



# Rapid HIV Antibody Testing Update

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# Purpose: Why Rapid HIV Testing?



- An example of an infectious disease test that has been waived
- Controversy around the waiver decision
- Previous CLIAC discussions
- Update CLIAC on testing scope and performance



# Rapid HIV Testing Overview of Presentations



- Introduction
- Results from the Model Performance Evaluation Program (MPEP)
- Use of waived rapid HIV testing in public health settings
- Use of rapid HIV testing in the private sector - hospitals and community settings



# Waived Tests Available for Infectious Diseases



## Direct antigen detection

- ❖ H. pylori
- ❖ Streptococcus, Group A
- ❖ Adenovirus
- ❖ Influenza A
- ❖ Influenza A/B
- ❖ Influenza B
- ❖ Respiratory syncytial virus
- ❖ Trichomonas

## Serological assays

- ❖ HIV-1 antibodies
- ❖ HIV-1/2 antibodies
- ❖ H. pylori antibodies
- ❖ Infectious mononucleosis
- ❖ Lyme disease (B. burgdorferi) antibodies



# Rapid HIV Antibody Tests Objectives for Use



- Decrease the time needed to obtain a result
  - ❖ Screening in high risk settings
  - ❖ Post-exposure for healthcare workers
- 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



# Examples of Sites Offering Rapid HIV Antibody Tests



- Hospitals –
  - ❖ ER, L&D, Occ Health
- Public health – state, county, city testing sites
- Counseling & testing sites
- STD clinics
- Drug treatment programs
- Mobile vans serving high-risk communities
- Community health centers
- Community based organizations
- Correctional facilities
- Student health clinics
- Homeless shelters
- Other outreach settings



# Timeline for Introduction of Rapid HIV-1 Antibody Tests

Test	Date approved	Specimen type	CLIA complexity
Murex SUDS (no longer available)	5/22/92	Serum/plasma	Moderate
OraSure OraQuick	11/7/2002	Fingerstick WB	Moderate
OraSure OraQuick	1/31/2003	Fingerstick WB	Waived
MedMira Reveal	4/16/2003	Serum, plasma	Moderate
OraSure OraQuick	9/30/2003	Venipuncture WB	Waived
Trinity Biotech Uni-gold Recombigen	12/23/2003	Venipuncture WB	Waived

WB = whole blood



## Waived Rapid HIV Antibody Tests Currently Available



Test Name	Manufacturer	Specimen type
OraQuick Advance Rapid HIV-1/2 Antibody Test	OraSure Technologies, Inc	Whole blood Oral fluid
Uni-Gold Recombigen HIV Test	Trinity Biotech	Whole blood
Clearview HIV 1/2 Stat Pak	Chembio Diagnostic Systems	Whole blood



## Moderate Complexity Rapid HIV Antibody Tests Currently Available

Test Name	Manufacturer	Specimen type
OraQuick Advance Rapid HIV-1/2 Antibody Test	OraSure Technologies, Inc	Plasma
Reveal G3 Rapid HIV-1 Antibody Test	MedMira Laboratories	Serum/plasma
Uni-Gold Recombigen HIV Test (HIV-1)	Trinity Biotech	Serum/plasma
Multispot HIV-1/HIV-2 RapidTest	Bio-Rad Laboratories	Serum/plasma
Clearview HIV 1/2 Stat Pak	Chembio Diagnostic Systems	Serum/plasma
Clearview Complete HIV 1/2 (Sure Check)	Chembio Diagnostic Systems	Whole blood Serum/plasma



# Past CLIAC Discussions

## RE: 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
- Fall 2002: Interagency HHS task force formed to debate the issues
- January 2003: First test waived (OraQuick<sup>®</sup> HIV-1 Antibody Test)



# Efforts to Promote Quality Assurance for Rapid HIV Testing



- January 2003: CDC workgroup convened to draft QA guidelines
- June 2003: Quality Assurance Guidelines for Testing Using the OraQuick<sup>®</sup> Rapid HIV-1 Antibody Test (under revision)
- 2003-2004: CDC training sessions for states, public health testing sites
- Training through State public health departments
- FDA sales restrictions for quality assurance



# FDA Sales Restrictions Apply to All Rapid HIV Tests



- Sale restricted to clinical laboratories that have an adequate quality assurance program
  - ❖ including planned systematic activities to provide adequate confidence that requirements for quality will be met; and
  - ❖ where there is assurance that operators will receive and use the instructional materials;
- Approved for use only by an agent of a clinical laboratory;
- Test subjects must receive the "Subject Information" pamphlet prior to specimen collection and appropriate information when test results are provided;
- The test is not approved for use to screen blood or tissue donors.



# Rapid HIV Testing Overview of Presentations



- Results from the Model Performance Evaluation Program (MPEP) – Dev Howerton (CDC)
- Use of waived rapid HIV testing in public health settings – Duncan Mackellar (CDC)
- Use of rapid HIV testing in the private sector - hospitals and community settings – Laura Bogart, PhD (RAND Corp)