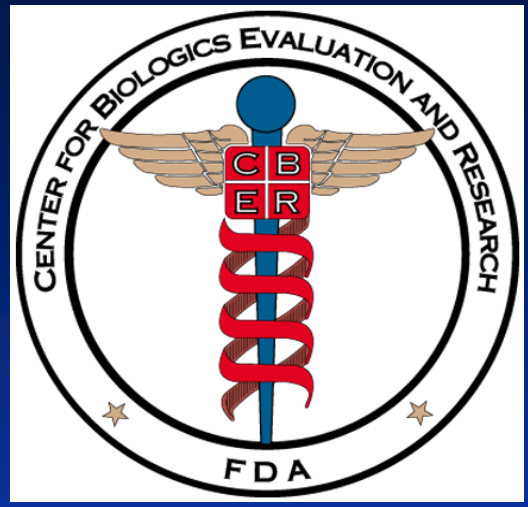


Update on Rapid HIV Test Waivers

CLIAC Meeting
September 22, 2004

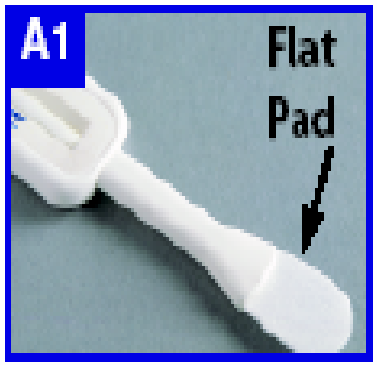
Elliot P. Cowan, Ph.D.
Associate Director
Division of Emerging and Transfusion Transmitted Diseases
FDA/CBER/OBRR

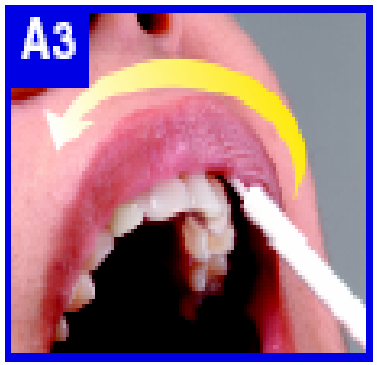
CLIA Waived Rapid HIV Tests

- OraQuick® ADVANCE Rapid HIV-1/HIV-2 Antibody Test (OraSure Technologies, Bethlehem, PA)
  - Detection of antibodies to HIV-1 in fingerstick whole blood: 1/31/03
  - Waiver subsequently carried over to detection of antibodies to HIV-1 and HIV-2 in both fingerstick and venipuncture whole blood
  - Detection of antibodies to HIV-1 and HIV-2 in oral fluid: 6/25/04

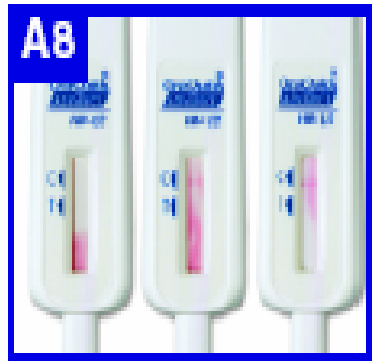
OraQuick®: Oral Fluid Test Procedure

COLLECT SAMPLE





RUN TEST



OraQuick®: Test Results

Non-Reactive

Reactive

Invalid

CLIA Waived Rapid HIV Tests

- Uni-Gold™ Recombigen® HIV (Trinity Biotech PLC, Wicklow, Ireland)
  - Detection of antibodies to HIV-1 in venipuncture whole blood: 6/23/04

Uni-Gold™: Test Procedure

1. Add sample

2. Wash

3. Read in 10 min

Uni-Gold™: Test Results

Non-Reactive

Reactive

Invalid

Rapid HIV Tests: Interpretation

- Non-reactive = Negative
- Reactive = Preliminary Positive
  - All reactive results must be confirmed using an appropriate supplemental test
  - Working with HIV supplemental test manufacturers to change labeling to allow use with rapid HIV tests
  - Screening test results are highly accurate, but reactive test result should be confirmed by supplemental testing
  - State law may preclude interpretation

Performance of Rapid HIV Tests

SENSITIVITY*

	Whole Blood	Oral Fluid
OraQuick	99.6%	99.3%
Uni-Gold	100%	-

SPECIFICITY*

	Whole Blood	Oral Fluid
OraQuick	100%	99.8%
Uni-Gold	99.7%	-

*Based on data from clinical trials

Rapid HIV Tests are Restricted Devices

- Sale restricted to clinical laboratories
  - that have an adequate quality assurance program 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
  - I.e., not for self-testing
- Test subjects must receive the “Subject Information” pamphlet and pre-test counseling prior to specimen collection, and appropriate counseling when test results are provided

Rapid HIV Test Restrictions, cont.

- Not approved for use to screen blood or tissue donors
- Customer letter included with all kits
  - "By purchasing this device, you are doing so as an agent of a clinical laboratory and agree that you or any of your consignees will abide by the…restrictions on the sale, distribution, and use of the device…"
- Sales and use restrictions apply to waived rapid HIV tests

Current Rapid HIV Test Issues

- Reporting a positive test result on the basis of rapid HIV testing
  - Statistical validation of reactive rapid test results by a second rapid test could obviate the need for supplemental testing by Western blot, IFA, or NAT
  - Development of a policy on validation of rapid test results through the use of multiple rapid test results is a joint effort by the PHS Agencies