

# Rapid Testing in Healthcare Facilities

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# HIV Rapid Testing (RT)

- Update on RT programs in OAPP funded medical outpatient clinics
- 5P21's RT program
- Funding for RT
- Explore interest in implementing RT
- Technical assistance for RT program set-up & implementation



# Rapid HIV Tests

- Simple to use & require little or no specialized equipment
- Test results are provided at the time of testing
- Six rapid HIV tests approved by the U.S. Food & Drug Administration
- Tests are either “waived” or categorized as “moderate complexity”



# Requirements for Performing Rapid HIV Tests

- Any organization that performs a rapid HIV test in order to provide results to patients is considered a laboratory under the Clinical Laboratory Improvement Amendments of 1988 (CLIA)
- All laboratories must comply with regulations of the CLIA program & applicable State requirements ( <http://www.cms.hhs.gov/CLIA/> )



# Requirements for Performing Rapid HIV Tests

- **Options for organizations**: apply for its own CLIA certificate, or if authorized by CMS, make arrangements to be included with a CLIA-certified laboratory under a multiple site exception



# Waived Testing

- No federal requirements for personnel, quality assessment, or proficiency testing
- Performed in traditional laboratories, clinical settings, HIV counseling & testing sites, mobile vans, health fairs
- Organizations **must** obtain a certificate of waiver from CLIA, be included in a CLIA - certified laboratory under a multiple site exception and follow manufacturer's instructions for the test (<http://wwwn.cdc.gov/clia/regs/toc.aspx> )



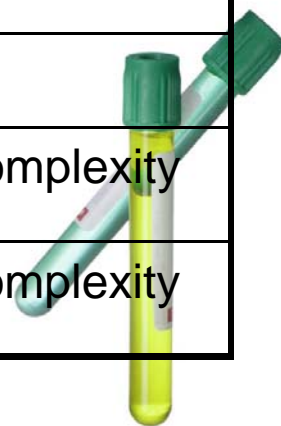
# Moderate Complexity Testing

- Must register with CLIA program & meet specific standards for personnel, quality assessment, proficiency testing and inspections (<http://wwwn.cdc.gov/clia/moderate.aspx> )



# Rapid Tests Available in the U.S.

Test Kit Name	Specimen Type	CLIA Category
OraQuick Advance Rapid HIV 1/2 Antibody Test	Whole blood Oral fluid	Waived
	Plasma	Moderate complexity
Reveal G3 Rapid HIV-1 Antibody Test	Serum, Plasma	Moderate complexity
Uni-Gold Recombigen HIV Test	Whole blood	Waived
	Serum, Plasma	Moderate complexity
Multispot HIV-1/HIV-2 Rapid Test	Serum, plasma	Moderate complexity



<http://www.cdc.gov/hiv/topics/testing/resources/factsheets/rt-lab.htm>



# Rapid Tests Available in the U.S.

Test Kit Name	Specimen Type	CLIA Category
Clearview HIV 1/2 Stat Pak	Whole blood	Waived
	Serum, plasma	Moderate complexity
Clearview Complete HIV 1/2	Whole blood	Waived
	Serum, plasma	Moderate complexity



<http://www.cdc.gov/hiv/topics/testing/resources/factsheets/rt-lab.htm>

# Rapid HIV Testing in Medical Outpatient Clinics

- 9 of 23 (40%) medical outpatient clinics are performing RT
- Testing partners & their family, walk-ins
- Approx. 10,000 RTs in 2006
- 2% - 11% positivity rate



OAPP-Clinical Services Division Survey of rapid testing in OAPP funded medical outpatient clinics, August 2007

