

# The State Perspective

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- “...high-risk transmitting behavior declined sharply after the receipt of the HIV-positive test result, indicating that the identification of recent seroconverters should be a priority of prevention programs.”

Colfax, G. N., S. P. Buchbinder, et al. (2002). “Sexual risk behaviors and implications for secondary HIV transmission during and after HIV seroconversion.” AIDS **16**(11): 1529-35.

# Undelivered test results

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- In California in CY 2001, **629 positive test results undelivered**
- Broad implementation of rapid HIV testing would eliminate problem
- Impact:
  - Reduced rates of transmission
  - Increased rates of treatment access
  - Increased rates of partner notification

# The Question:

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- How do we do accurate, quality rapid HIV testing, and make it accessible to the populations in greatest need?

**Impact of CLIA Status**

# CLIA Moderate Complexity

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# California Legal Issues

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- Personnel requirements – BPC 1206.5
  - Requires laboratory or medical personnel to conduct moderate complexity tests
- Lab licensure and HIV approval – 17 CCR 1230
  - Requires labs conducting HIV tests to be state licensed and specifically approved for HIV
- Lab director requirements – BPC 1209
  - Applies additional requirements for lab director qualifications

# Practical Concerns

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- Workforce shortages
  - Lab Technician – BPC 1260.3
    - New category of laboratory personnel for California
- Lab director “buy-in”
  - Lab director workload
  - Broad geographic areas
  - Non-business hours

# Impact

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# California testing settings

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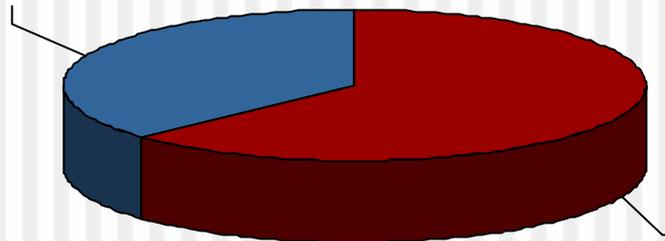
- 450+ publicly-funded testing sites in California
- About 47% of testing conducted in settings such as mobile/street outreach, community-based clinics, youth centers, etc.
- 1,314 HIV-positive tests in these settings.

# Limited access

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- Of the 629 positive test results undelivered in CY 2001,
- **397 of these were in settings that would NOT have access to moderate complexity rapid HIV testing.**

Some access



No access

# Increased Costs

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- Current annual cost for counseling personnel about \$1.5 million
- Testing personnel requirement alone will increase costs by a *minimum* of \$1.7 million – more than double.
- Increases could be as high as \$7M for a full implementation under moderate complexity – *for personnel costs alone.*

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**What are we getting in return for these “costs?”**

# Costs vs. Benefits?

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- Increased expense
  - Decreased testing
  - Decreased care
  - More infection
  - **More Deaths**
- Greater accuracy?



# Alternatives

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# Limited Public Health Use?

- Does not remove personnel from the system
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- Will not allow access in most needed settings!
- approval
- lab director
- ad

# CLIA Waiver

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- Will allow OA-trained counselors to conduct tests
- May supercede specific California licensure and approval requirements
- Allows for the distribution of oversight responsibilities to counseling and testing coordinators

# Training & QA Systems

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- Existing training certification for counselors
  - Includes “Basic I,” “Basic II,” annual CET
  - Add training & certification for conducting waived rapid HIV tests
- Existing quality assurance database
  - Tracks adherence to training requirements, counselor workload, client referral rates, etc.
  - Add adherence to testing certification requirements
  - Data reported/examined monthly
- Site visits/evaluations conducted annually

# The Upshot

**The costs – both human and financial - of implementing moderate complexity testing are immense. Let's be sure they're necessary...**

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# Criteria for Waiver

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- 493.15b(2):
  - Employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible.
- Clarification:
  - Must be able to demonstrate a level of accuracy and precision that would ensure the correct result regardless of the users level of expertise.