

HIV and HCV – Is Eradication Within Reach?

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Director
Scientific Affairs LLC



Outline

- Where we've been
- Where we are
- Where we can be

MNWR

MORBIDITY AND MORTALITY WEEKLY REPORT

Epidemiologic Notes and Reports

- 305 Kaposi's Sarcoma and *Pneumocystis* Pneumonia Among Homosexual Men — New York City and California
- 308 Cutaneous Larva Migrans in American Tourists — Martinique and Mexico
- 314 Measles — U.S. Military

Epidemiologic Notes and Reports

Kaposi's Sarcoma and *Pneumocystis* Pneumonia Among Homosexual Men — New York City and California

During the past 30 months, Kaposi's sarcoma (KS), an uncommonly reported malignancy in the United States, has been diagnosed in 26 homosexual men (20 in New York City [NYC]; 6 in California). The 26 patients range in age from 26-51 years (mean 39 years). Eight of these patients died (7 in NYC, 1 in California)—all 8 within 24 months after KS was diagnosed. The diagnoses in all 26 cases were based on histopathological examination of skin lesions, lymph nodes, or tumor in other organs. Twenty-five of the 26 patients were white, 1 was black. Presenting complaints from 20 of these patients are shown in Table 1.

1983 Almanac

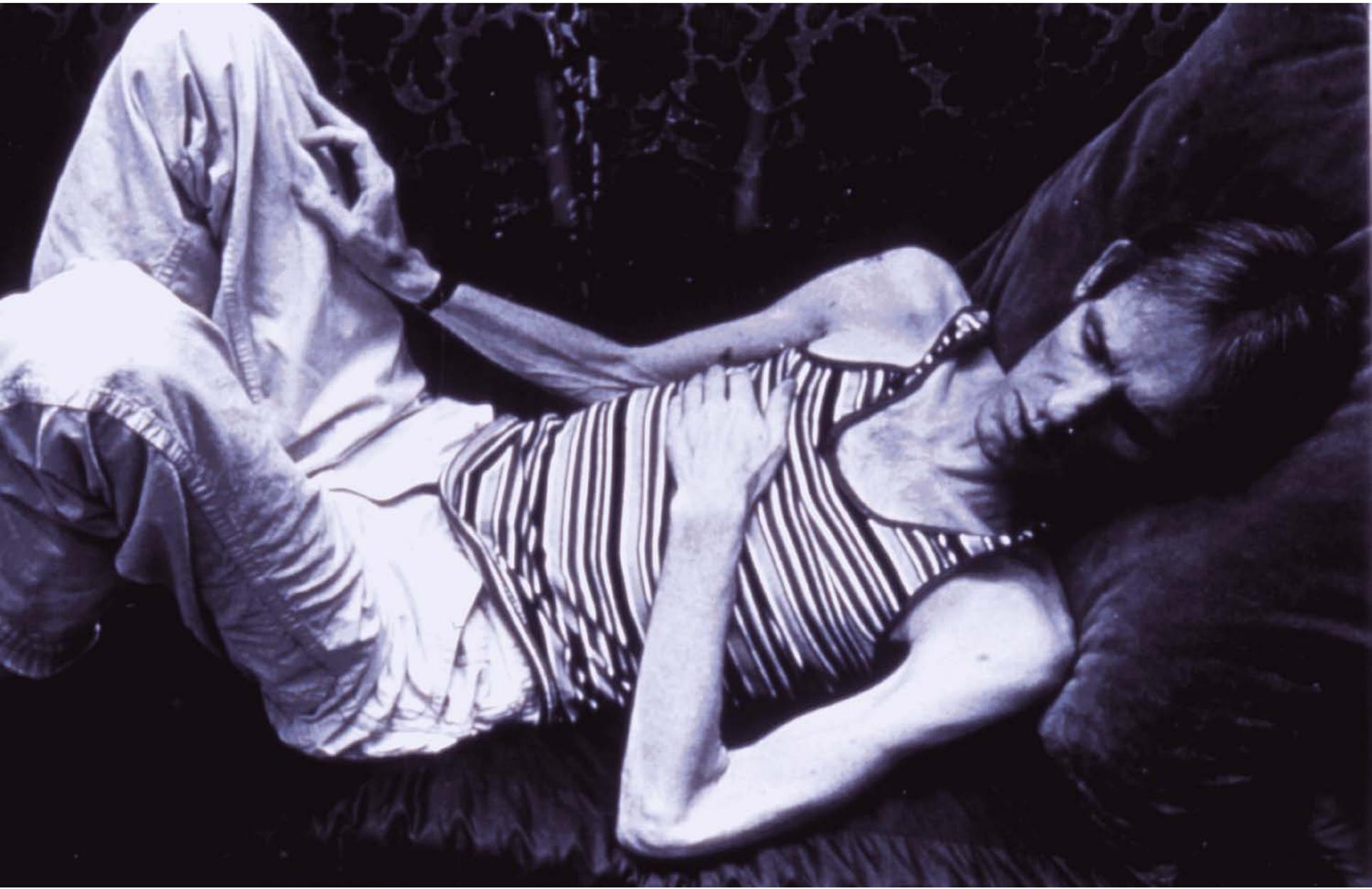


- “Evil Empire” speech
- Mortgage rate: 12%
- “Year of the Bible”
- U.S. invades Granada



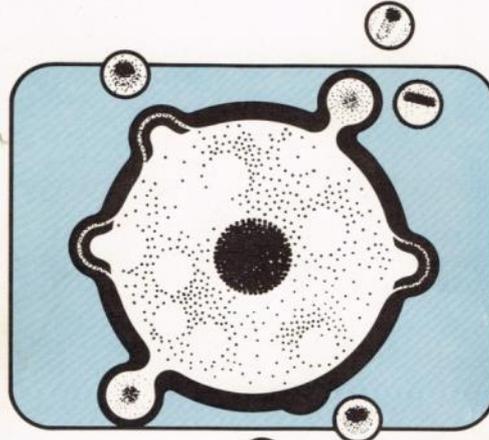








Official Program



INTERNATIONAL  CONFERENCE
ON **ACQUIRED**
IMMUNODEFICIENCY
SYNDROME (AIDS)

April 14-17, 1985

Georgia World Congress Center , 285 International Blvd., N.W.
Atlanta, Georgia, U.S.A.

International Conference on Acquired Immunodeficiency Syndrome (AIDS)

Atlanta, Georgia 30333 • U.S.A. • April 14-17, 1985

Monday, April 15

8:30 OPENING SESSION

Auditorium, Georgia World Congress Center

Call to Order

Gary R. Noble, Program Chairman

Welcome

The Honorable Andrew Young, Mayor of Atlanta

Fakhry Assaad, The World Health Organization, Geneva

Introduction of the Keynote Speaker

Donald R. Hopkins, Acting Director

Centers for Disease Control, Atlanta

Keynote Address:

The AIDS Challenge

The Honorable Margaret M. Heckler

Secretary of Health and Human Services

Washington, DC

9:15 PLENARY SESSION A

CHAIR: *James B. Wyngaarden*, Director

National Institutes of Health, Bethesda

9:15 The Epidemiology and Prevention of AIDS

James W. Curran, Center for Infectious Diseases, Centers for Disease Control, Atlanta

2. EPIDEMIOLOGY

Room 313

CHAIR: *Mervyn Silverman*, San Francisco Hlth. Dept.

- 11:15 Surveillance for AIDS in Children
*Martha F. Rogers**, *P. A. Thomas*, *R. M. Selik*, *A. M. Hardy*, *M. C. Rogers*, *W. M. Morgan*, CDC, Atlanta, and New York City Dept. of Hlth.
- 11:30 Mothers of Infants with the Acquired Immunodeficiency Syndrome: Outcome of Subsequent Pregnancies
*Gwendolyn B. Scott**, *M. Fischl*, *N. Klimas*, *M. A. Fletcher*, *G. Dickinson*, *W. Parks*, Univ. Miami, FL
- 11:45 Epidemiological Features of Pediatric Acquired Immunodeficiency Syndrome in New Jersey
*James M. Oleske**, *M. Zabala*, *A. Minnefor*, *T. N. Denny*, *R. Bobila*, *V. V. Joshi*, et al., UMD-New Jersey Med. Sch.; Children's Hosp. of New Jersey; St. Michael's Med. Ctr., Newark; and St. Joseph's Med. Ctr., Paterson, NJ
- 12:00 Immunodeficiency and HTLV-III/LAV Serology in Heterosexual Partners of AIDS Patients
*C. A. Harris**, *C. Cabradilla*, *M. Robert-Guroff*, *R. S. Klein*, *G. H. Friedland*, *V. S. Kalyanaraman*, et al. Montefiore Med. Ctr., Bronx, NY; NCI, NIH, Bethesda, MD; and CDC, Atlanta
- 12:15 Household Transmission of HTLV-III in Zaire
*Jonathan M. Mann**, *H. Francis*, *B. M. Kapita*, *K. Ruti*, *T. Quinn*, *J. W. Curran*, CDC, Atlanta; NIAID, NIH, Bethesda, MD; Mama

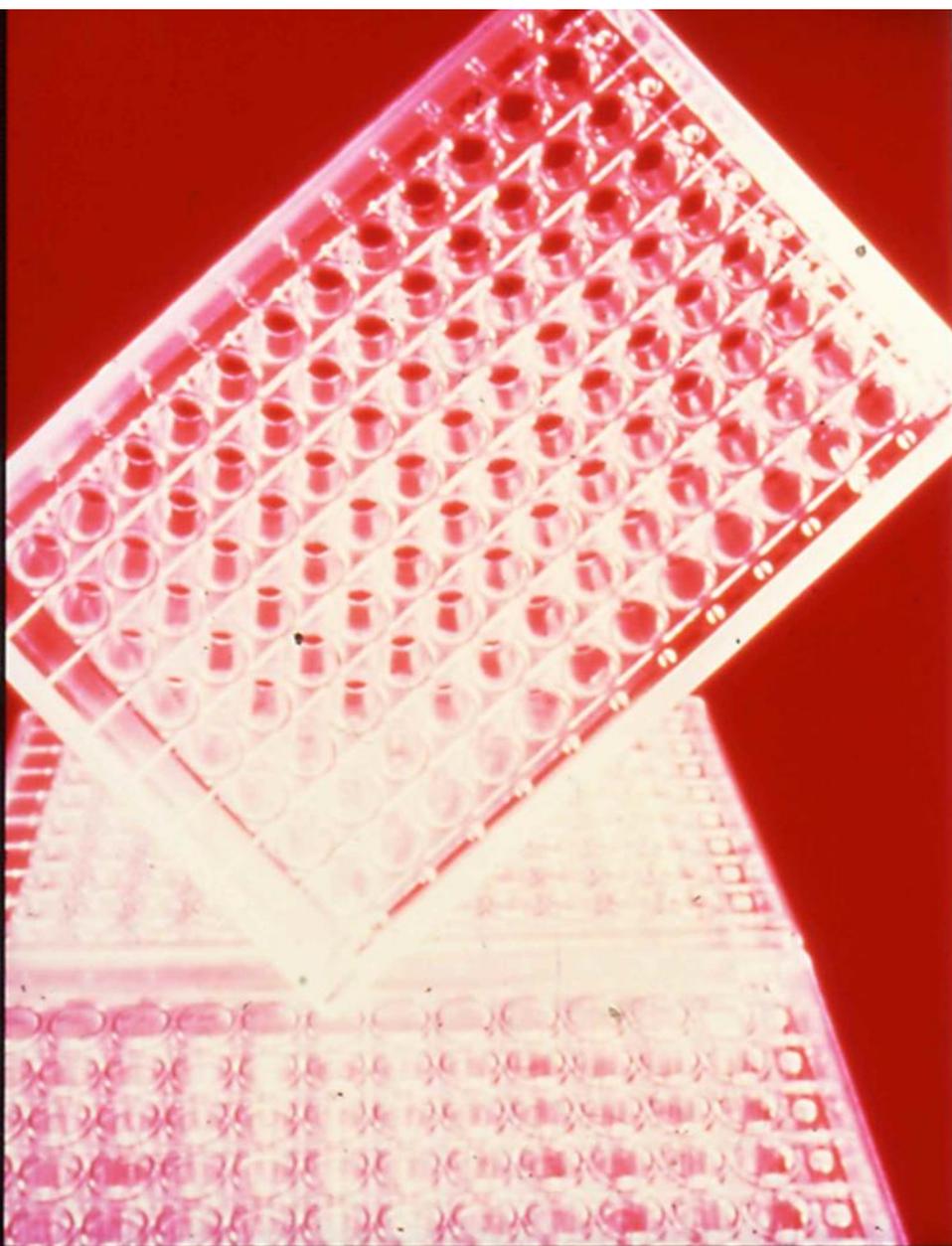
4/15

CURRAN

Utral Infa: AIDS (84) 28: 1

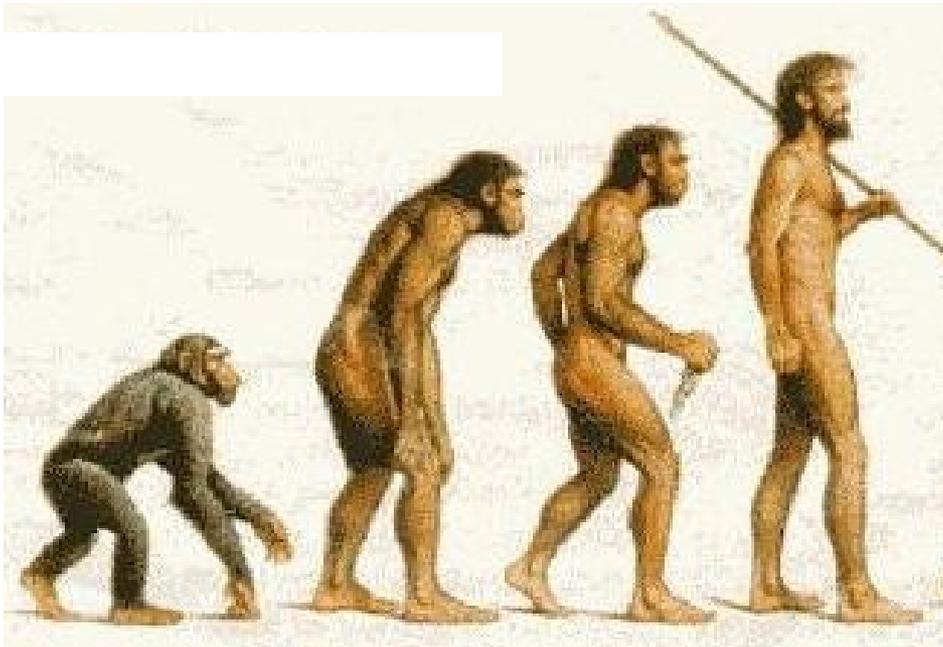
Guess: 500,000 - 1,000,000 infected.

1-2% "complication rate" = AIDS.



ELISA
Test For
HTLV-III
Antibody

Evolution of HIV Tests



Four Generations



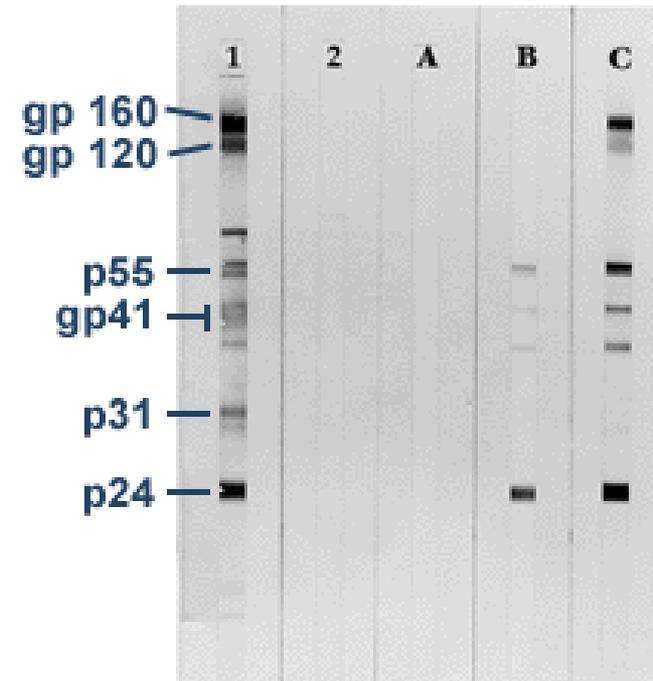
Evolution of HIV Tests

- 1st generation: whole viral lysate, detects IgG antibody

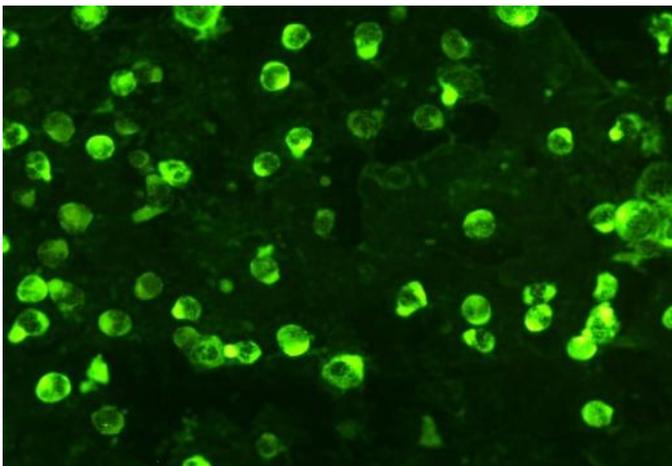
EA



Western blot



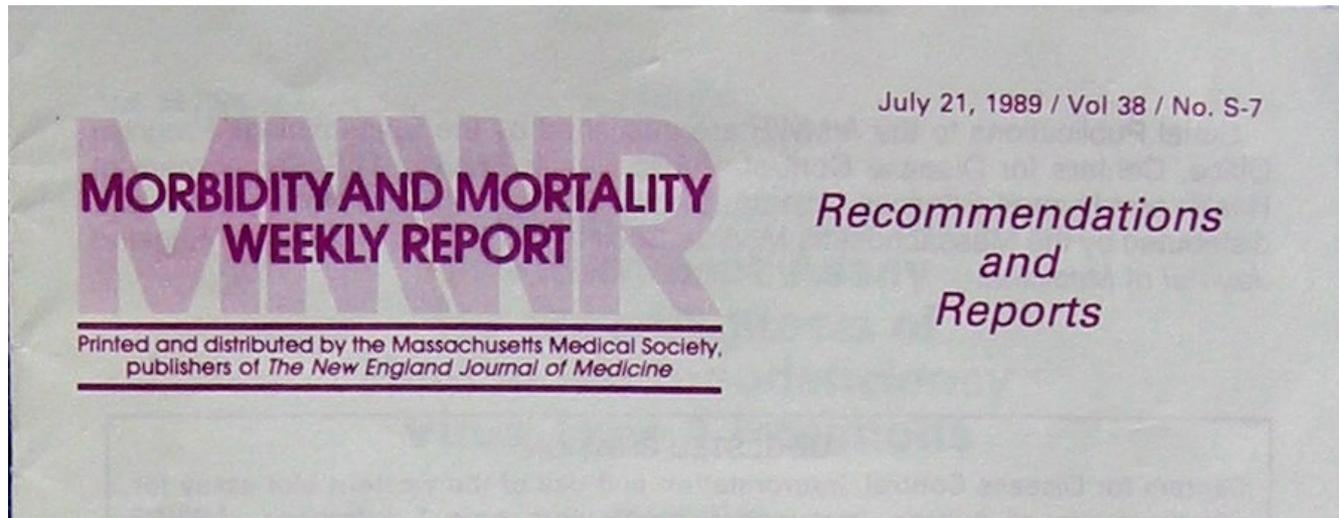
IFA



1st Generation



Diagnostic Algorithm: 1989



The Public Health Service recommends that no positive test results be given to clients/patients until a screening test has been repeatedly reactive (i.e., greater than or equal to two tests) on the same specimen and a supplemental, more specific test such as the Western blot has been used to validate those results

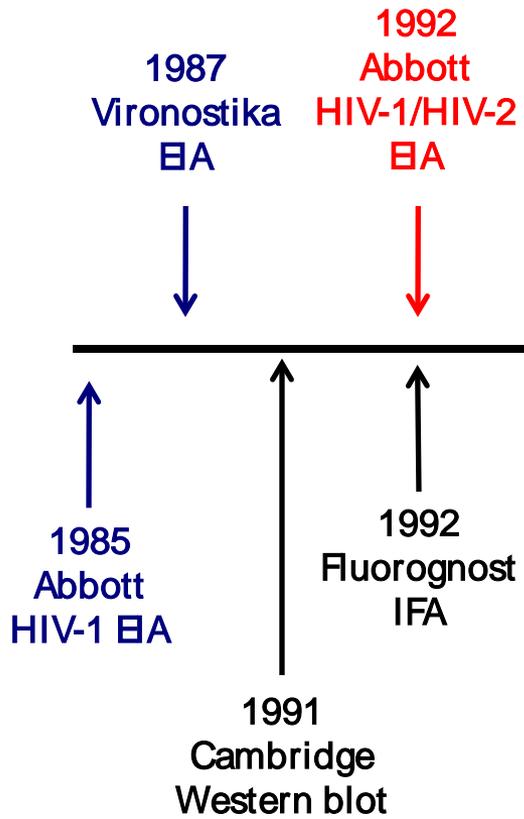
1989 Almanac

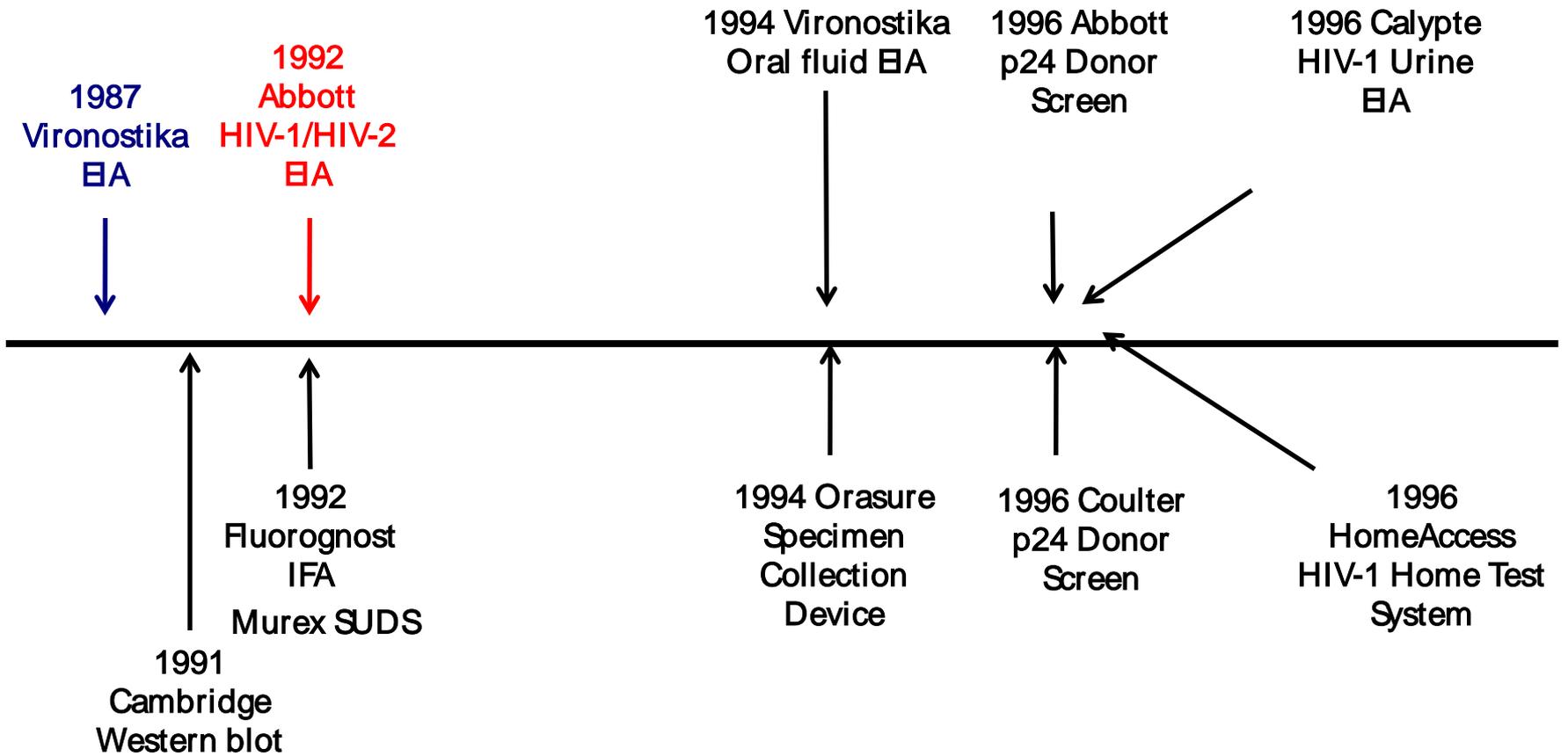


- Berlin Wall dismantled
- Tiananmen Square
- Exxon Valdez
- U.S. invades Panama

Also State of the Art in 1989







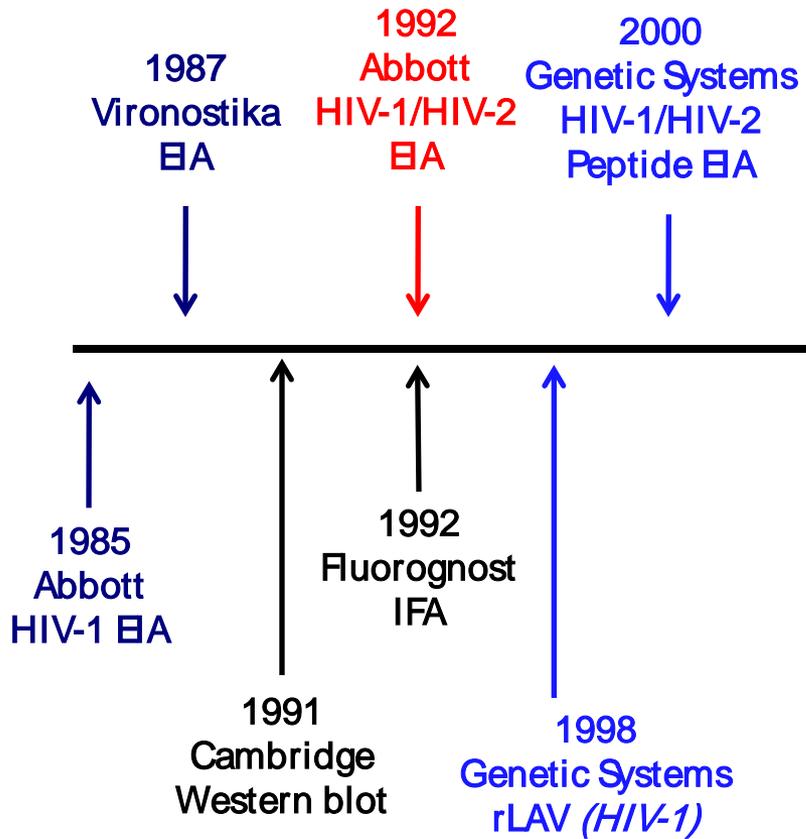


1996 Almanac

- U.S. Government shutdown
- Boris Yeltsin re-elected
- Mad cow disease strikes Britain
- Militant Taliban seize Kabul
- U.S. invades no one

Evolution of HIV Tests

- 1st generation: whole viral lysate, detects IgG antibody
- 2nd generation: synthetic peptides, detects IgG antibody



MNWR™

MORBIDITY AND MORTALITY WEEKLY REPORT

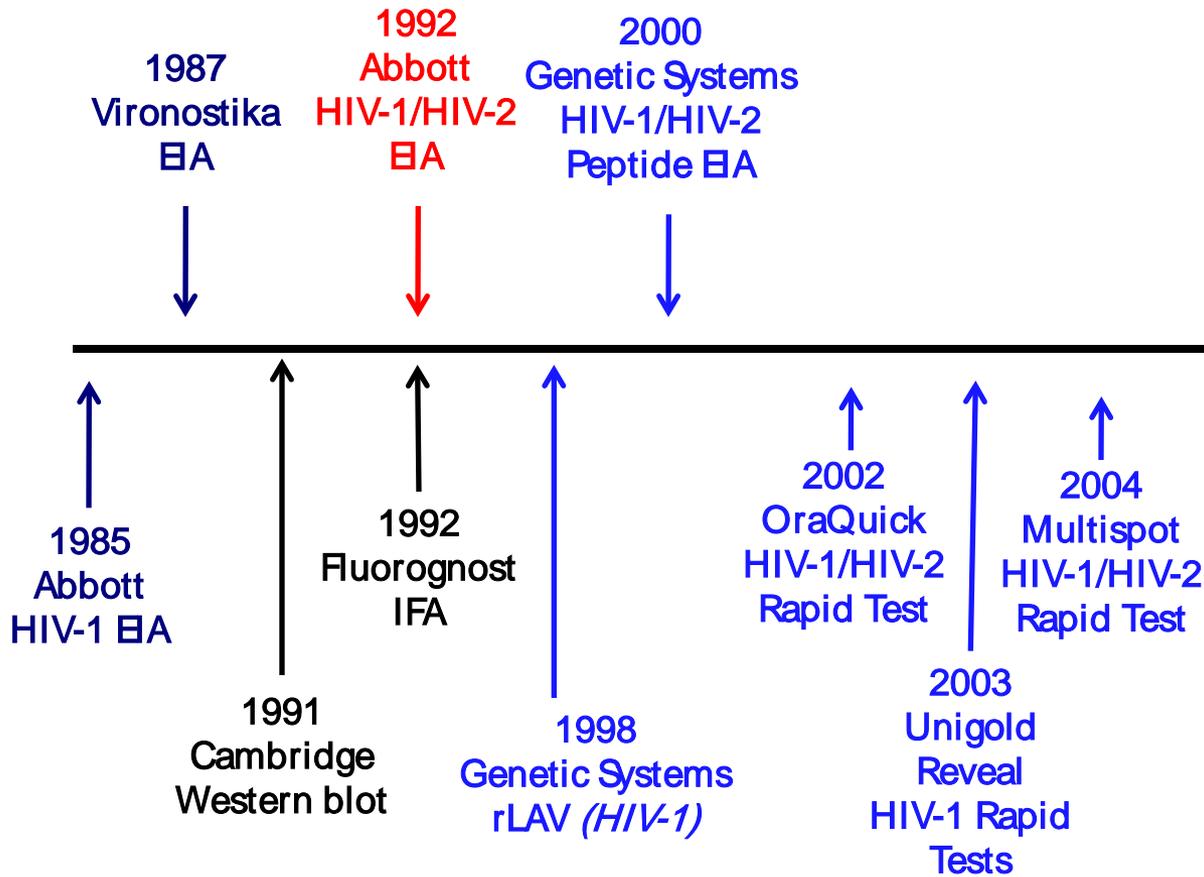
- 209 Imported Dracunculiasis — United States, 1995 and 1997
- 211 Update: HIV Counseling and Testing Using Rapid Tests — United States, 1995
- 215 Strategies for Providing Follow-Up and Treatment Services in the National Breast and Cervical Cancer Early Detection Program — United States, 1997
- 218 World Health Day — April 7, 1998
- 219 Notices to Readers

Update: HIV Counseling and Testing Using Rapid Tests — United States, 1995

Approximately 25 million persons each year in the United States are tested for antibody to human immunodeficiency virus (HIV). Publicly funded counseling and testing (CT) programs conduct approximately 2.5 million of these tests each year. CT can have important prevention benefits (1); however, in 1995, 25% of persons testing HIV-positive and 33% of persons testing HIV-negative at publicly funded clinics did not return for their test results (2). Rapid tests to detect HIV antibody can be performed in an average of 10 minutes (3), enabling health-care providers to supply definitive

New Recommendation

- Health-care providers should **provide preliminary positive test results** before confirmatory results are available in situations where tested persons benefit.





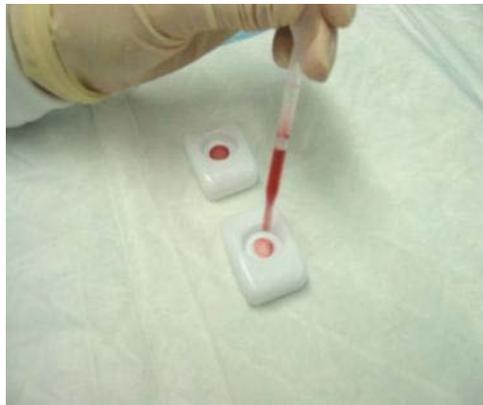
OraQuick Advance



Multispot HIV-1/HIV-2



Clearview Complete



MedMira Reveal G3



INSTI



Chembio Stat Pak

2nd Generation

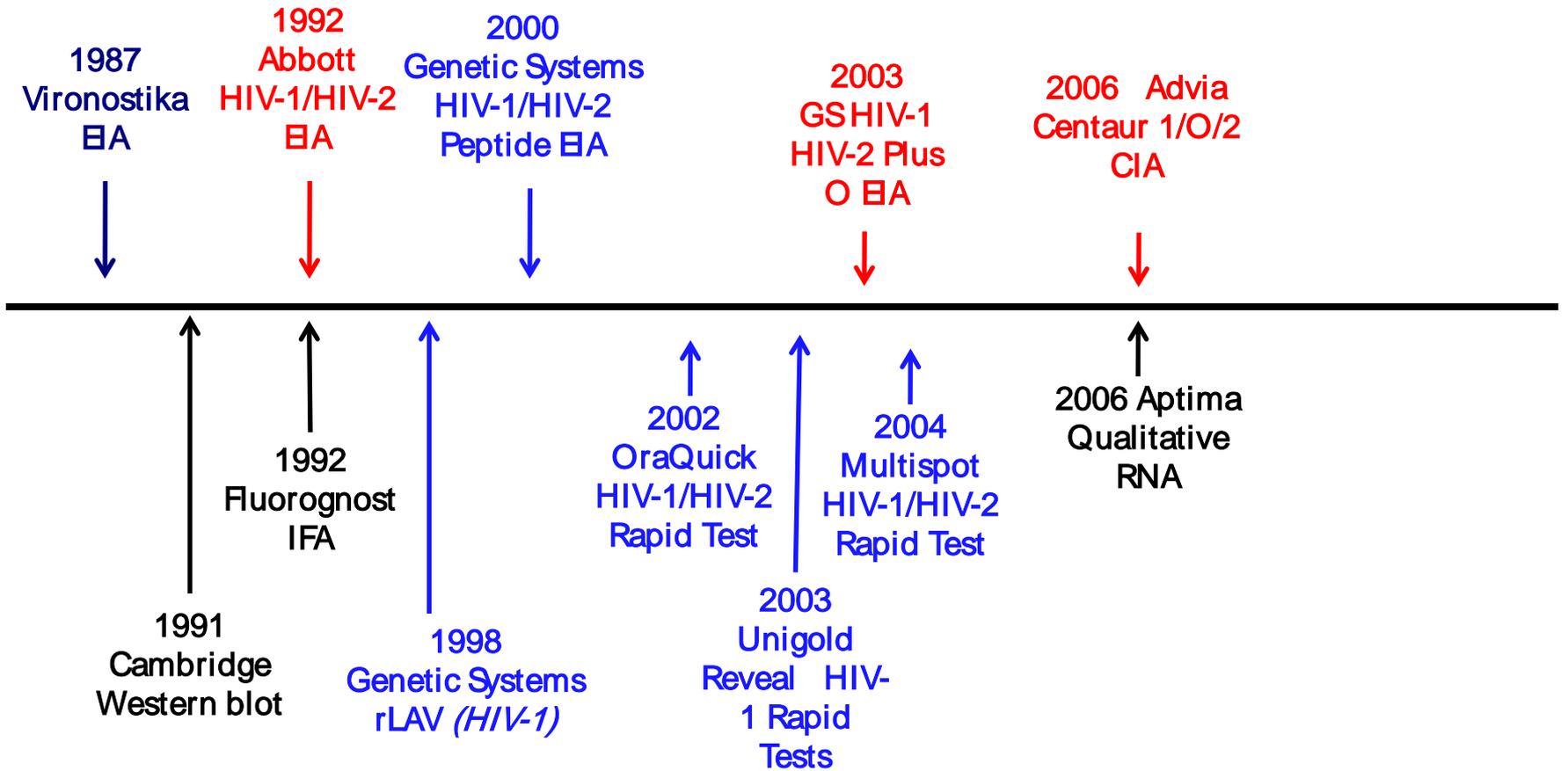
2004 Almanac



- Department of Homeland Security Established
- Euro adopted by the EU
- Enron collapses
- U.S. invades Iraq

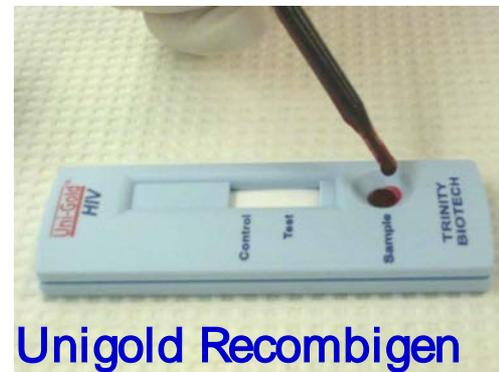
Evolution of HIV Tests

- 1st generation: whole viral lysate, detects IgG antibody
- 2nd generation: synthetic peptides, detects IgG antibody
- 3rd generation: detect IgM and IgG antibody





Bio-Rad GSHIV-1/2 *PLUS O*
2003



Unigold Recombigen
2003



Siemens Advia Centaur
2006



Ortho Vitros
2008

3rd Generation



**Abbott Architect Ag/Ab Combo
2010**



**Siemens Advia Centaur
2006**



**Ortho Vitros
2008**



Random Access Multiplatform
analyzers for HIV testing

On-board Refrigeration of Multiple Different Assays

A close-up photograph of a person wearing a white lab coat and a white glove, loading a sample into a multiplatform analyzer. The analyzer is a white, modern-looking machine with a large opening on the right side. Inside the opening, several sample tubes are visible, some with yellow caps. The person's hand is positioned to insert a sample into one of the tubes. The background is slightly blurred, showing a laboratory setting.

Random Access Multiplatform
analyzers for HIV testing

STAT sample requests without pausing
Results in < 60 minutes

Evolution of HIV Tests

- 1st generation: whole viral lysate, detects IgG antibody
- 2nd generation: synthetic peptides, detects IgG antibody
- 3rd generation: detect IgM and IgG antibody
- 4th generation: detects IgM, IgG antibodies, p24 antigen

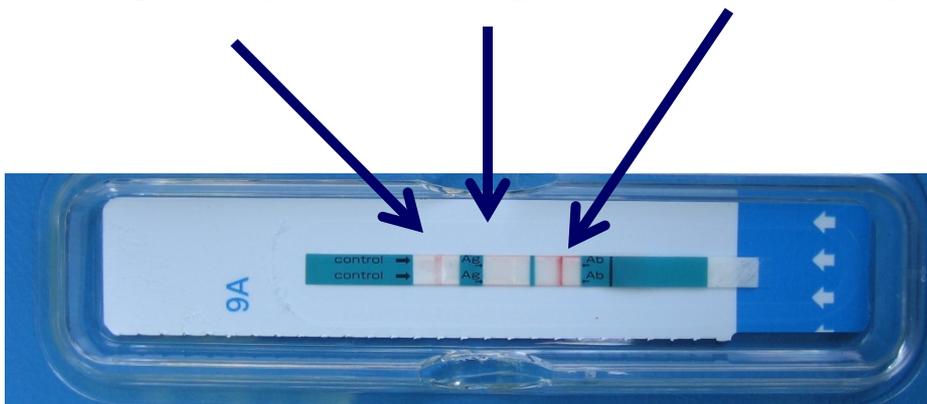


Abbott Architect Ag/Ab Combo
2010



Bio-Rad Ag/Ab Combo
2011

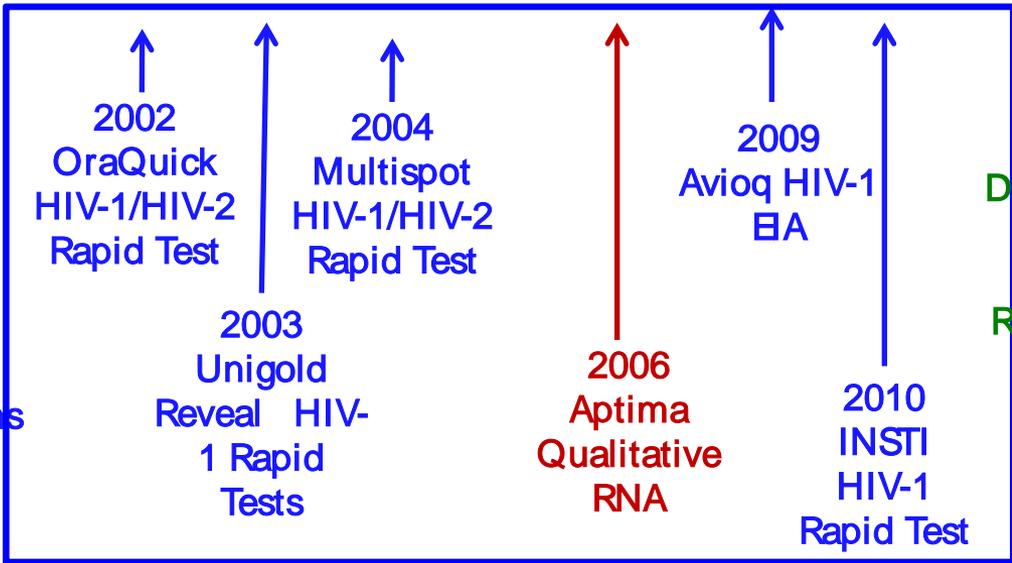
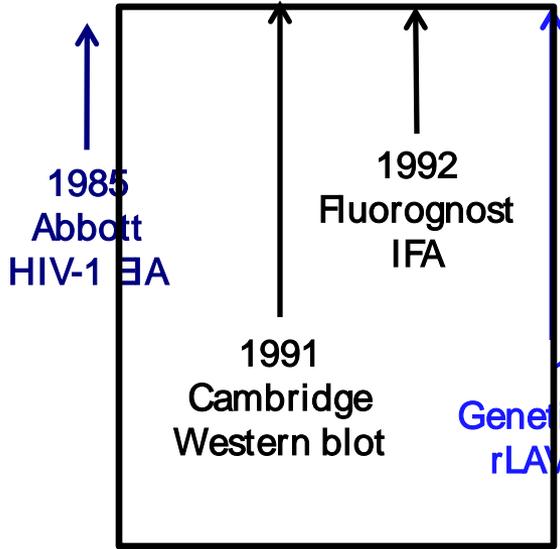
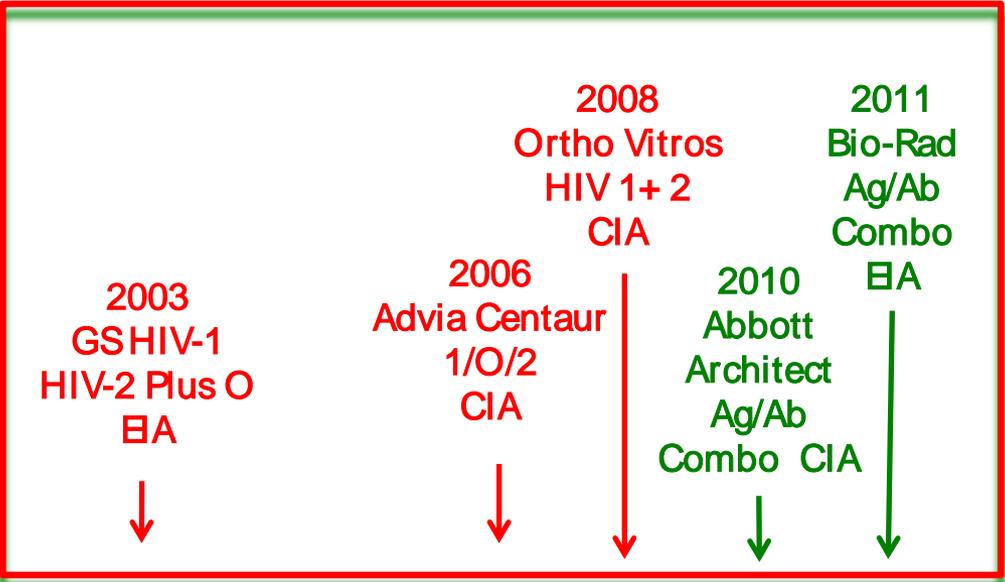
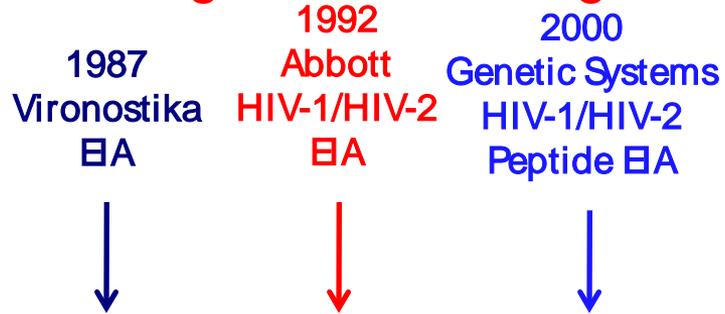
Control Antigen Antibody



Determine Combo Ag/Ab Rapid Test
2013

4th Generation

3rd & 4th gen lab screening tests



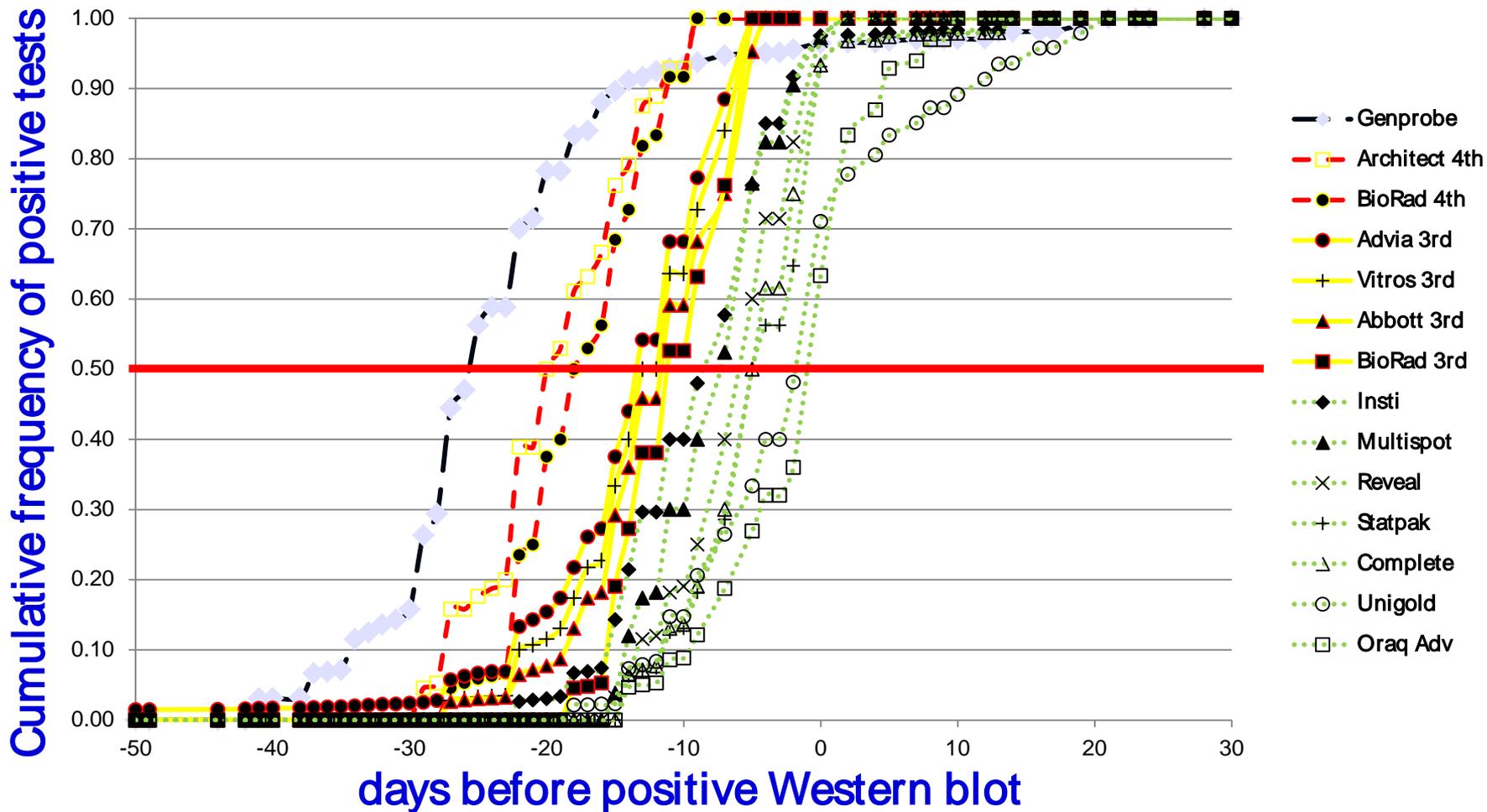
1st gen confirmatory tests

2nd gen rapid tests

Limitations of the 1989 Algorithm

- Antibody tests do not detect infection in $\sim 10\%$ of infected persons at highest risk of transmission
- Western blot confirmation is less sensitive during early infection than many widely used screening tests
- Western blot misclassifies as HIV-1 $> 60\%$ of HIV-2 infections

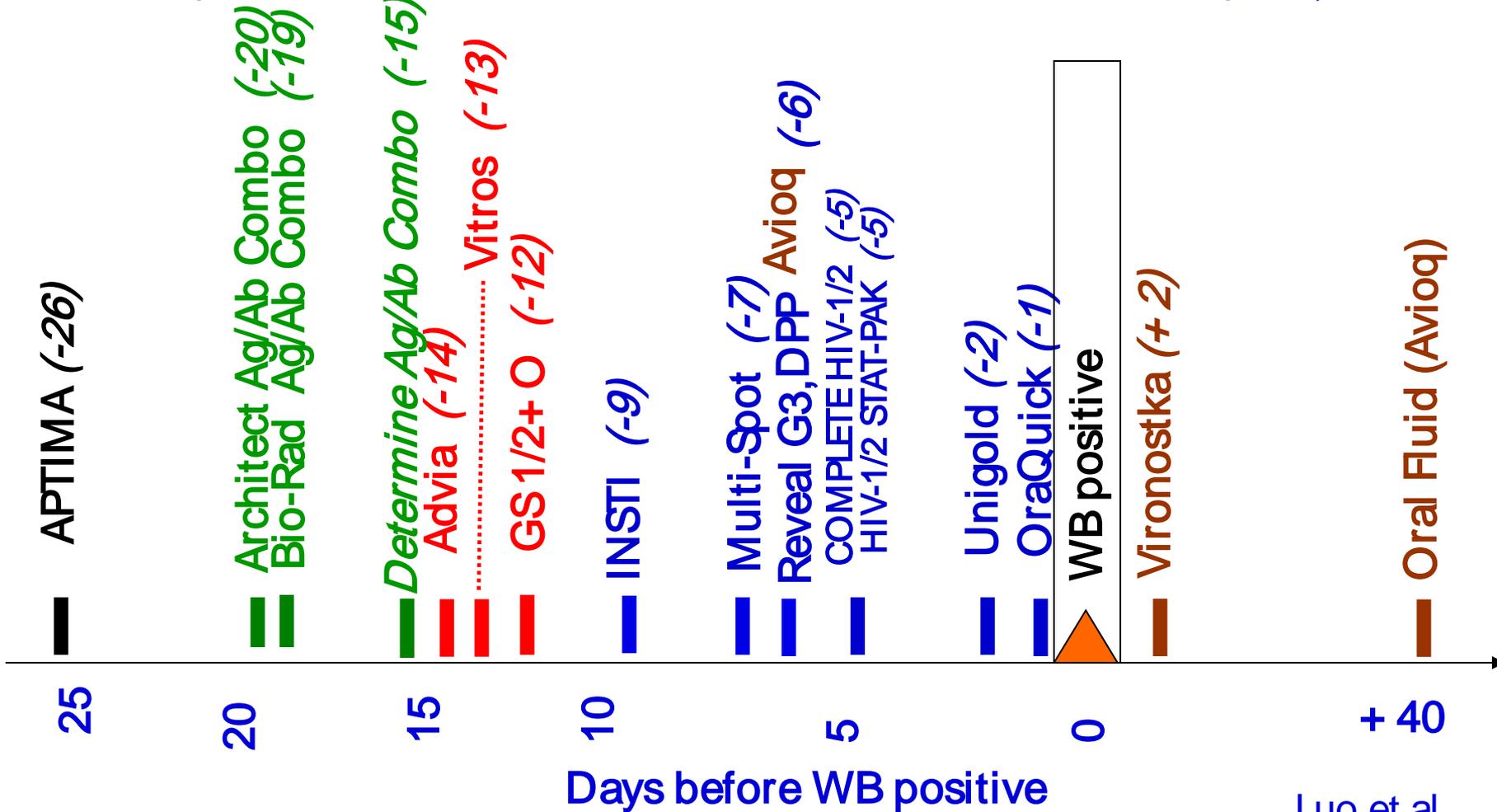
Relative Seroconversion Sensitivity (Plasma)



- 26 seroconverters were analyzed with 14 tests
- 17 seroconverters with WB positive used for cumulative frequency analysis

Sequence of Test Positivity Relative to WB (plasma)

166 specimens, 17 Seroconverters - 50 % Positive Cumulative Frequency



Modified from *Masciotra et al, J Clin Virol 2011, 2013*
and *Owen et al, J Clin Micro 2008*

Luo et al,
J Clin Virol
2013

Why Does It Matter?

- Sensitivity among frequently-tested MSM in Seattle
 - 192 infected with HIV
 - 23 (12%) detected only by RNA
 - *(15/16 tested detected by Ag/Ab immunoassay)*
 - 169 (88%) detected by serum Ab immunoassay
 - 153 (80%) detected by oral fluid rapid test

- *Stekler et al, Clin Inf Dis 2009*

HIV-2 Infection

- ❑ **Remains uncommon in U.S., but**
 - Does not respond to NNRTIs, some PIs (first line therapy)
 - Undetectable by HIV-1 viral load tests

- ❑ **Misclassification by HIV-1 Western blot:**
 - 54/58 (93%) HIV-2 patients tested had positive HIV-1 WB (NYC)*
 - 97/163 (60%) HIV-2 cases reported had positive HIV -1 WB (CDC)**

- ❑ **HIV-2 often diagnosed after immunologic deterioration in patient with negative viral load**

**Torian et al, Clinical Infectious Disease 2010*

***MMWR July 2011*

Laboratory Testing for the Diagnosis of HIV Infection

Updated Recommendations

Published June 27, 2014

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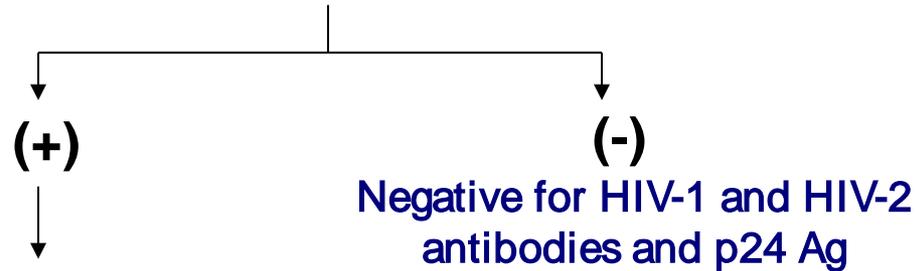
Kelly E. Wroblewski, MPH^b

Michael A. Pentella, PhD^{b,e}

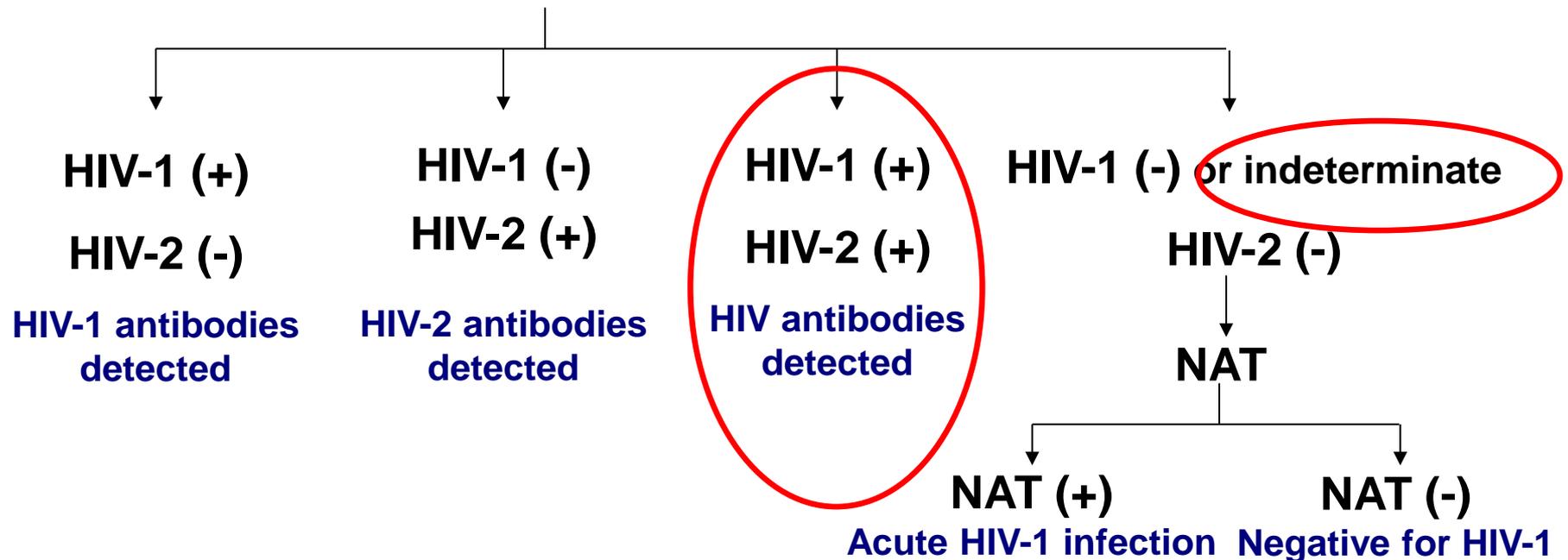


Centers for Disease
Control and Prevention
National Center for HIV/AIDS,
Viral Hepatitis, STD, and
TB Prevention

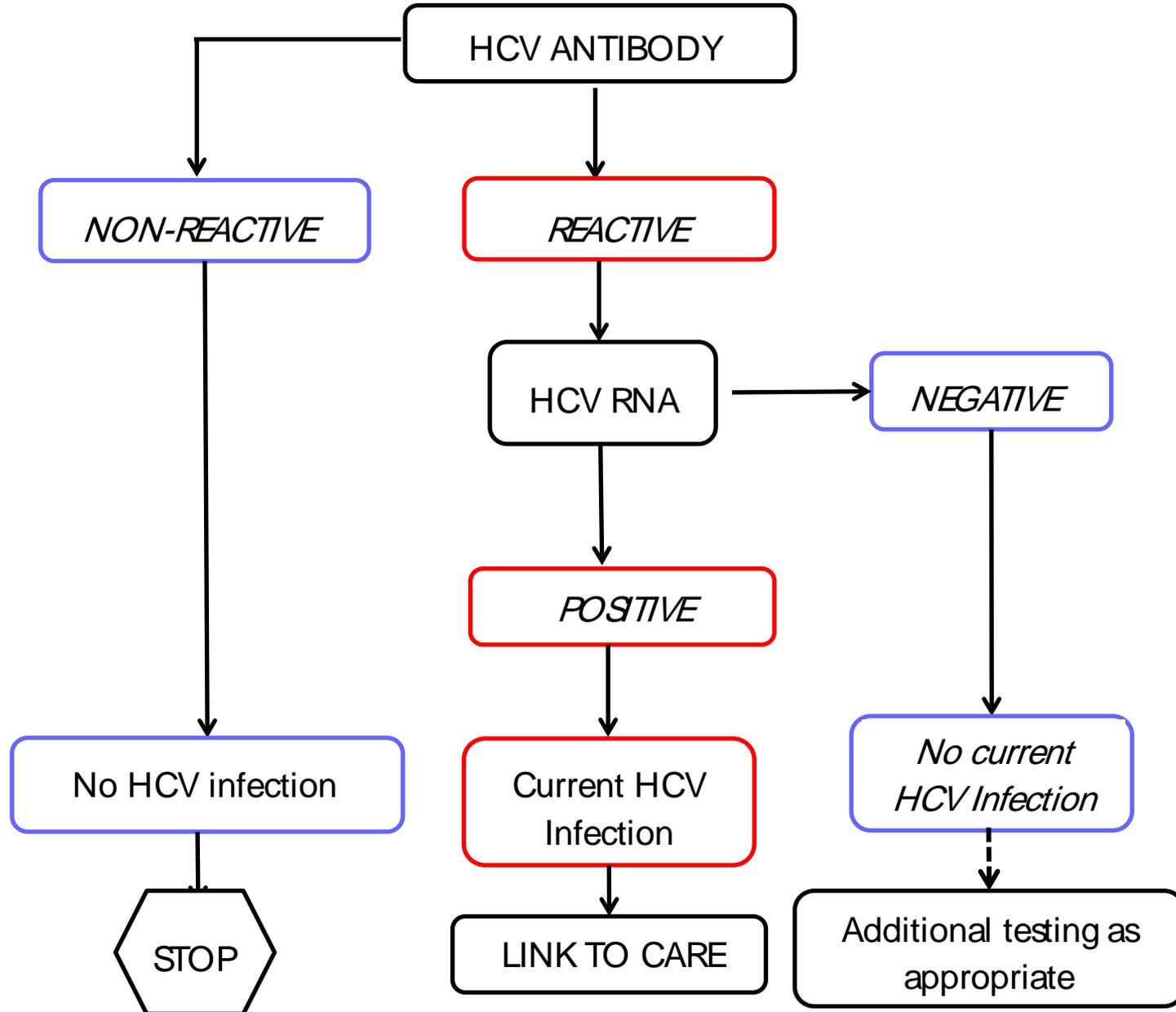
HIV-1/2 Combination Ag/Ab immunoassay



HIV-1/HIV-2 antibody differentiation immunoassay



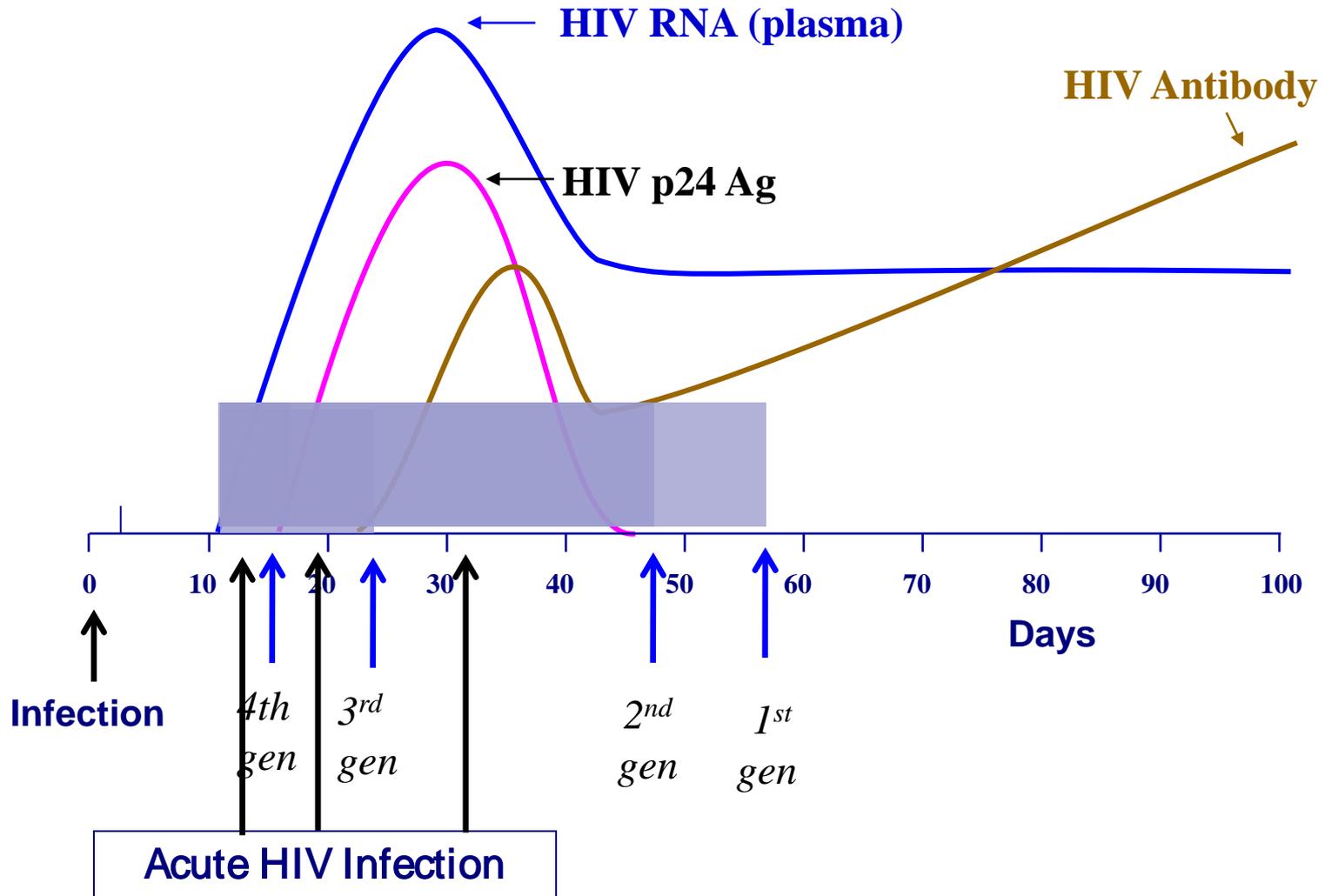
Laboratory testing to identify HCV infection



Nucleic Acid Test (NAT) for Diagnosis

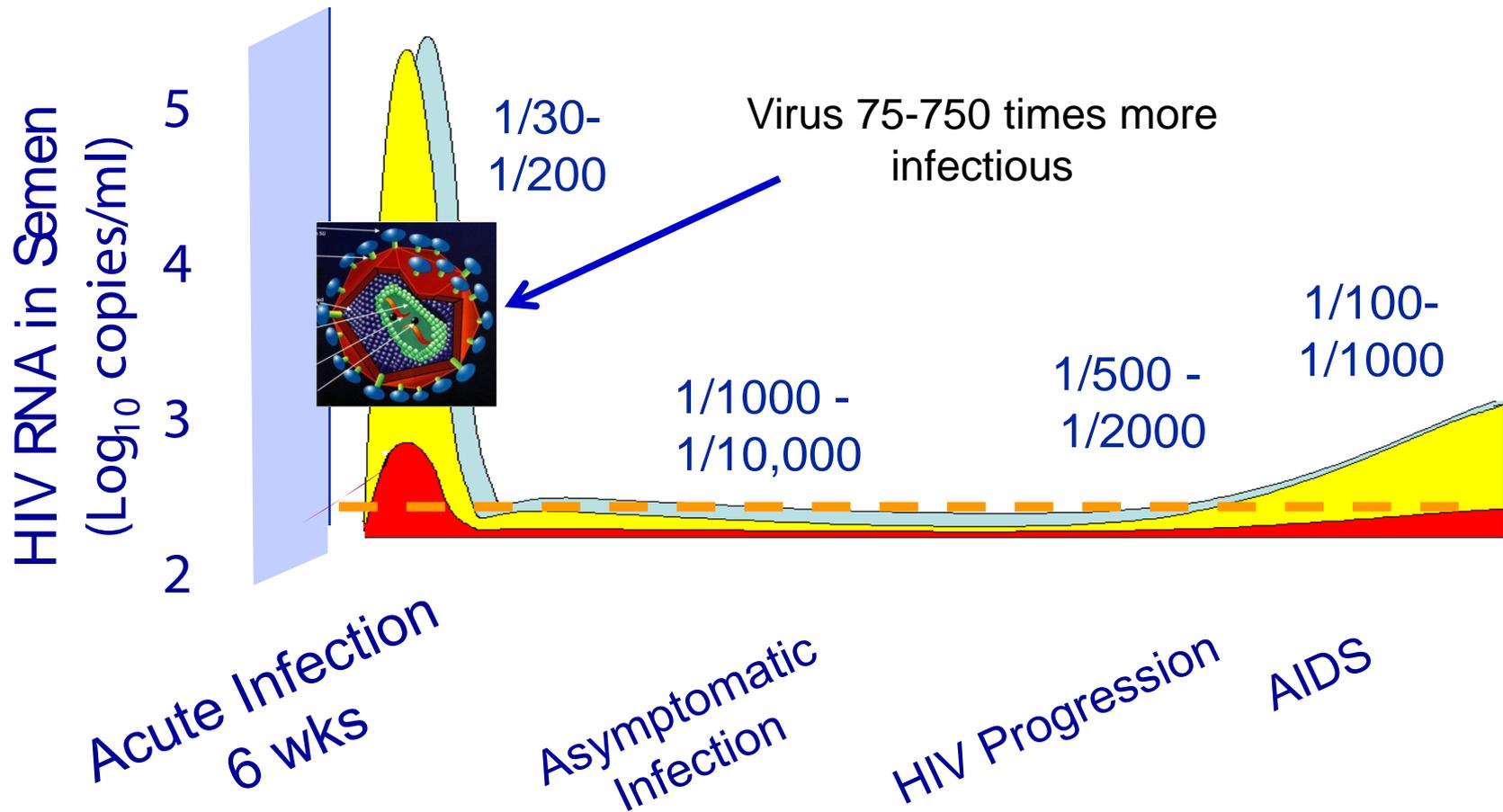
- APTIMA HIV-1 qualitative RNA assay is only NAT FDA-approved for diagnosis
- Viral load tests: Clinicians can order them, but labs cannot use them as a reflex part of the algorithm

HIV Infection and Laboratory Markers

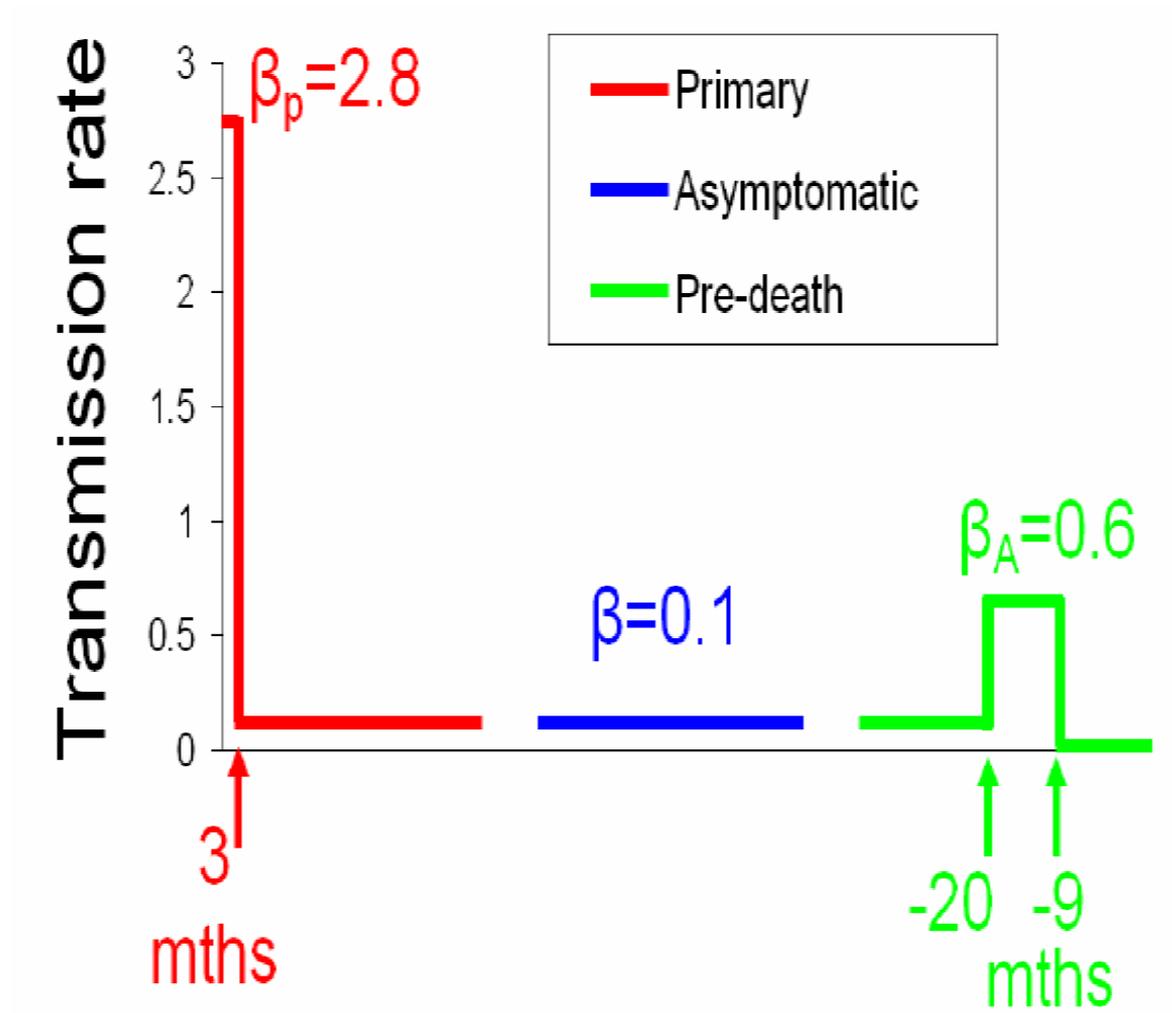


Modified after Busch et al. *Am J Med.* 1997

Acute HIV: Risk of Sexual Transmission



Transmission Rate by Stage of Infection



Phoenix ED Screening July 2011 through February 2013

- 4th gen screening of patients who had blood drawn
 - 15% of patients declined testing
 - 13,014 patients tested
 - 37 (0.3%) new HIV infections
 - 12 (32.4%) had Acute HIV Infection (antibody negative)

- Median viral load:
 - Patients with acute infections: 6 million
 - Patients with established infections: 25,000

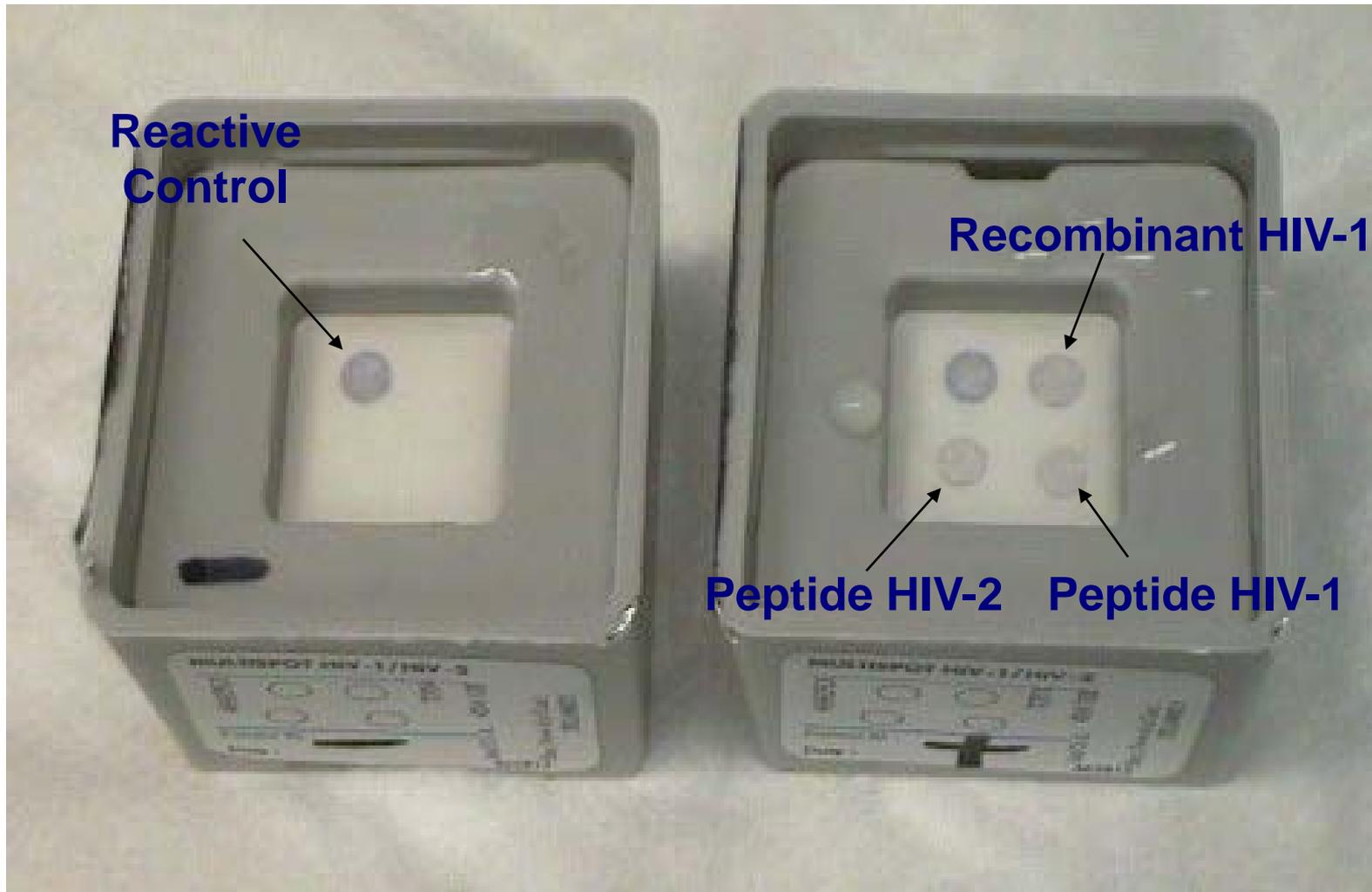
Acute HIV: Partner Notification

- Persons with acute HIV infection named
 - 2.5 times as many sex partners
 - 1.9 times as many partners newly diagnosed with HIV

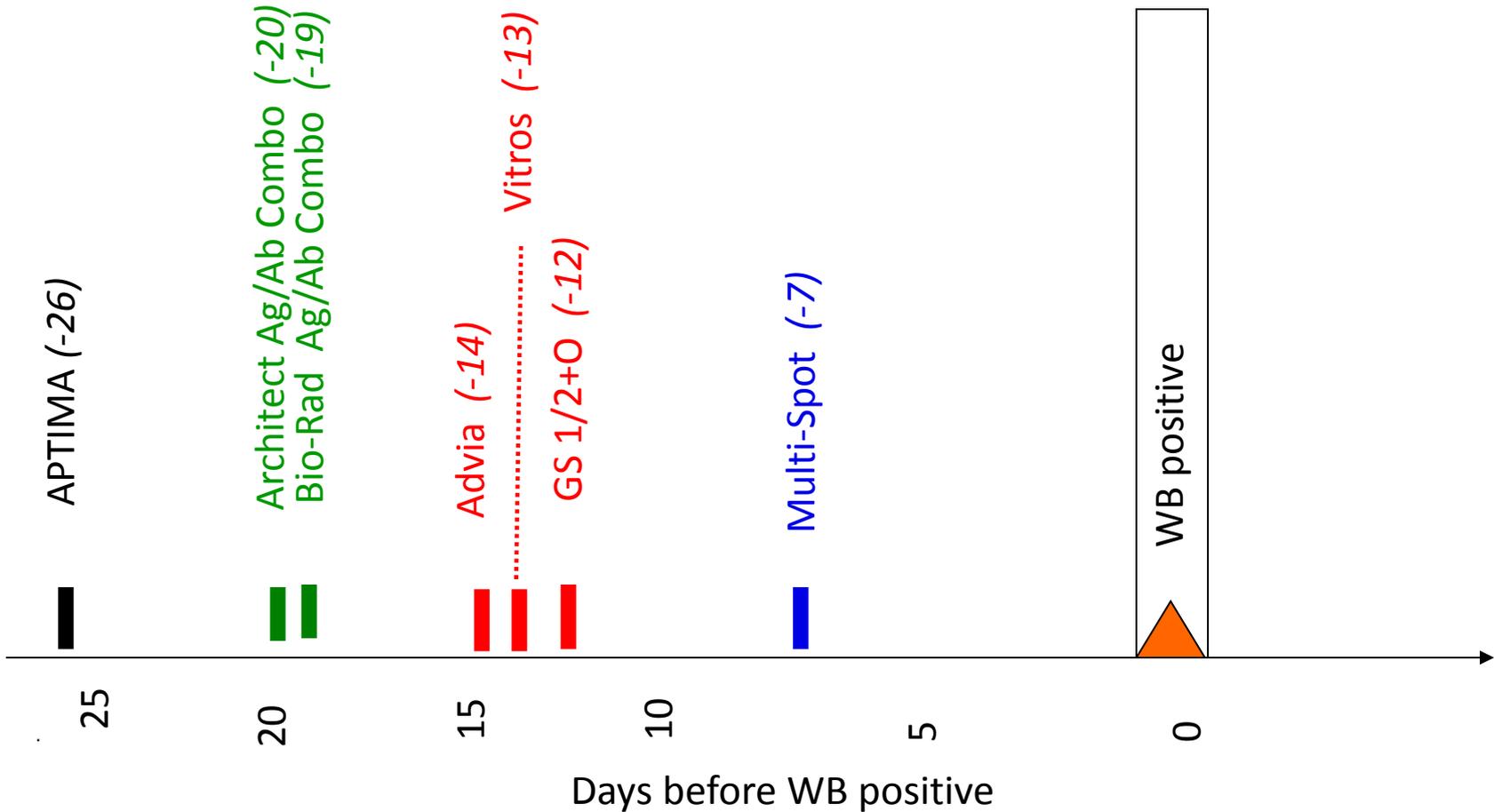
...as did persons with new diagnosis of established HIV infection

Moore et al, JAIDS 2009

FDA-approved HIV-1/HIV-2 Antibody Differentiation Assay



Major change with new algorithm: Continue beyond IgG serology



Where's My Western Blot?

What HIV Specialists Need to Know about
Updated HIV Testing Recommendations





**Support
GROUP**



Geenius™ HIV 1/2 Supplemental Assay

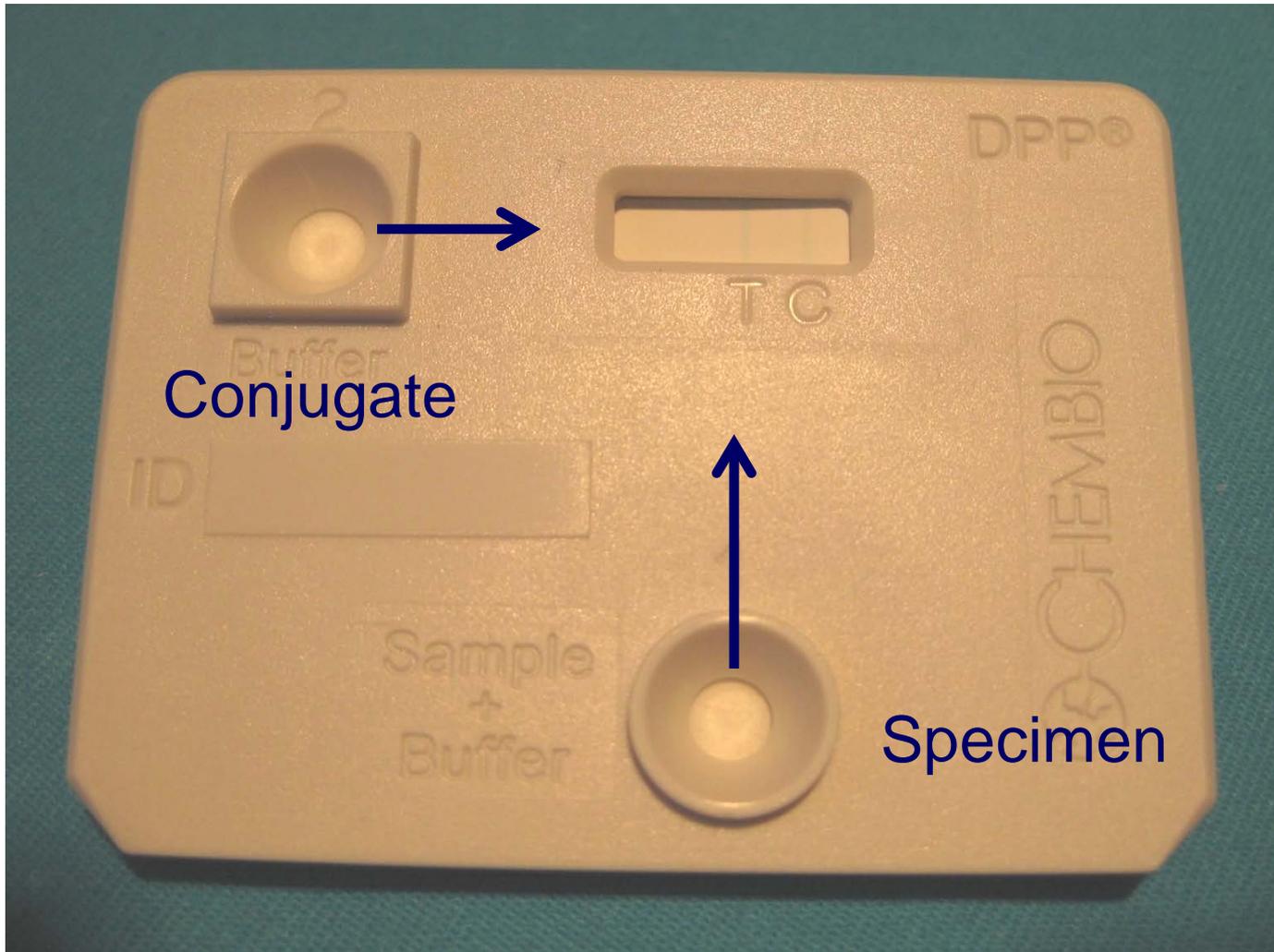
The Geenius HIV-1/2 Cassette

Dual Path Platform (DPP^R) licensed from CHEMBIO Diagnostic Systems, Inc.



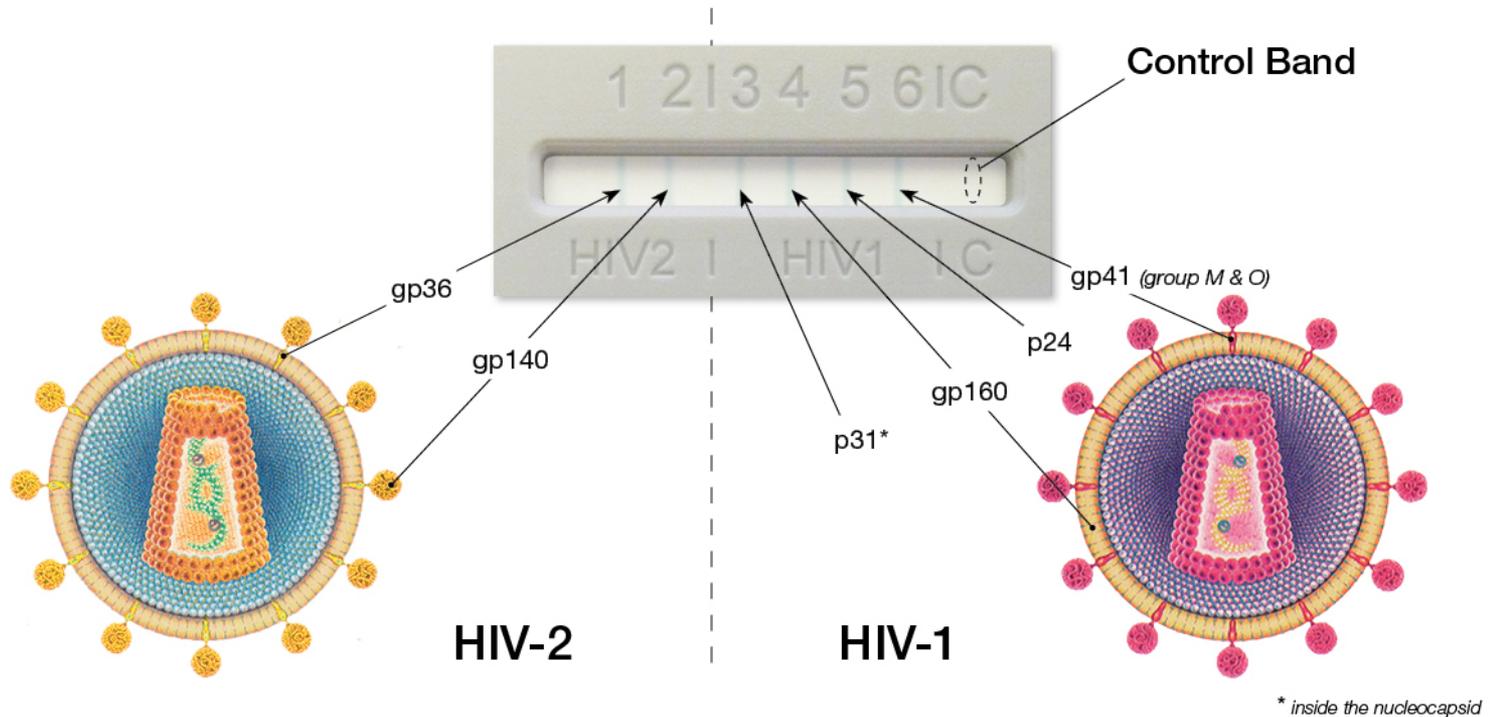
- Whole blood, fingerstick, serum plasma
- FDA-approved October 24, 2014
- CLIA moderate complexity; potential for waiver

Dual Path Platform



The Geenius™ HIV-1/2 Lines

HIV-1 & HIV-2 Associated Lines

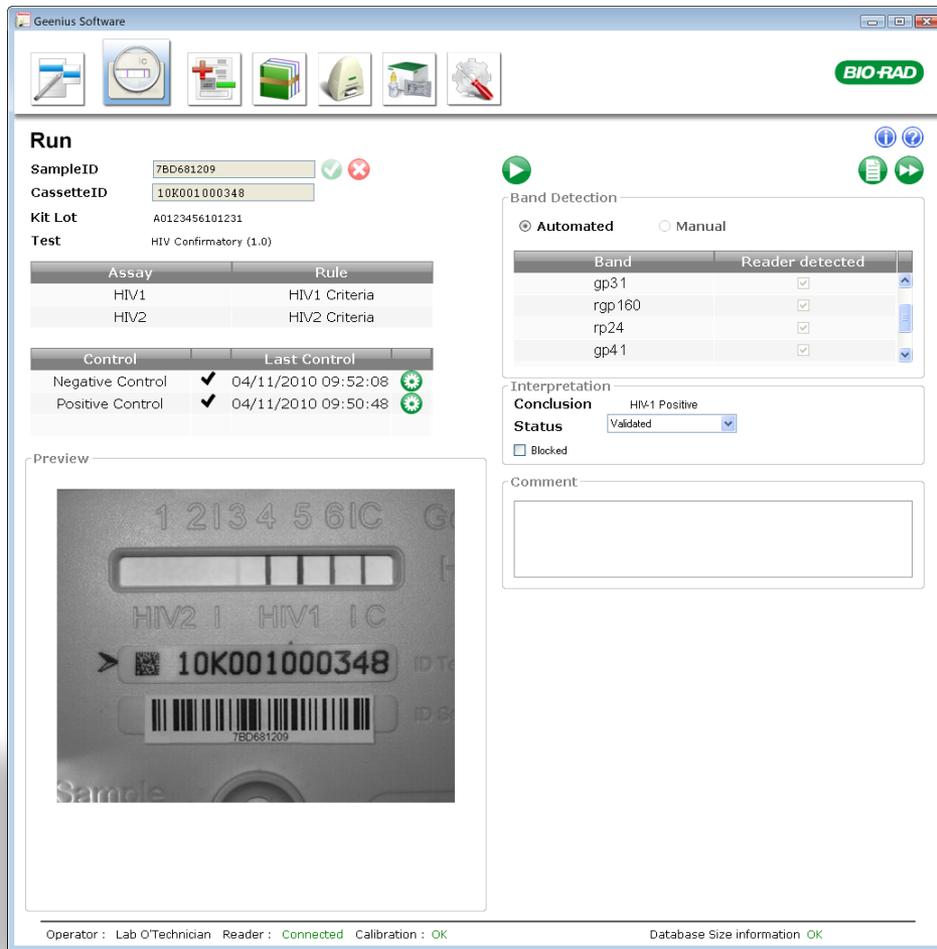


The Geenius Reader



- Automated reading and interpretation
- No visual reading
- Automatic Calibration
- LIS Connectivity
- USB connection to laptop computer containing Geenius software (provided)

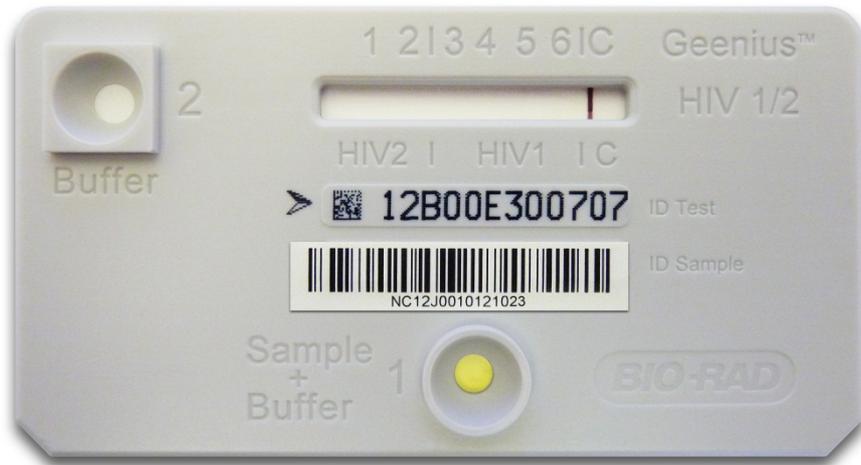
The Geenius Software



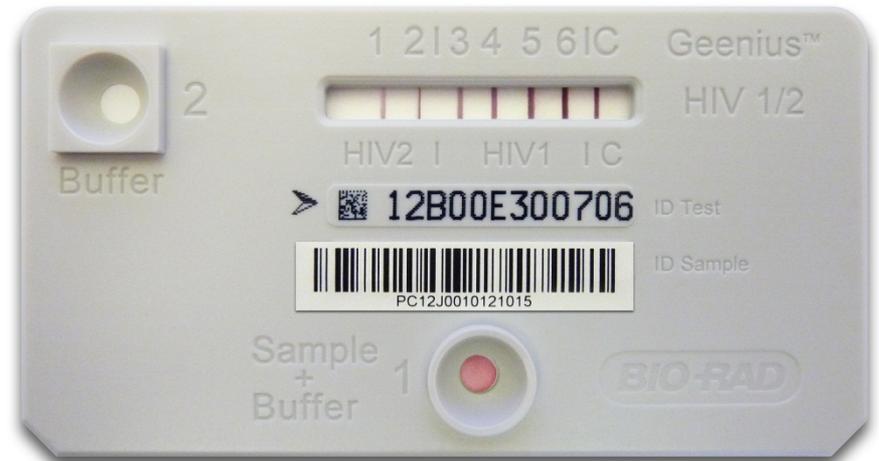
- Automated reading and validated results generation
- Pre-programmed and validated assay validity criteria
- Archiving of test results including a picture of each cassette

The Geenius HIV-1/2 Cassette : Assay Controls

- Built-in assay Control Line to demonstrate assay validity
- HIV Negative Control and combined HIV-1/2 Positive Control
- Fingertstick whole blood, serum, plasma
- Performed in 15 minutes



Negative Control



Positive Control

EDWARD R. ROYBAL
INFECTIOUS DISEASE
LABORATORY



- **Wait 5 minutes.** The blue colored TEST lines should have disappeared from the TEST window. If not, discard the test device and repeat the procedure with a new test device.
- NOTE: A slight bluish-greenish colour may remain on the membrane, but none of the actual colored lines should be seen at this point.
- Holding the dropper bottle VERTICALLY above the well ADD 5 DROPS of running buffer into the BUFFER WELL.
- **Wait 15 minutes.** Read the test results within 15 to 20 minutes of adding the Running Buffer to BUFFER Well.

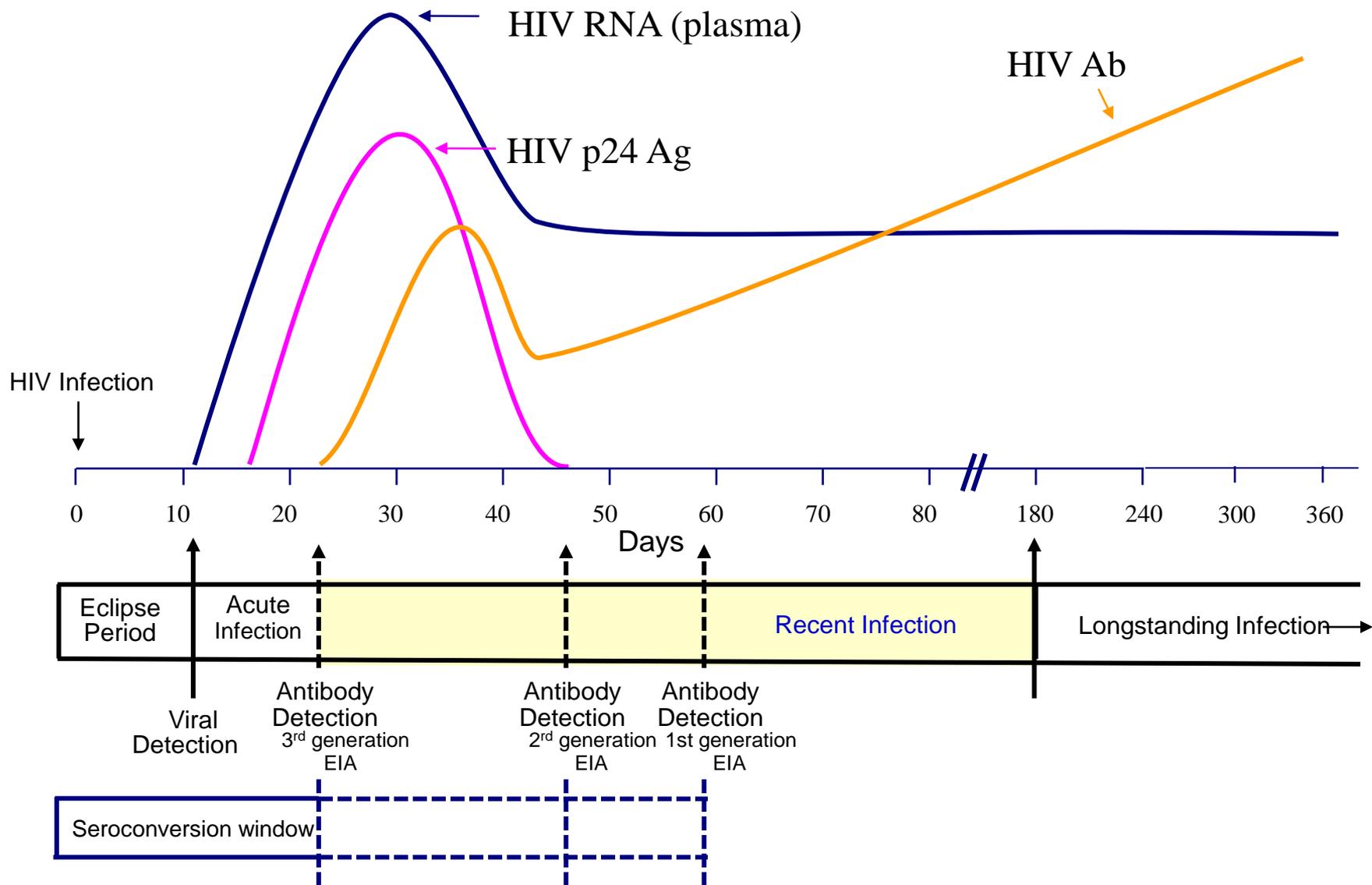
BUFFER WELL

BIO-RAD

For Research Use Only.
Not for use in diagnostic procedures.

Genieus Reader





Persons with HIV and Awareness of HIV Status, United States - 2011

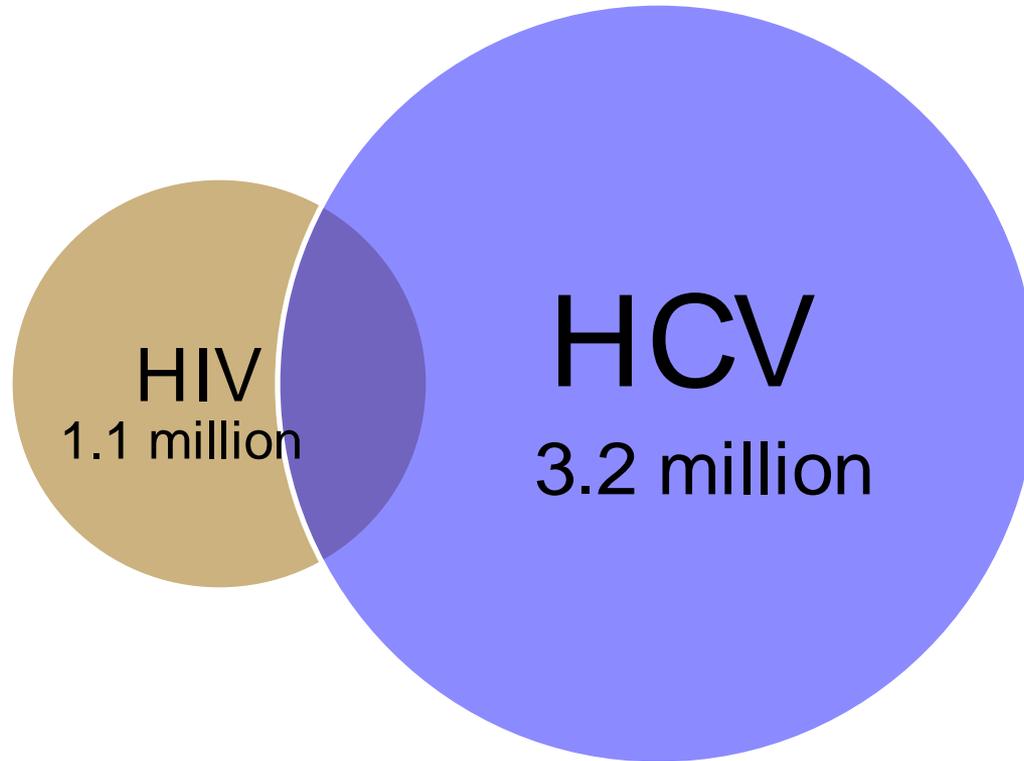
Number HIV infected	1,144,500
Number unaware of their HIV infection	180,831 (18 %)
Estimated new infections annually	47,500

Burden of HCV Infection and Disease

■ United States

- ~ 3.2 M (2.7-3.9) persons living with chronic HCV
- 16,000 deaths/year

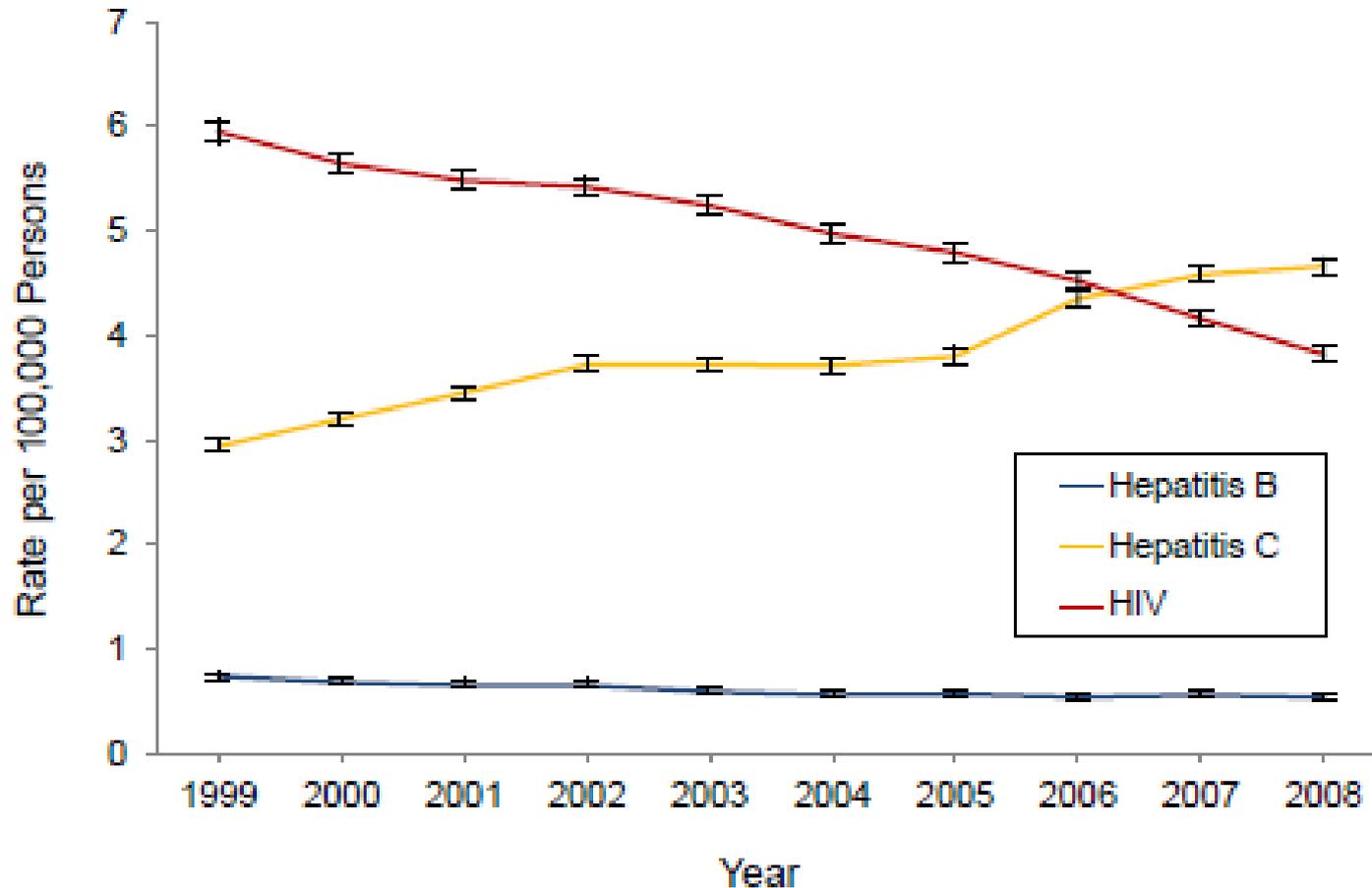
HCV in the Context of HIV in the US



HIV and HCV Co-infection

- Prevalence of co-infection varies by region
 - 25% of HIV infected persons in US
- HIV hastens progression of HCV related liver disease
- Liver disease is second leading cause of death for persons with HIV

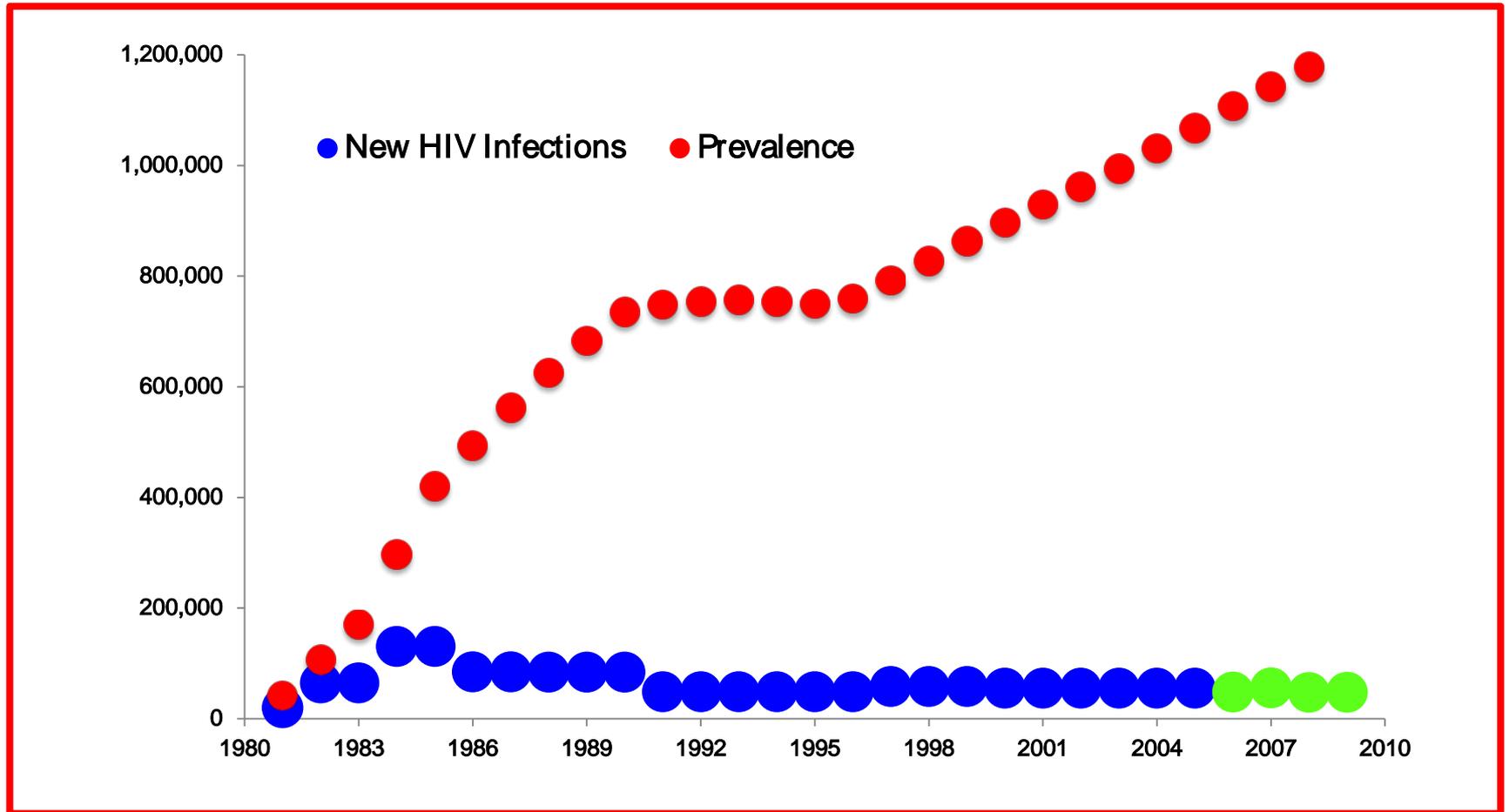
Mortality associated With Hepatitis B, Hepatitis C, and HIV, United States, 1999 – 2008



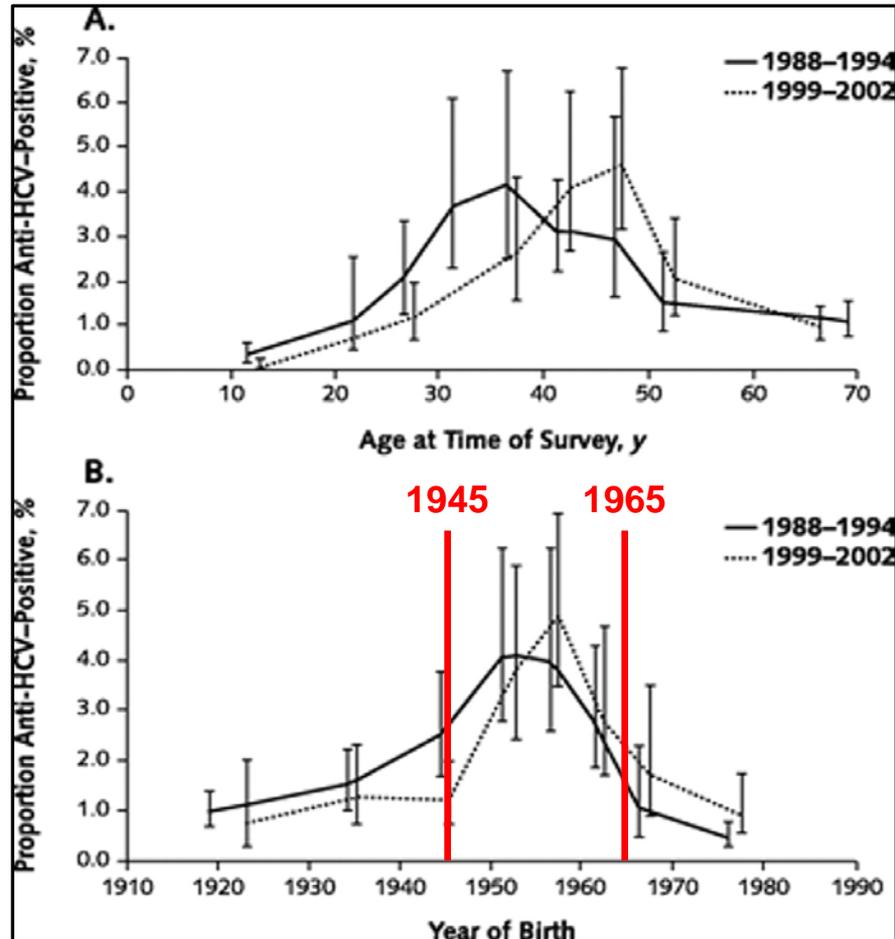
*

From: K Ly et al, *Ann Intern Med* 2012; 156:271-8

HIV Prevalence and Incidence



HCV Prevalence Among Persons Born 1920-1980



Terminology

- ***Targeted testing:*** performing a test on subpopulations of persons at higher risk based on behavioral, clinical or demographic characteristics
- ***Screening:*** performing a test for all persons in a defined population

Criteria that Justify Routine Screening

1. Serious health disorder that can be detected before symptoms develop
2. Treatment is more beneficial when begun before symptoms develop
3. Reliable, inexpensive, acceptable screening test
4. Costs of screening are reasonable in relation to anticipated benefits
5. Treatment must be accessible

*Principles and Practice of Screening for Disease
-WHO Public Health Paper, 1968*

Limited Effectiveness of Risk-based HCV Testing Strategies

- Prior CDC recommendations:
 - Injection drug use
 - Blood transfusion before 1992 and other blood exposures
 - Many clinicians are not aware of HCV testing guidelines
- Clinicians may be reluctant to ask about risks
- Patients may be reluctant to disclose or may not recall risks
- 45-85% are unaware of their HCV infection



MMWRTM

Morbidity and Mortality Weekly Report

Recommendations and Reports

September 22, 2006 / Vol. 55 / No. RR-14

Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings

Centers for Disease Control and Prevention

MMWR

Morbidity and Mortality Weekly Report

Recommendations and Reports / Vol. 61 / No. 4

August 17, 2012

Recommendations for the Identification of Chronic Hepatitis C Virus Infection Among Persons Born During 1945–1965



US Preventive Services Task Force

- 2013 Recommendation for HIV screening:
 - All pregnant women - Grade A
 - Persons at increased risk for HIV – Grade A
 - Adolescents and adults ages 15 to 65 years – Grade A

- 2013 Recommendation for HCV screening
 - Persons at increased risk: Grade B
 - Persons born between 1945-1965: Grade B



Screening: Cervical Cancer

	Cervical CA
Annual new cases	11,270
Deaths	4,070

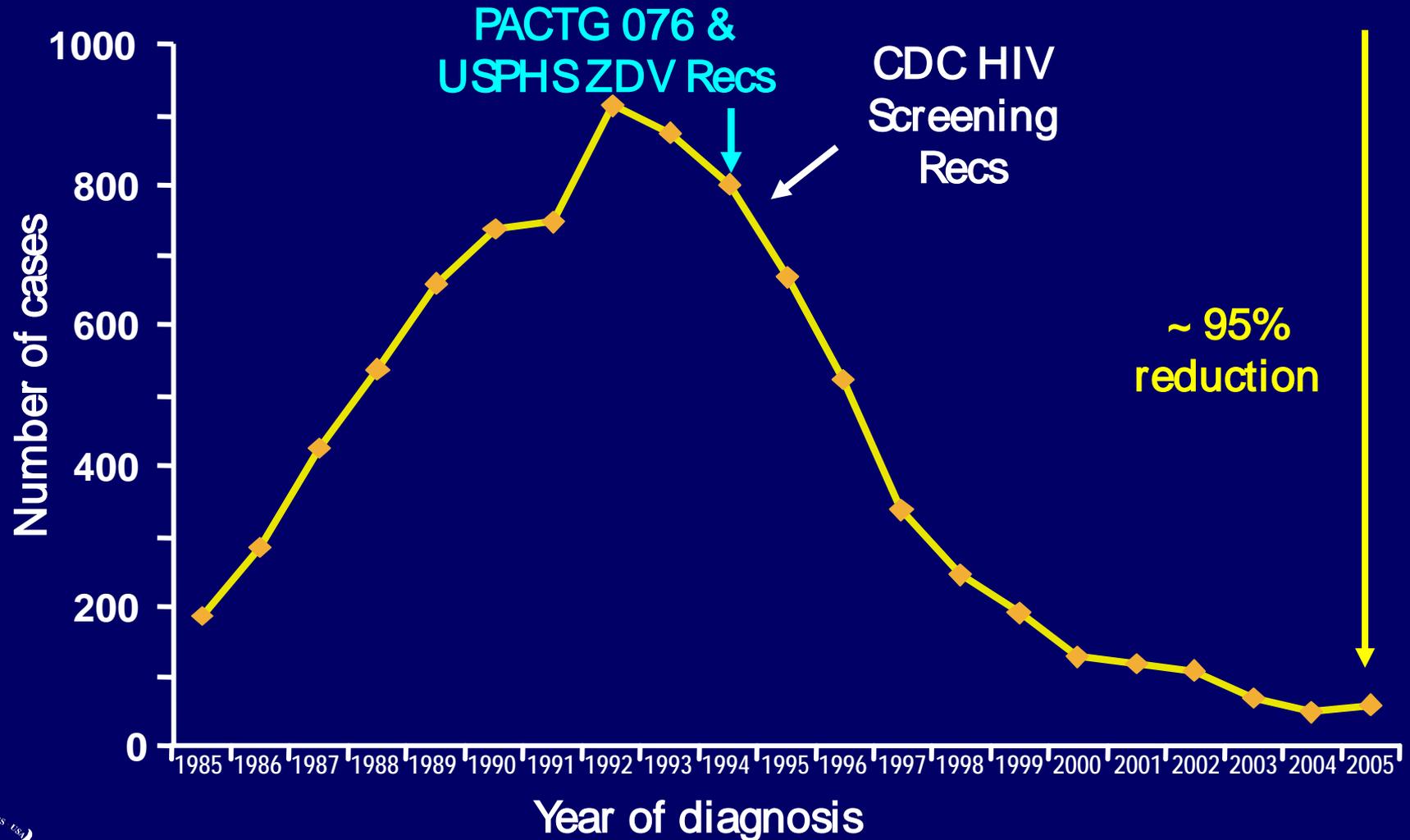
Screening: Cervical Cancer vs. HIV

	HIV	Cervical CA
Annual new cases	50,000	11,270
Deaths	15,564	4,070



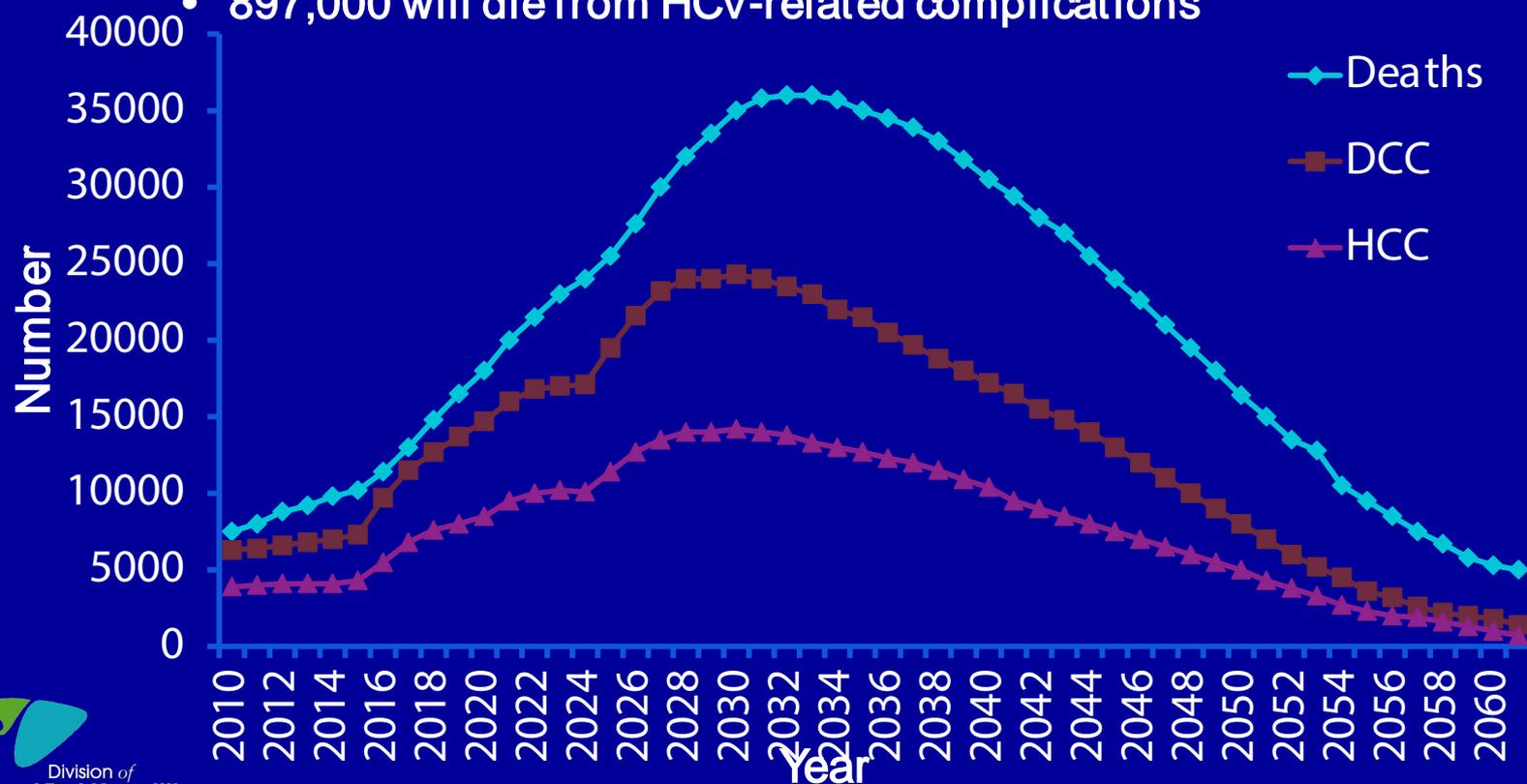
Screening works.

Estimated Number of Perinatally Acquired AIDS Cases, by Year of Diagnosis, 1985-2005 – United States



Future Burden of Hepatitis C Related Morbidity and Mortality in the US

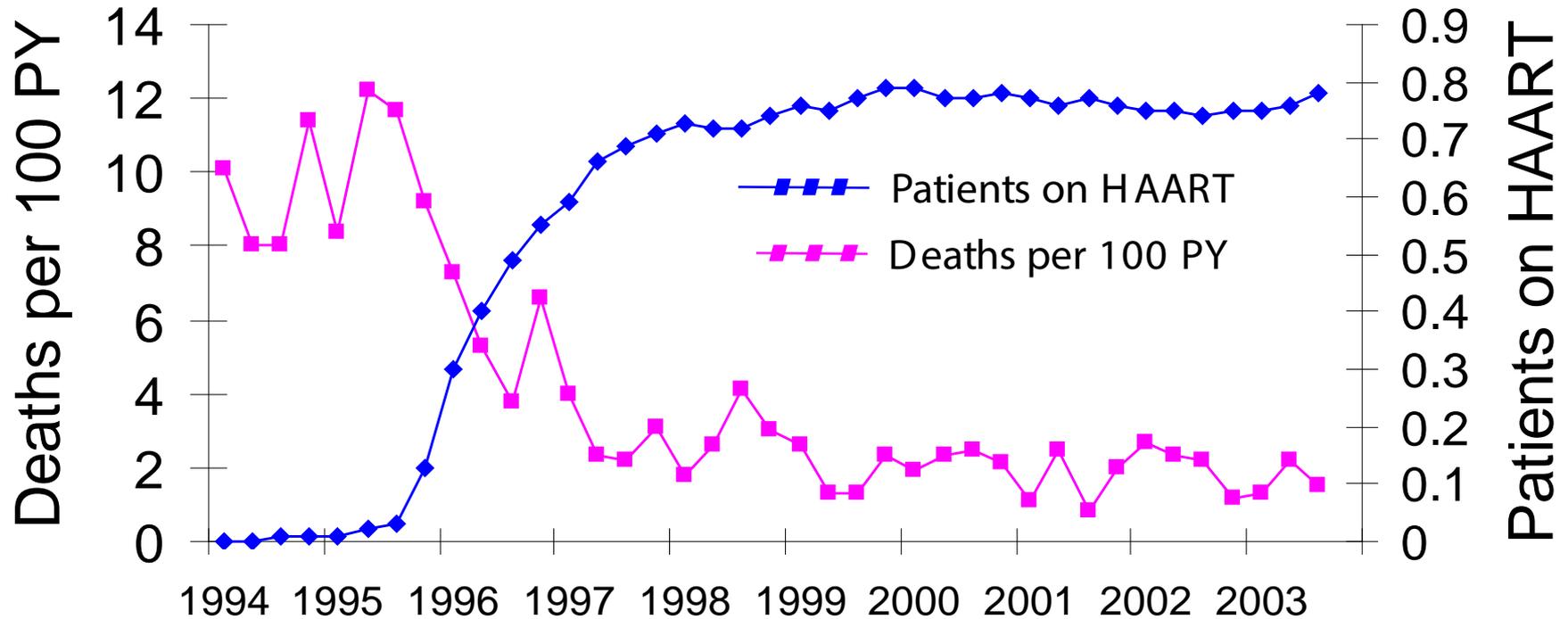
- Markov model of health outcomes
 - Of 2.7 M HCV infected persons in primary care
 - 1.47 M will develop cirrhosis
 - 350,000 will develop liver cancer
 - 897,000 will die from HCV-related complications



1. The Medical Rationale

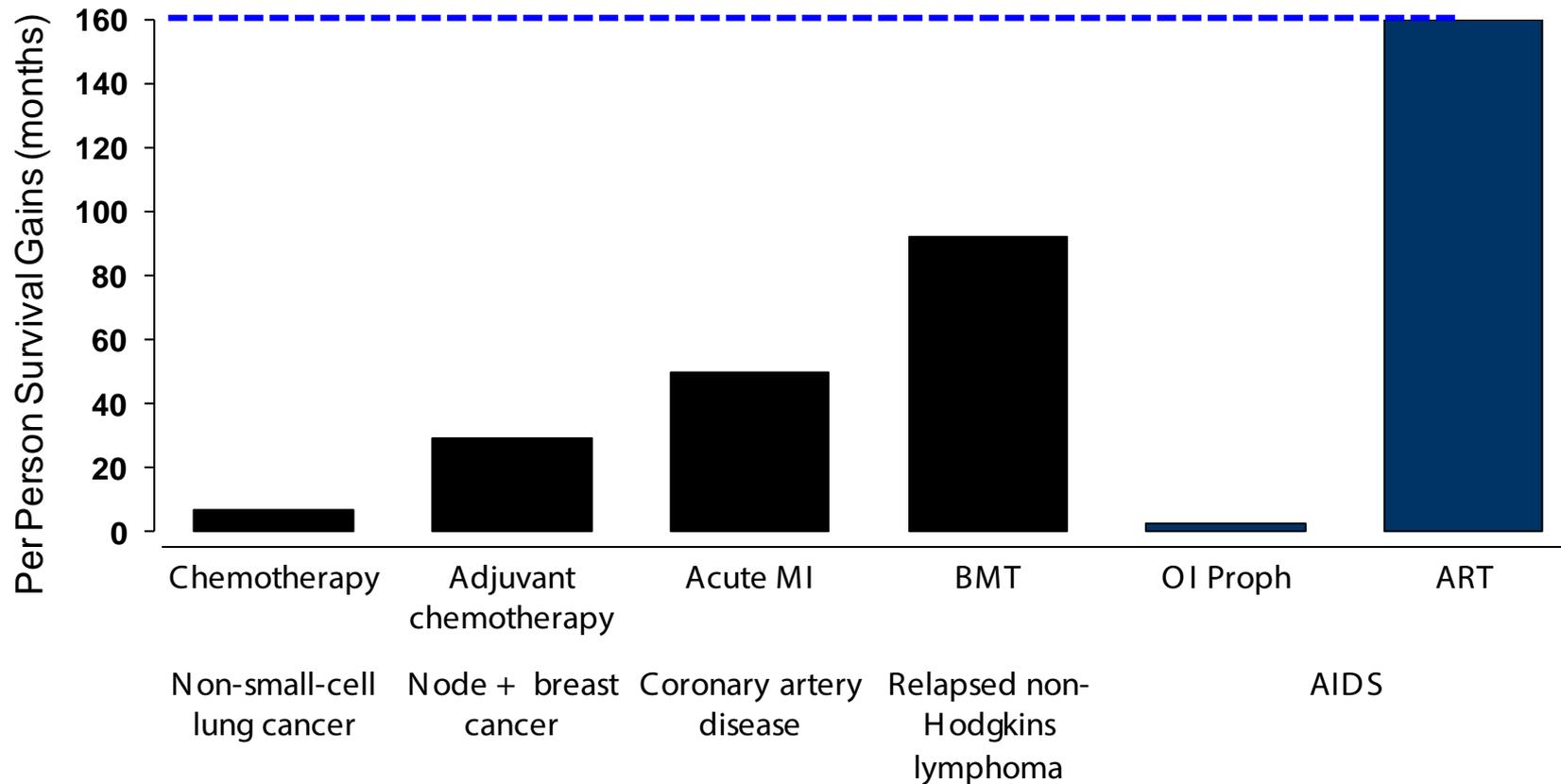
- Treatment is Effective.
- Treatment is recommended for everyone with HIV
 - *March 2012 – DHHS Treatment Guidelines*
- Treatment cures HCV

HIV Antiretroviral Therapy Improves Survival



Mortality and HAART Use Over Time
HIV Outpatient Study, CDC, 1994-2003

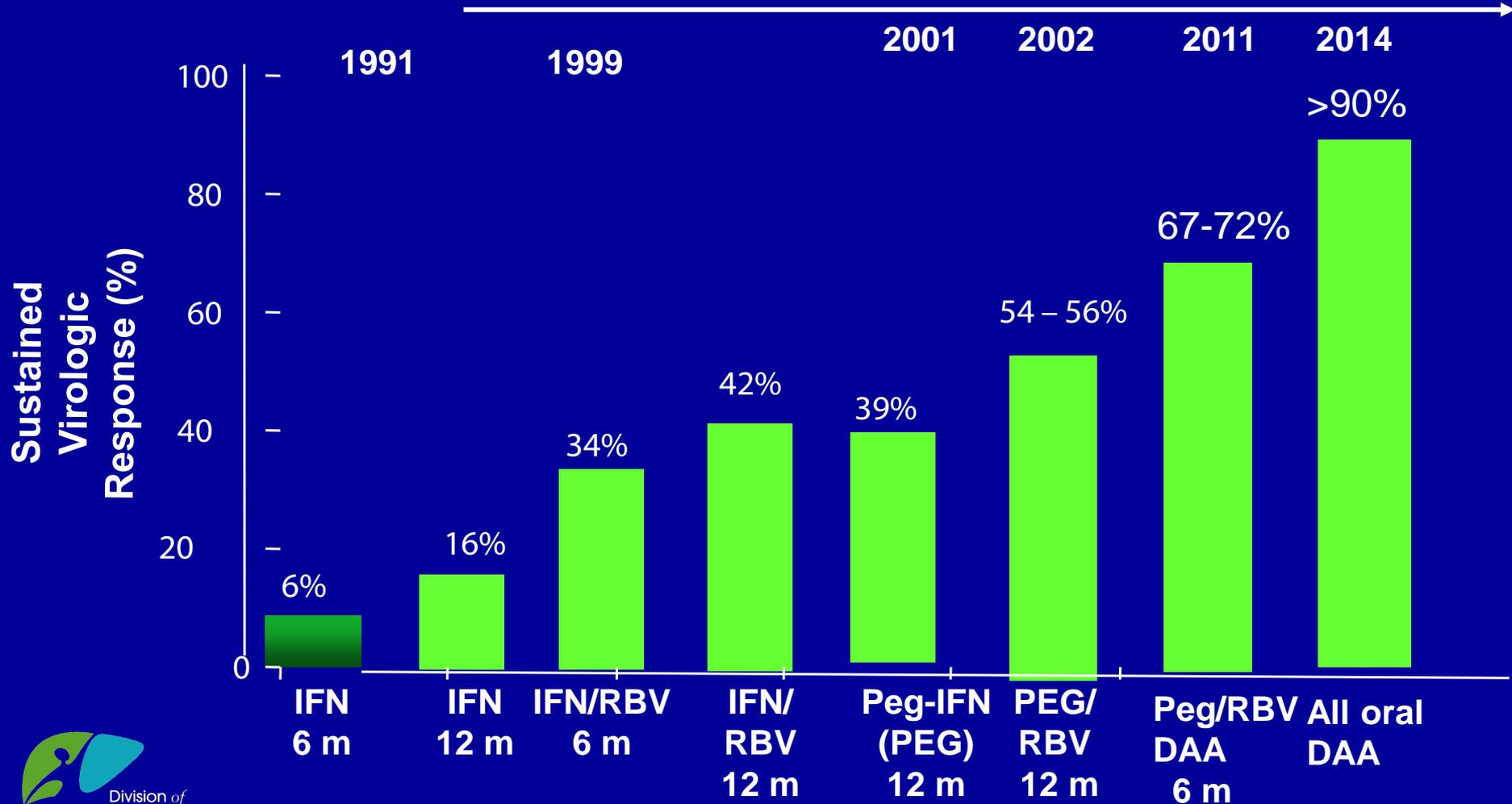
Per-Person Survival Gains with Various Disease Interventions

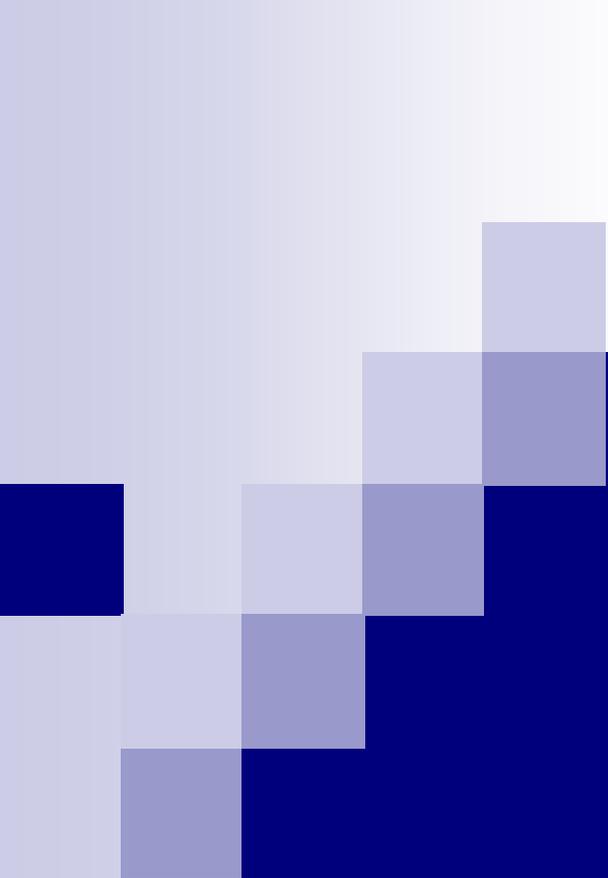


HCV Therapy Can Eliminate HCV Infection and Reduce Morbidity/Mortality Risks

- Therapy can cure HCV infection -sustained virologic response (SVR)
- SVR is associated with
 - 70% reduction in Hepatocellular carcinoma
 - 50% reduction in all-cause mortality

Advances in HCV Therapy





2. Potential Effects on Transmission

Persons Whose HIV is Diagnosed Are Less Likely to Transmit

After people become aware they are HIV-positive, the prevalence of high-risk sexual behavior is reduced substantially.

Reduction in Unprotected Anal or Vaginal Intercourse with HIV-neg partners:
HIV-pos Aware vs. HIV-pos Unaware

68%

Meta-analysis of high-risk sexual behavior in persons aware and unaware they are infected with HIV in the U.S
Marks G, et al. AIDS 2005;39:446

ART Stops HIV Transmission

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Prevention of HIV-1 Infection with Early Antiretroviral Therapy

Myron S. Cohen, M.D., Ying Q. Chen, Ph.D., Marybeth McCauley, M.P.H.,
Theresa Gamble, Ph.D., Mina C. Hosseinipour, M.D.,
Nagalingeswaran Kumarasamy, M.B., B.S., James G. Hakim, M.D.,
Johnstone Kumwenda, F.R.C.P., Beatriz Grinsztejn, M.D., Jose H.S. Pilotto, M.D.,
Sheela V. Godbole, M.D., Sanjay Mehendale, M.D., Suwat Charialertsak, M.D.,
Breno R. Santos, M.D., Kenneth H. Mayer, M.D., Irving F. Hoffman, P.A.,
Susan H. Eshleman, M.D., Estelle Piwowar-Manning, M.T., Lei Wang, Ph.D.,
Joseph Makhema, F.R.C.P., Lisa A. Mills, M.D., Guy de Bruyn, M.B., B.Ch.,
Ian Sanne, M.B., B.Ch., Joseph Eron, M.D., Joel Gallant, M.D.,
Diane Havlir, M.D., Susan Swindells, M.B., B.S., Heather Ribaudo, Ph.D.,
Vanessa Elharrar, M.D., David Burns, M.D., Taha E. Taha, M.B., B.S.,
Karin Nielsen-Saines, M.D., David Celentano, Sc.D., Max Essex, D.V.M.,
and Thomas R. Fleming, Ph.D., for the HPTN 052 Study Team*



23 December 2011 | \$19

Science

BREAKTHROUGH OF THE YEAR

HIV Treatment as Prevention

AAAS

HPTN 052: HIV Transmissions

1,763 sero-discordant couples (97% heterosexual)
HIV infected partners: 890 men, 873 women

39 HIV transmissions

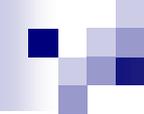
28 linked HIV transmissions

11 unlinked transmissions

Immediate ART:
1 transmission

Deferred ART:
27 transmissions

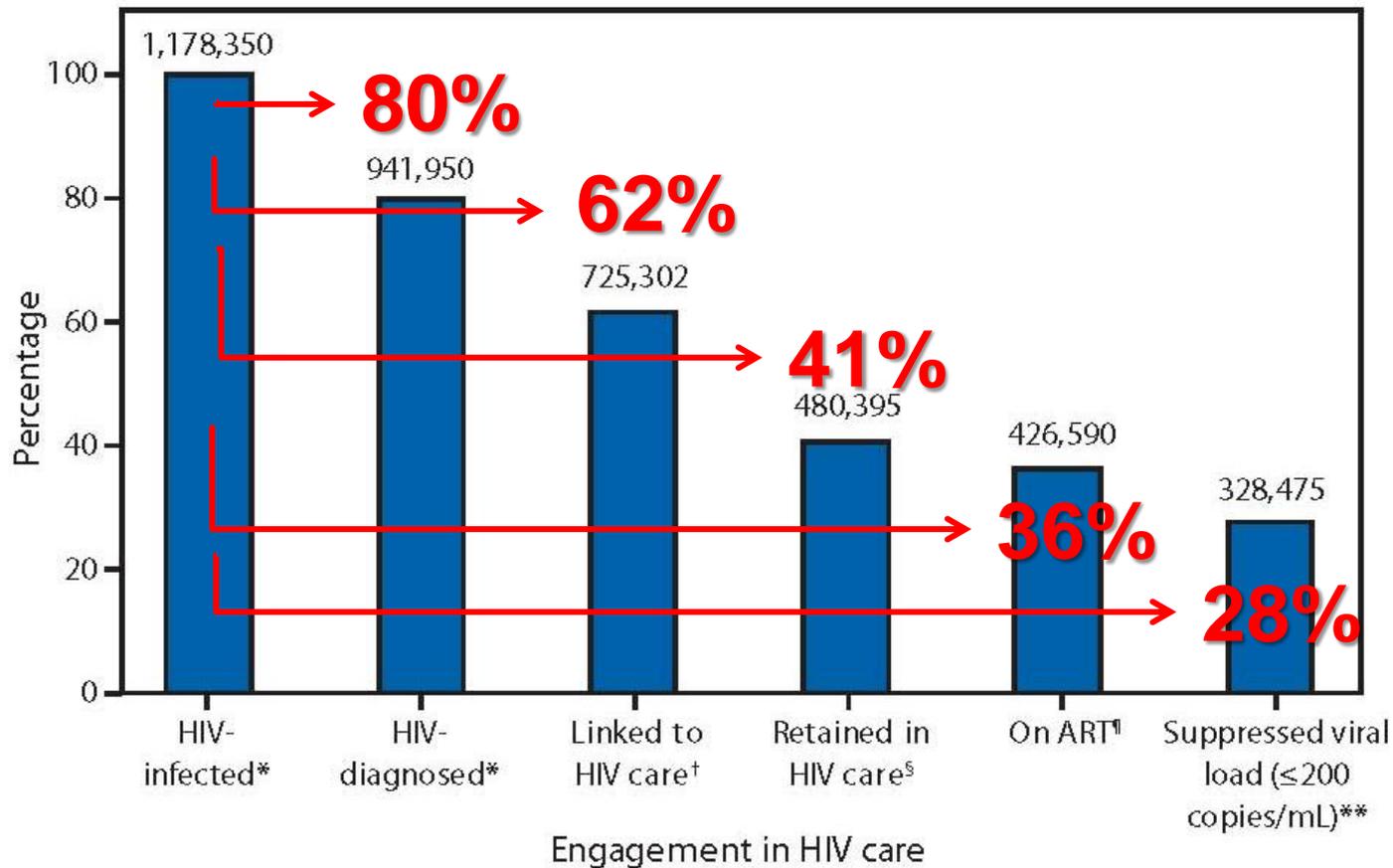
96% reduction with ART



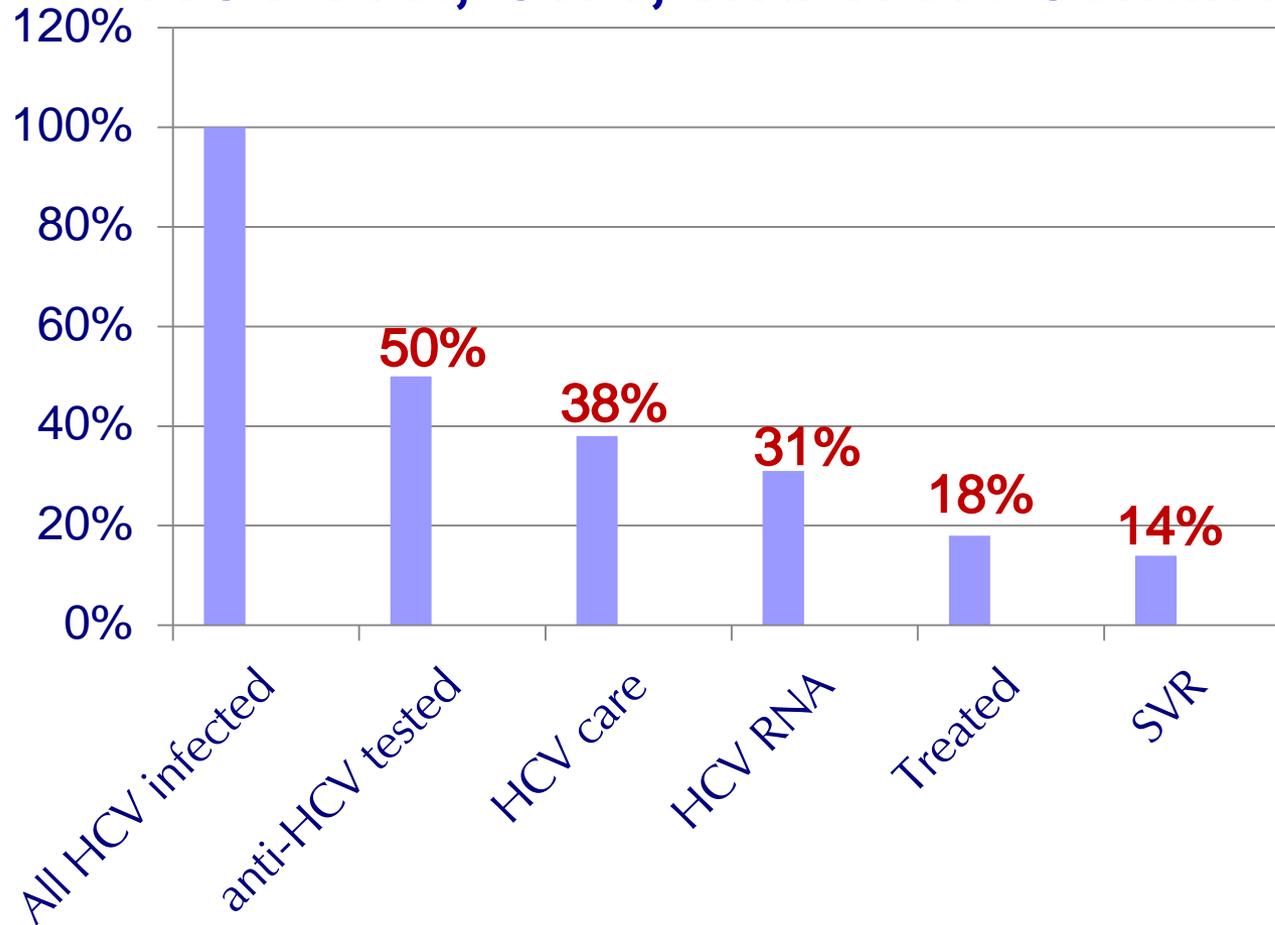
Viral Suppression as Prevention

- To increase the % of persons with viral suppression in the U.S.:
 - Test
 - Link to care
 - Remain in care
 - Receive ART
 - Adhere to ART

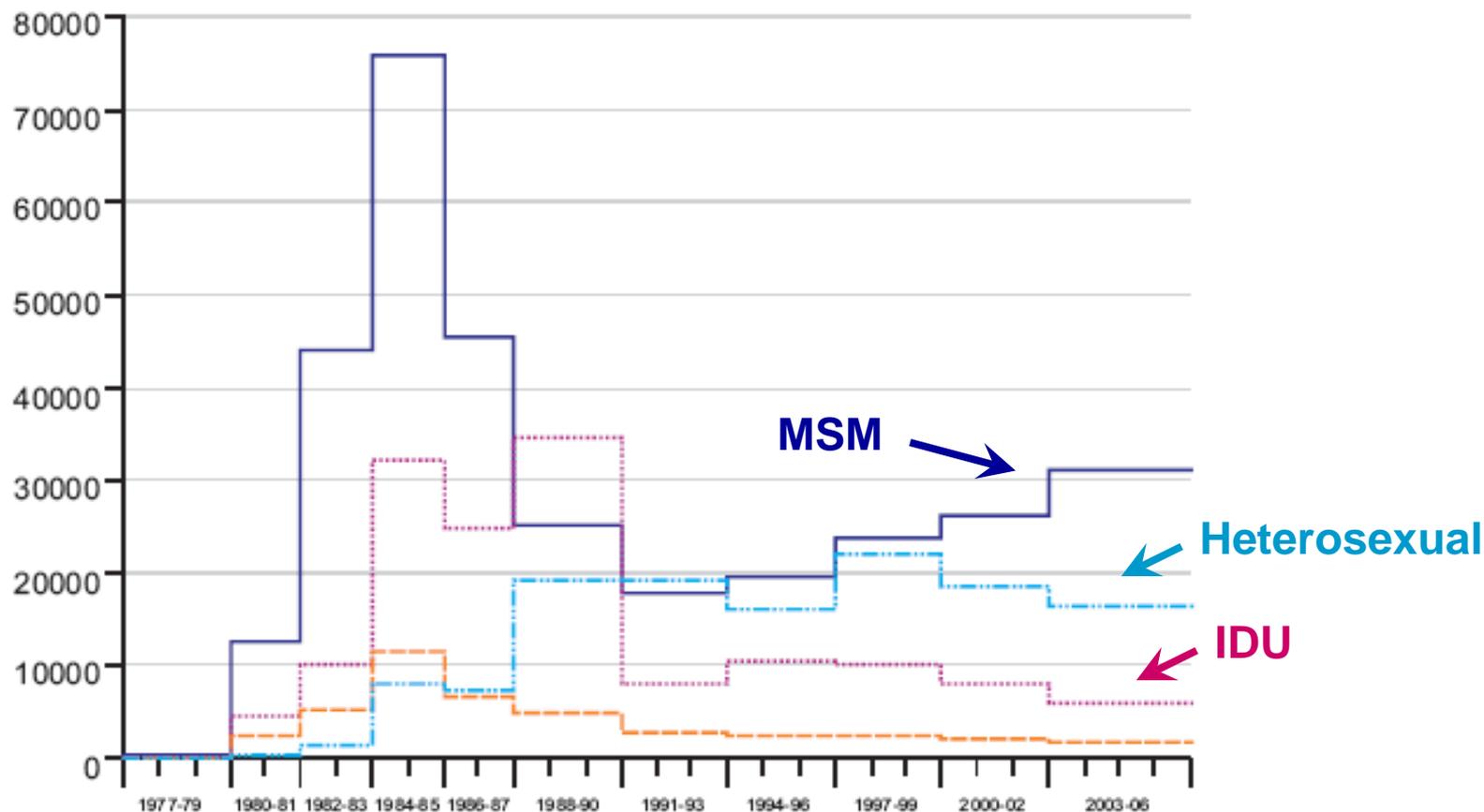
The Percentage with Viral Suppression



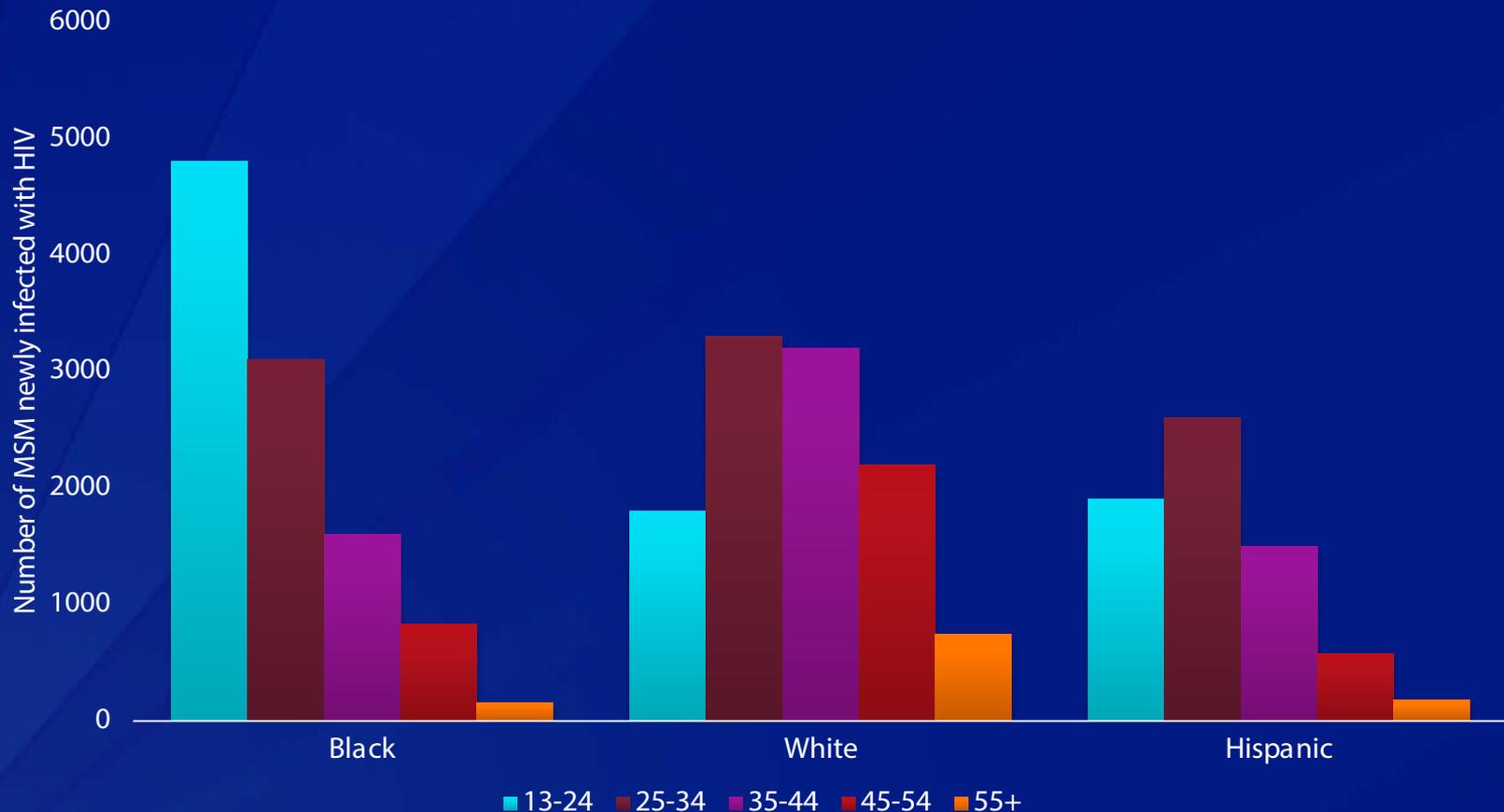
HCV Test, Care, and Treat Continuum



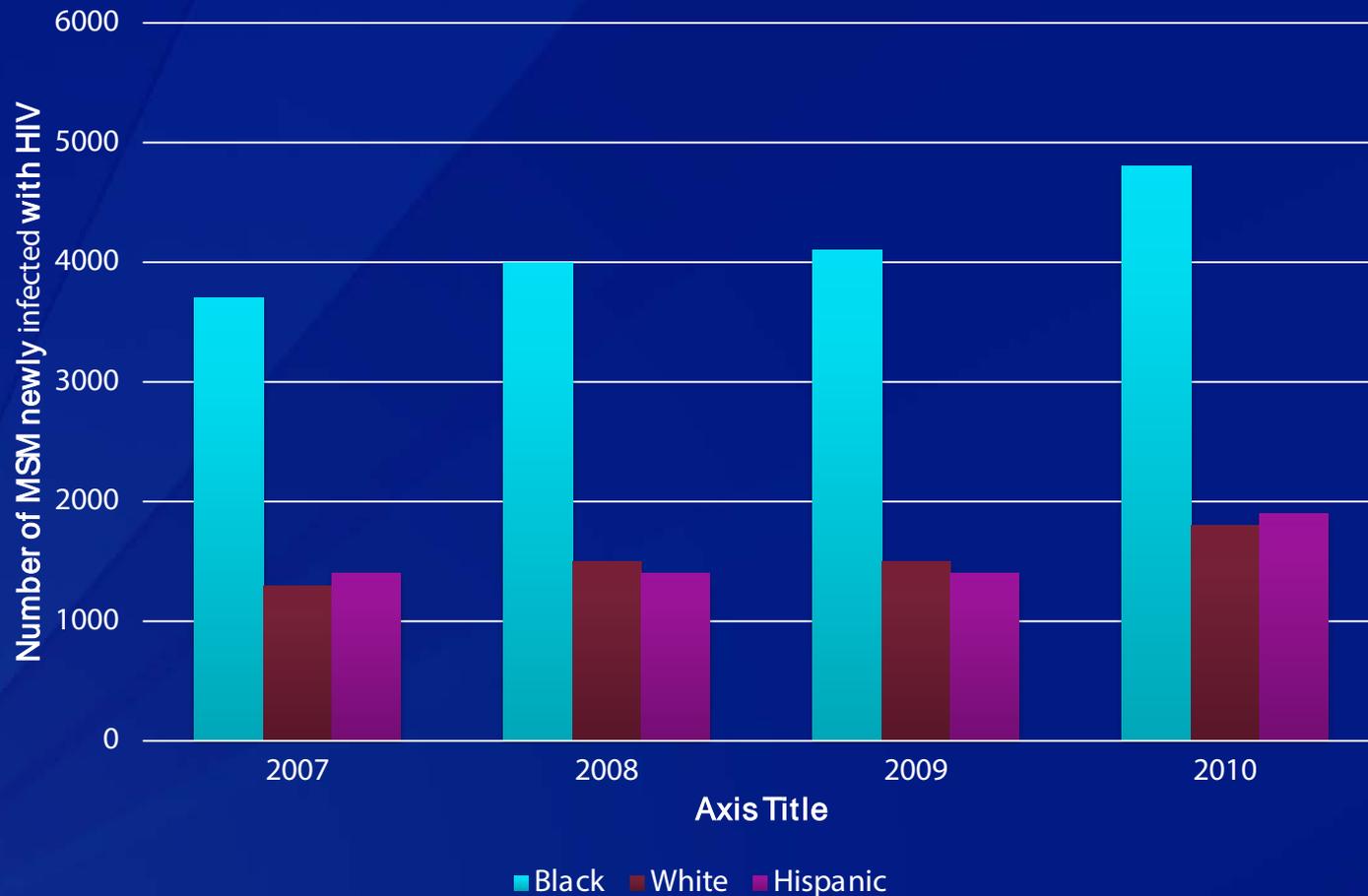
Estimated Number of New HIV Infections by Transmission Category Extended Back-Calculation Model, 50 U.S. States & DC, 1977-2006



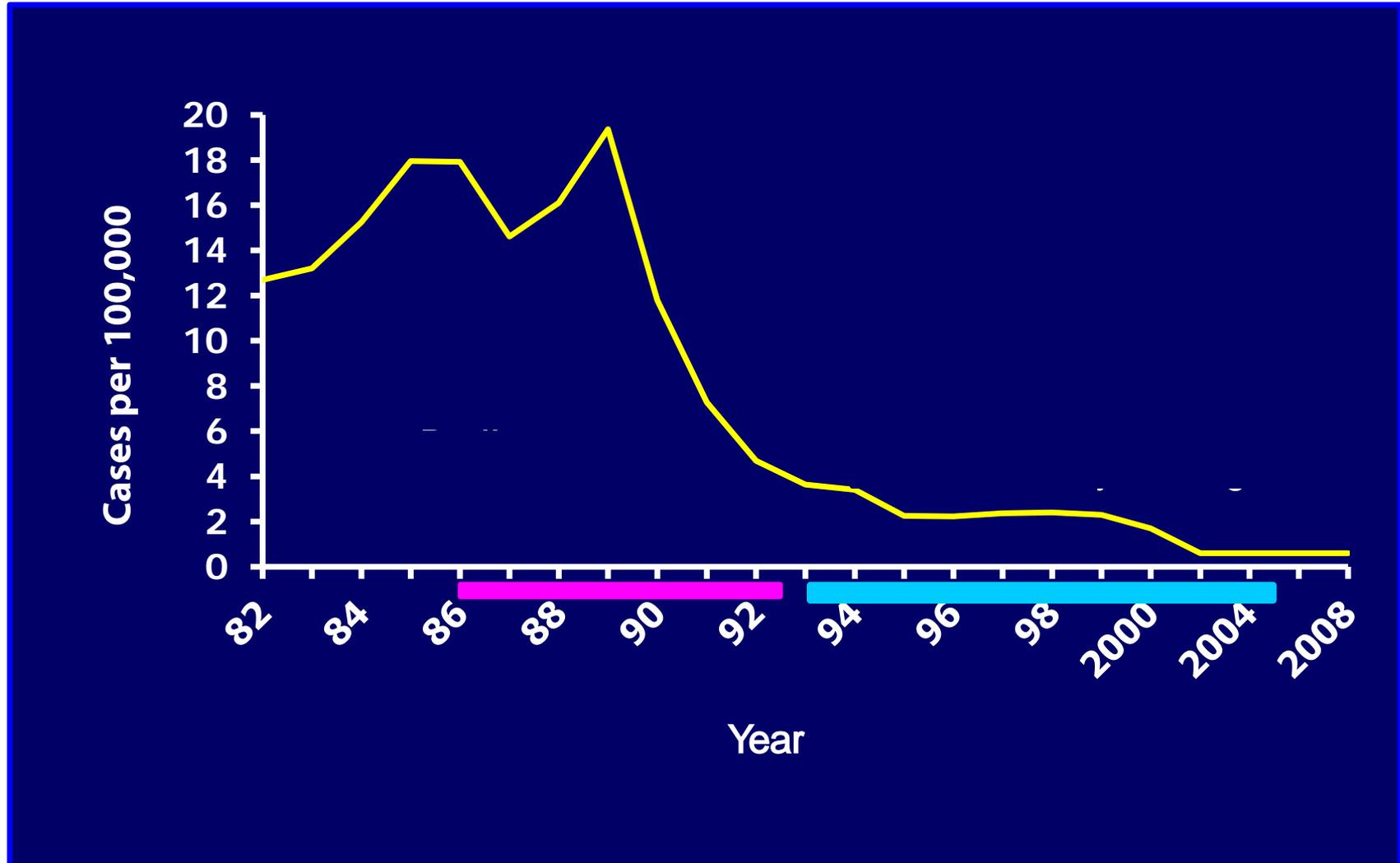
Estimated New HIV Infections in MSM 2010, by race/ethnicity and age group



HIV Incidence in Young MSM ages 13-24 years, 2007-2010



Estimated Incidence of Acute Hepatitis C: United States, 1982 – 2009



Source: Sentinel Counties Study of Viral Hepatitis and State Disease Surveillance, CDC

Acute Infections in MSM detected by RNA only

- 0.3% of 14,005 frequently tested MSM in Seattle STD clinic; **20% of all HIV infections detected**
- Stekler et al, Clin Infect Dis 2009
- 26 (74%) of 35 AHI cases detected in LA at MSM clinic; **25% of all HIV infections detected**
- Patel et al, Archives Int Med 2010
- 0.08% of 21,425 STD clinic patients in New York City; **9% of all HIV infections detected**; 94% were MSM
- Shepard et al, MMWR 2009



NDC 61958-0701-1

Truvada[®]
(emtricitabine and tenofovir
disoproxil fumarate)
Tablets

30 tablets

Rx only

DISPENSER: Each time Truvada[®] is dispensed
give the patient the attached Medication Guide.

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Daily Oral PrEP Efficacy by Adherence

Intervention	mITT	Drug detected
MSM (iPrEx, TDF/FTC)	44%	92%
Heterosexuals (Partners PrEP, TDF/FTC)	75%	90%
IDU (Bangkok Tenofovir Study, TDF)	49%	70%

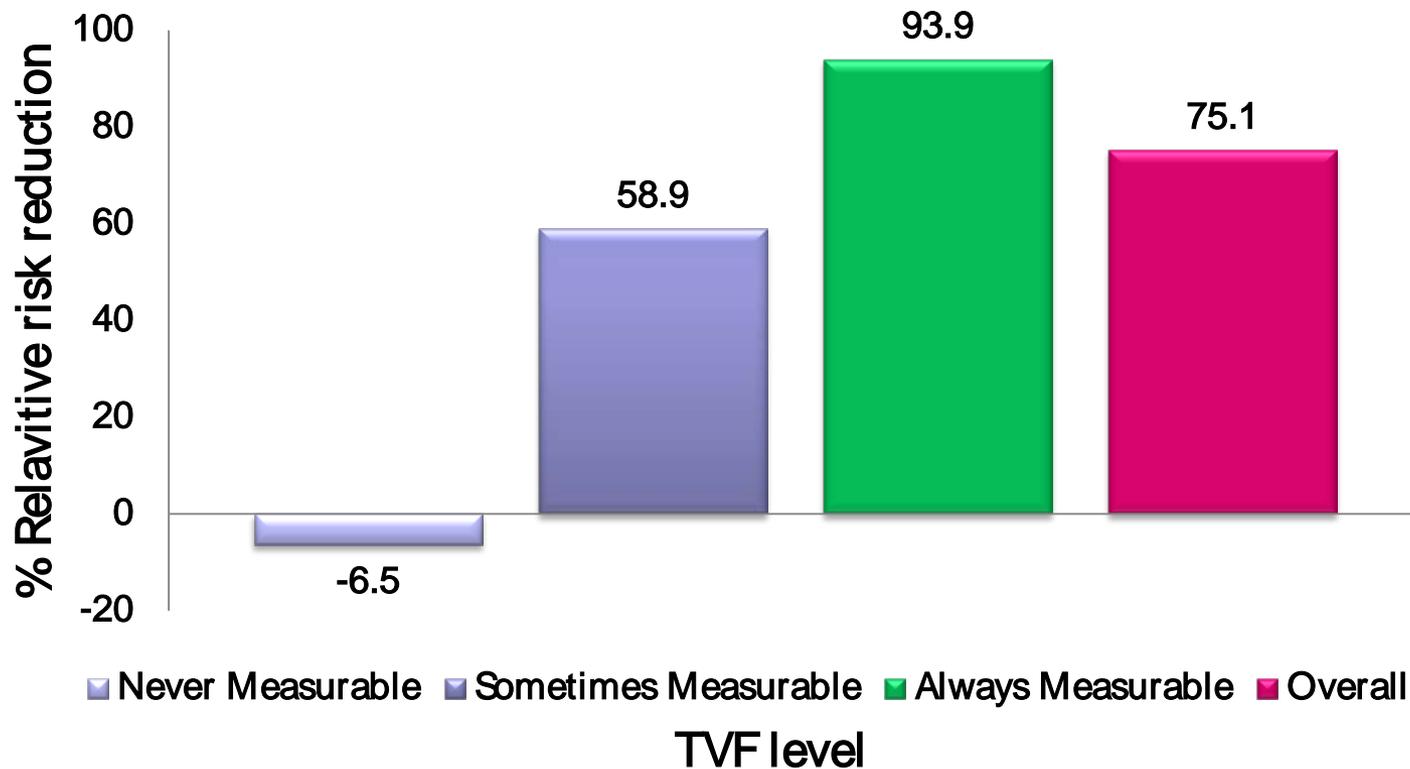
Grant RM et al. Preexposure chemoprophylaxis for HIV prevention in men who have sex with men. *NEJM*. 2010;363(27):2587-2599.

Baeten JM et al. Antiretroviral Prophylaxis for HIV Prevention in Heterosexual Men and Women. *NEJM*. 2012;367(5):399-410.

Choopanya K et al. Antiretroviral prophylaxis for HIV infection in injecting drug users in Bangkok, Thailand. *Lancet* 2013;381(9883):2083-2090.

Efficacy and Adherence Over Time

Activated drug (TVF) across multiple visits in Partners PrEP trial



Clinical Practice Guideline

- Review of efficacy and safety evidence
- Identifying patients with
 - *Indications for PrEP*
 - *Contraindications for PrEP*
- Prescribing, laboratory testing, and follow-up care
- Supporting adherence and risk reduction

<http://www.cdc.gov/hiv/pdf/PrEPguidelines2014.pdf>

Indications for PrEP

- Brief sexual history
 - *Sex with men, women, or both?*
 - *Consistent condom use?*
 - *Number and HIV status of sex partners*
 - *Recent STIs?*
- Brief drug use history
 - *Injection drug use?*
 - *Drug treatment*
- Most recent potential HIV exposure



Contraindications

- HIV infection
- Recent signs/symptoms of acute viral illness
- Renal or bone disease

Initial laboratory testing

- HIV test
- Creatinine
- Hepatitis B (if unvaccinated)
- Pregnancy test
- STI testing (including extragenital for MSM)

PrEP Follow-up Visits

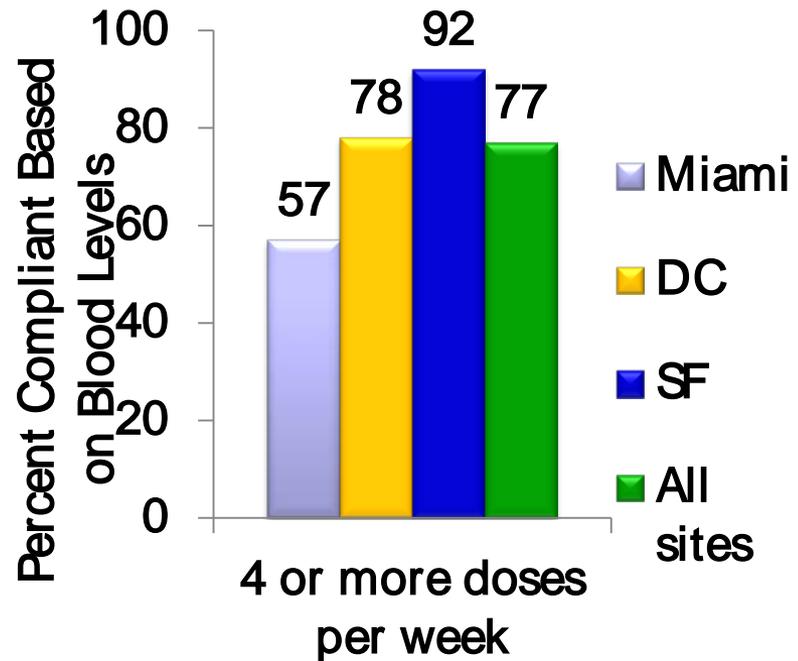
- HIV test every 3 months
- Creatinine at 3 months, then every 6 months
- Pregnancy test every 3 months
- STI tests every 6 months if asymptomatic
- Assess
 - Medication adherence
 - HIV risk and protective behaviors

PrEP works if you take it (in community settings)

iPrEx Open Label Extension Study (MSM)

Adherence by Drug Concentration	HIV Incidence per 100 PY
0 pills/week	4.7
< 2 pills/week	2.3
2-3 pills/week	0.6
≥ 4 pills/week	0.0

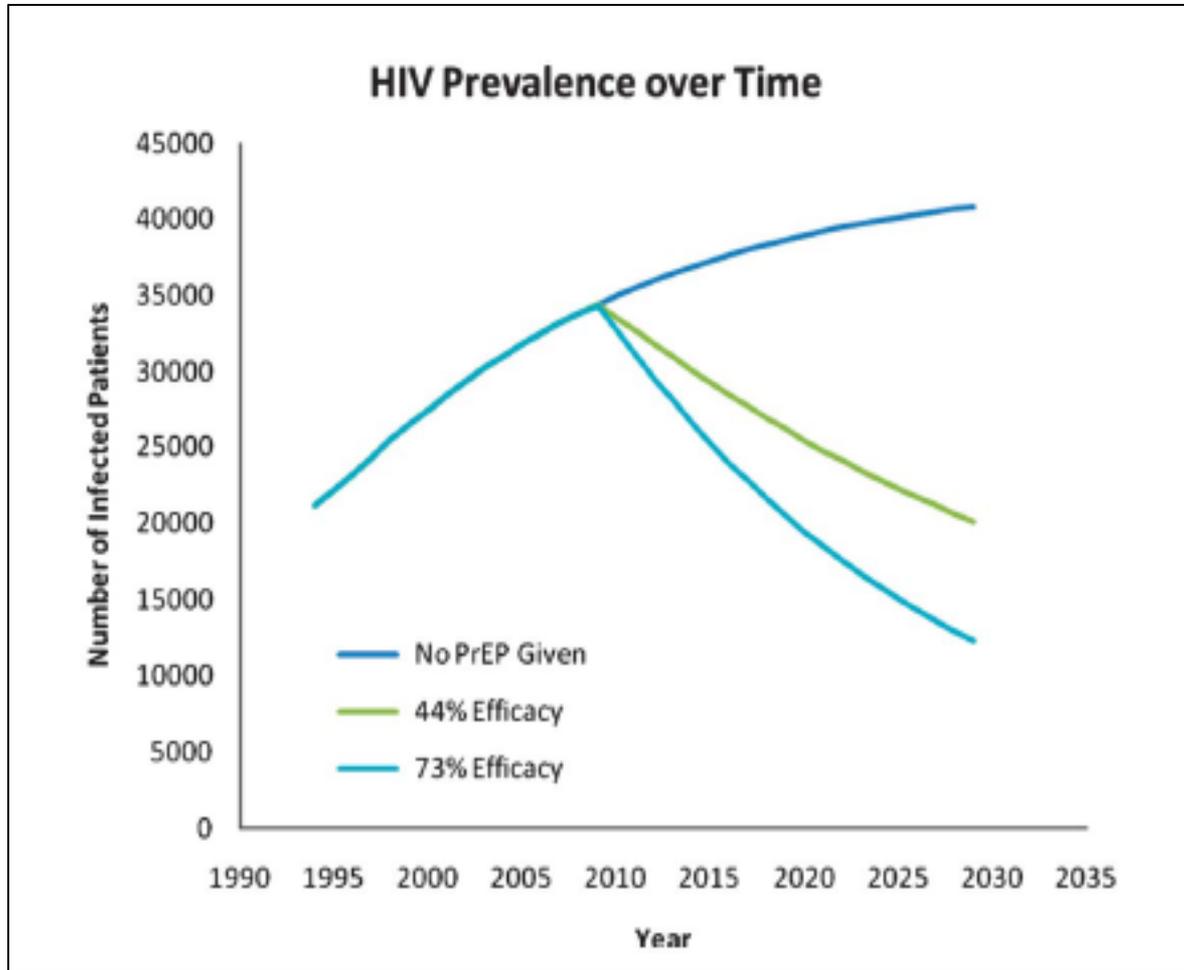
STD clinics (MSM)



Adherence Matters

- Daily PrEP provides high levels of protection if taken consistently
- PrEP has some “forgiveness” if occasional doses are missed
- No evidence PrEP is effective when taken sporadically or intermittently

Potential Impact of PrEP for MSM in New York City



Koppenhaver et al. J Acquir Immune Defic Syndr (2011) 58(2):e51-e52



PReP!

can prevent forest fires

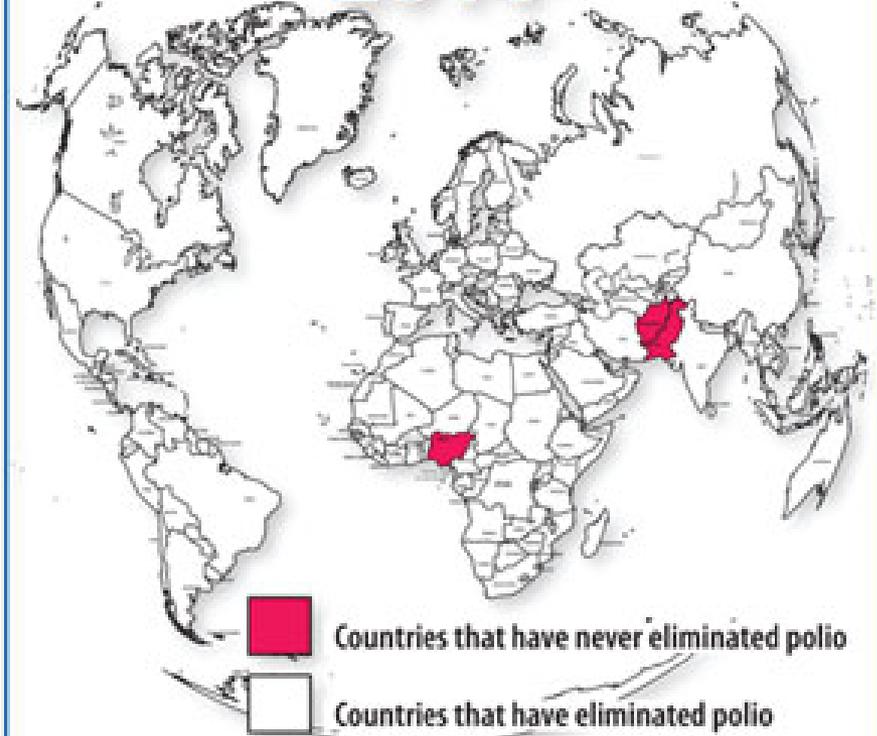


Polio Eradication

1988



2014*



*As of April 29, 2014

Tell It Like It Is.

- Epidemic is over.
 - No matter what the Communications people say.

- Prevention versus Care and Treatment?
 - Prevention Goal: 0 new transmissions
 - Treatment Goal: 0 new cases of AIDS

- “AIDS-free generation”
 - Use the tools we have
 - Use the techniques that worked before
 - Start young



the end