalid

Invalid

Invalid

Invalid

The challenge:
Weakly Reactive

The Need for Training

- Blood & body fluid precautions
- Obtaining the specimen (finger stick or blood draw)
- Performing the test
- Providing test results and counseling
- Quality assurance
- OSHA requirements

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		
HIV Prevalence	**OraQuick**	**EIA**	**Reveal**
10%	99%	98%	92%
5%	98%	96%	85%
2%	95%	91%	69%
1%	91%	83%	53%
0.5%	83%	71%	36%
0.3%	75%	60%	25%
0.1%	50%	33%	10%
Test Specificity	**99.9%**	**99.8%**	**99.1%**

Reports from the 2003 HIV Prevention Conference

- Promising news with rapid HIV tests for –
  - Routine screening in emergency rooms
  - Increasing receipt of results at CT sites
  - Screening in labor and delivery
  - Outreach testing

Routine Screening of Emergency Department Patients Using OraQuick® Rapid HIV-1 Antibody Test

Cook County Bureau of Health Service

Chicago, Illinois

Rapid Test Outcomes

Number rapid tested	1664
Number received results	1624 (98%)
Number new HIV+	39 (2.3%)
Number who entered care	28 (76%) median 18 days

Characteristics
Rapid Test Positive Patients

	N=39
No previous test	22 (57%)
Risk Factors	
MSM	12 (31%)
IDU	5 (13%)
Sex Partner IDU	3 (8%)
No identified risk	19 (49%)

HIV Screening in Acute Care Settings

	New HIV+
Cook County ED, Chicago	2.3%
Grady ED, Atlanta	2.7%
Johns Hopkins ED, Baltimore	3.2%
HIV testing sites	*1.3%*

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
  - 3178 women screened
  - 27 new HIV infections identified
  - 2 false positive OraQuick tests, no false negatives
  - 7 false-positive EIAs

Point-of-Care Testing Station

- The rapid test is done on this counter, extra supplies are stored below.
- OB physicians and midwives share MIRIAD testing

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

MMWR 52:36, Sept 16, 2003

OraQuick Outreach to High Risk Persons of Color

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OraQuick Outreach Study (7/02 – 6/03) N =1021

- On-site group pretest counseling.
- Individual testing and post-test counseling.
- Testing procedure:
  - Fingerstick OraQuick (results given)
  - Fingerstick neg -> OraSure backup
  - Fingerstick pos -> venous EIA/WB

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

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.

OraQuick Fingerstick 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%)

Client Survey Results I

- "I have tested for HIV in the past and I prefer receiving my results the same day"

  Strongly agree or agree = 98%

  Disagree or strongly disagree = 2%

Client Survey Results II

- "I would rather have my finger stuck than have blood drawn from my vein"

  Agree or strongly agree = 95%
  Disagree or strongly disagree = 5%

Client Survey Results: III

- "I understand the results of my test."

  Agree or strongly agree = 99%
  Disagree or strongly disagree = 1%

Confirmatory Testing

- For Western blot:
  - Venipuncture for whole blood
  - Oral fluid specimen
  - Dried blood spots on filter paper

Requirements for OraQuick Testing

- Register as a laboratory
  - *CLIA "Certificate of Waiver" or*
  - *Limited Public Health Use Exception*
- Train staff
- Establish Quality Assurance Program
- For CDC testing programs:
  - *Postmarketing surveillance*

Additional Resources

- General and technical information (updated frequently):

www.cdc.gov/hiv/testing.htm