

The Current State of HIV Testing

Introduction to Session

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This Session

- Introduction
 - HIV testing
 - Previous CLIAC discussions
- Presentation by Dr. Branson

HIV Testing

- Traditional, laboratory-based testing for HIV requires two visits to a clinic/healthcare provider
 - Provide sample
 - Receive test result ~1 week later
 - CDC has estimated that each year approximately 8,000 HIV positive individuals do not return to receive their test results
- Point-of-care testing
 - Tests that can provide a test result in a relatively short time so that only a single visit is required

Rapid HIV Tests

- Decrease the time needed to obtain a result
 - Screening in high risk settings
 - Post-exposure for healthcare workers
- Potential to:
 - Increase access to testing
 - Reduce the number of unrecognized infections
 - Support CDC's 2006 recommendations to include HIV testing as a routine part of healthcare

The Access Issue: To Waive or Not to Waive

Access to rapid HIV tests is critical in identifying those who are infected. Waive the tests.

Lack of oversight risks no confirmation by additional more specific tests (follow-up testing), or QA. Classify the tests as moderately complex.



Past CLIAC Discussions on Waiving Rapid HIV Tests

- May 2001
 - Recommendation to BPAC expressing that HIV tests are inappropriate for the waived category
- September 2002
 - Controversial issues of access and quality
 - Recommended waiver not appropriate at this time

Resolution of the Access Issue

- Approve rapid HIV tests as “restricted devices”
 - Sales, distribution restricted to clinical labs with adequate QA system
 - Use restricted to agent of clinical laboratory
 - Must give Subject Information to test subjects and provide information on test results per CDC guidelines
- Customer agreement with each order
- Approve as moderate complexity device
- Company applies for waiver and performs necessary studies. If effective, waive test.
- Sales and use restrictions continue to apply

Rapid HIV Tests Waived under CLIA

- January 2003
 - First test waived (OraQuick[®] HIV-1 Antibody Test for use with whole blood)
- Tests currently waived under CLIA
 - OraQuick[®] (OraSure Technologies) for use with whole blood and oral fluid
 - Uni-Gold[™] for use with whole blood
 - Clearview[®] HIV 1/2 Stat-Pak for use with whole blood
 - Clearview[®] Complete HIV 1/2 with whole blood

Rapid HIV Tests and Multi-Test Algorithms

- Each rapid test package insert states:

“When multiple rapid HIV tests are available, this test should be used in appropriate multi-test algorithms.”

Issues to be Discussed Here

- Multi-test algorithms
- Reporting of test results
- Mechanisms for implementation of new testing recommendations
- Evolving technologies and consistency with package inserts