



Agency Preparedness and Self-Assessment Tool for Rapid HIV Testing Implementation

Please read carefully. This tool has been created for organizations considering the implementation of rapid HIV testing into existing HIV Counseling, Testing & Referral (CTR) or Family Planning (FP) programs using approved rapid HIV testing (RHT) devices. Some of the required elements below are required of Massachusetts Department of Public Health funded programs only and may not apply to all organizations.

If you have questions about rapid HIV testing implementation, please call Joanne de Vries at the HIV/AIDS Bureau at (617) 624-5372 or via email at joanne.devries@state.ma.us. Thank you.

SECTION 1: Regulatory Considerations

- This section should assist your program in determining if your organization complies with current federal and state licensing and regulatory requirements for the implementation of RHT.

Required Elements	Key Considerations	Program Status
Current CLIA certificate (and)	Does your organization currently have a CLIA certificate? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know	<input type="checkbox"/> Program meets all regulatory requirements to implement rapid HIV testing (e.g. CLIA certificate and HIV serology license or CLIA certificate and Special Projects Waiver) <input type="checkbox"/> Program meets CLIA requirement but not state regulatory requirements <input type="checkbox"/> Program does not meet regulatory requirements and needs to apply for both the CLIA and Special Projects Waiver
Current MA Clinical Laboratory License/Approval with subspecialty to perform HIV serology	If existing certificate, what type: <input type="checkbox"/> Waiver <input type="checkbox"/> PPMP <input type="checkbox"/> Compliance <input type="checkbox"/> Accreditation	
(or)	Does your program have MA Clinical Lab license or approval? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know Has program applied for a Special Projects Waiver? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know	
MA Waived Special Projects Waiver Application		

SECTION 2: Informed Consent and Client Confidentiality

- This section should assist your program in assessing compliance with informed consent and protecting client confidentiality.

Required Elements	Key Considerations	Program Status
<p>Policies and protocols to protect client confidentiality (MGL c.111 s.70F and 105 CMR 180.300)</p>	<p>Do program protocols and policies assure the privacy and confidentiality of the client throughout the testing process?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p> <p>Does your program maintain confidential client records?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p> <p>Does your program have a secure place for records storage?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p> <p>Is there a system to identify each specimen tested?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p>	<p><input type="checkbox"/> Program is prepared to meet all requirements in this section</p> <p><input type="checkbox"/> Program will need to make preparations/modifications to current practice in order to comply with this section</p> <p><input type="checkbox"/> Program will require technical assistance and resources to comply with all elements in this section</p>
<p>Patient informed consent</p>	<p>Is there a written consent form in place for HIV testing?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p> <p>Does the written consent have language specific to rapid HIV testing and confirmatory testing?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p>	<p><input type="checkbox"/> Program is prepared to meet all requirements in this section</p> <p><input type="checkbox"/> Program will need to make preparations/modifications to current practice in order to comply with this section</p> <p><input type="checkbox"/> Program will require technical assistance and resources to comply with all elements in this section</p>

SECTION 3: Testing Procedures and Considerations

- This section should assist your program in determining whether testing protocols are inclusive of rapid HIV testing specifics and programmatic requirements

Required Elements	Key Considerations	Program Status
<p>Protocols and policies for RHT specimen collection and preparation</p>	<p>Has your program established protocols and policies that address specimen collection and preparations per rapid testing guidelines?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p> <p>Does your program have the materials needed for RHT implementation such as room temperature gauges, safety goggles, work space covers, timers, etc?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p>	<p><input type="checkbox"/> Program is prepared to meet all requirements in this section</p> <p><input type="checkbox"/> Program will need to make preparations/modifications to current practice in order to comply with this section</p> <p><input type="checkbox"/> Program will require technical assistance and resources to comply with all elements in this section</p>
<p>Protocols for follow-up testing on all reactive rapid tests with a serum specimen</p>	<p>Has your program made arrangements with the State Laboratory for confirmatory testing of all reactive rapid tests?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p> <p>Has your program made arrangements with another laboratory for confirmatory testing of all reactive rapid tests?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p> <p>If yes, what lab? _____</p> <p>Has your program developed follow-up testing protocols for discordant test results?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p>	<p><input type="checkbox"/> Program is prepared to meet all requirements in this section</p> <p><input type="checkbox"/> Program will need to make preparations/modifications to current practice in order to comply with this section</p> <p><input type="checkbox"/> Program will require technical assistance and resources to comply with all elements in this section</p>

SECTION 4: Quality Control Procedures & Considerations

- This section will assist your program in assessing that all quality control (QC) and quality assurance (QA) procedures are in place prior to RHT implementation

Required Elements	Key Considerations	Program Status
Protocols that describe the handling, storage and disposing of testing reagents	<p>Does your program have QA and QC measures in place to assure accurate testing outcomes and the safety of work space and RHT operators?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p>	<p><input type="checkbox"/> Program is prepared to meet all requirements in this section</p> <p><input type="checkbox"/> Program will need to make preparations/modifications to current practice in order to comply with this section</p> <p><input type="checkbox"/> Program will require technical assistance and resources to comply with all elements in this section</p>
Procedures that monitor proper test performance, interpretation of internal & external controls	<p>Does your program have QA and QC measures in place to assure accurate testing outcomes?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p>	
Documentation of controls	<p>Does your program have a system to record the performance of internal and external controls?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p>	
Enrollment in an independent proficiency testing program	<p>Has your program made arrangements to enroll into an independent proficiency testing program for QA and QC purposes?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p>	

SECTION 5: Work Space Safety Considerations

- This section should aid your program in assessing the safety of RHT operators and the prevention of contamination of the physical space where RHT is being performed.

Required Elements	Key Considerations	Program Status
<p>Program must properly dispose of regulated medical waste (used lancets, specimen collection loops, used test kits)</p>	<p>Does your program have a plan for the disposal of medical waste?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p>	<p><input type="checkbox"/> Program is prepared to meet all requirements in this section</p> <p><input type="checkbox"/> Program will need to make preparations/modifications to current practice in order to comply with this section</p> <p><input type="checkbox"/> Program will require technical assistance and resources to comply with all elements in this section</p>
<p>Testing area should be properly sanitized and kept contaminant-free</p>	<p>Does your program have procedures in place to assure work space cleanliness?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p>	
<p>Designated staff must have received Occupational Safety and Health Administration training and follow universal precautions</p>	<p>Does your program have a current exposure control plan?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p> <p>Does your program mandate that testing staff receive training on universal precautions?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p>	

SECTION 6: Programmatic Considerations

- This section should help assess whether your program staff have been trained to appropriately offer HIV CTR services to clients during the rapid testing process.

Required Elements	Key Considerations	Program Status
Adherence to MDPH AIDS Bureau pre-post test counseling requirements and recommendations	<p>Have your program staff attended the MDPH HIV CTR trainings?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p>	<p><input type="checkbox"/> Program is prepared to meet all requirements in this section</p> <p><input type="checkbox"/> Program will need to make preparations/modifications to current practice in order to comply with this section</p>
Development of referral lists and support networks	<p>Does your program have referral references and lists in place for immediate access in the case of a reactive rapid test result?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p>	<p><input type="checkbox"/> Program will require technical assistance and resources to comply with all elements in this section</p>

SECTION 7: Record Maintenance Considerations

- This section should determine whether required RHT records are properly stored and maintained.

Required Elements	Key Considerations	Program Status
<p>Adherence to CLIA documentation and record keeping</p>	<p>Does your program have protocols in place to store the necessary records for CLIA certification and renewal?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p>	<p><input type="checkbox"/> Program is prepared to meet all requirements in this section</p>
<p style="text-align: center;">Adherence to your organization's protocols on record keeping</p> <p><small>AIDS Bureau requires storage of one year- if your internal protocol dictates longer storage, follow your agency protocols.</small></p>	<p>Does your program adhere to the protocols set forth by your organization regarding the storage of records?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p>	<p><input type="checkbox"/> Program will need to make preparations/modifications to current practice in order to comply with this section</p>
<p>Adherence to required QA and QC documentation such as control and temperature logs</p>	<p>Does your program have protocols in place to properly document and maintain temperature and control logs?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p>	<p><input type="checkbox"/> Program will require technical assistance and resources to comply with all elements in this section</p>

SECTION 8: Personnel Qualification Considerations

- This section assesses RHT operator/counselor qualifications and competency as related to rapid HIV testing

Required Elements	Key Considerations	Program Status
Documentation of operator qualifications	<p>Have your RHT operators and counselors received MDPH RHT training certification?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p>	<p><input type="checkbox"/> Program is prepared to meet all requirements in this section</p> <p><input type="checkbox"/> Program will need to make preparations/modifications to current practice in order to comply with this section</p>
Documentation of competency	<p>Does your program possess copies of the RHT training certificates and competency scores?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p>	<p><input type="checkbox"/> Program will require technical assistance and resources to comply with all elements in this section</p>