

Implementation Under CLIA: Moderate Complexity

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WHY LABORATORY OVERSITE

1. HIV *is* “different”
 - Several States have Separate Regulations
 - Confidentiality Issues
 - Non-names reporting – HIV infection
 - Anonymous testing sites
 - Impact on the Client → Care in Reporting
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WHY LABORATORY OVERSITE

1. HIV *is* “different”
 2. Potential for Abuse: “Storefront” testing vs. Counseling & Testing Site
Ex: Cholesterol testing → AB185 (Calif)
 - Bloodborne pathogens
 - Lack of post-test counseling
 - Referral to medical care
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WHY LABORATORY OVERSITE

1. HIV *is* “different”
 2. Potential for Abuse: “Storefront” testing vs. Counseling & Testing Site
 3. Laboratorians Do It Best – Trained in the concepts of Quality Assurance
 - Use of control samples
 - Temperature abuse – kit, environment
 - Kit expiration
 - Etc.
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Moderate Complexity Laboratory Scenario

Example – STD Clinic Lab

1. Testing done by clinicians
 2. Technical Oversight by laboratory scientist
 - Training
 - Proficiency Testing
 3. Administrative Oversight
 - Performance evaluation
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