Purpose

The intent of this Quality Management Plan is to formalize and standardize the quality assurance practices at all Point-of-Care Testing (POCT) sites performing Rapid HIV-1/2 Antibody Testing under the oversight of The Johns Hopkins Medical Institutions Department of Pathology Point-of-Care Testing Program.

Quality assurance practices refer to planned, step-by-step activities that let one know that testing is being carried out correctly, results are accurate, and mistakes are found and corrected to avoid adverse outcomes. Quality assurance is an ongoing set of activities throughout the entire testing process that help ensure that the test results provided are as accurate and reliable as possible for all persons being tested.

This Quality Management Plan incorporates the quality assurance requirements of the federal laboratory testing standards, the Clinical Laboratory Improvement Amendments of 1988 (CLIA’88), the Joint Commission (TJC) accreditation standards, the Maryland Department of Health and Mental Hygiene Infectious Disease and Environmental Health Administration (IDEHA) and the State of Maryland Laboratories Administration standards.

Goal

The goals of the Rapid HIV POCT sites are to achieve, to the extent possible, excellence in clinical testing and performance by addressing the following objectives:

- To assure that patient test results are accurate and complete.
- To encourage uniformity in test procedures and quality assurance practices performed in all participating testing sites.
- To rapidly identify and correct problems encountered while following written procedures.
- To ensure that records are maintained that permit the evaluation of the quality and reliability of the data produced.
- To provide both the professional and non-professional staff with the cost-efficient procedures, reagents and equipment needed to confidently perform testing and implement this quality management program.
- To assure sample identity, integrity and quality.
- To identify needs and provide training and other resources required to maintain and improve the skills of the staff.
- To create mechanisms for communication so that those who need to know are informed about QA issues, as well as all staff, when appropriate.
- To develop and implement mechanisms to ensure the site meets all applicable federal, state, and other regulatory requirements.

Definitions

**Laboratory Test:**
the medical laboratory examination or analysis of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the management of health of, human beings.

**Point-of-Care Testing:**
laboratory testing or services that are performed outside the physical facilities of the main clinical laboratory. It is often referred to as near patient testing, ancillary testing, or bedside testing.
### Definitions (continued)

**Waived Testing:** laboratory testing so simple and accurate as to render the likeliness of erroneous results negligible and pose no risk or harm to the patient if the test is performed inaccurately.

**POCT Coordinator:** a fully qualified Medical Technologist/Clinical Laboratory Scientist with at least 4 years experience in the disciplines of laboratory testing.

**Site Medical Director:** a physician (MD, DO) with a current Maryland medical license who is the Director of the Service/Unit performing point-of-care testing or designee who has supervisory authority over the Site Coordinator.

**Site Coordinator:** is appointed by the Site Medical Director, has direct supervisory authority over the authorized testing personnel; should possess a Bachelor’s degree or an RN and have clinical experience; position requires understanding of the technical aspects and clinical relevance of the point-of-care test(s).

**HIV Counselors:** professionally trained staff who performs pre- and post- HIV test counseling; obtains patients’ informed consent; refers patients for appropriate follow-up treatment.

**Testing Personnel:** staff with at least a high school diploma or certificate of equivalency who performs waived testing; should minimally possess the qualities of sincerity and commitment, literacy, organizational skills, decision-making skills, and communication skills.

### Responsibilities

**Point-of-Care Testing Coordinator:**

- Responsible for the technical oversight of all testing performed at the point-of-care.
- Establishes a quality control program appropriate for the tests performed.
- Establishes a training and competency program appropriate for the tests performed and the staff performing testing.
Responsibilities (continued)

Point-of-Care Testing Coordinator:
(continued):

• Responsible for writing the test procedure and developing any needed log sheets; keeping the procedure/log sheets up-to-date, and acquiring the POCT Director’s approval and review as required.

• Resolves technical problems and ensures that remedial actions are taken whenever test systems deviate from established specifications.

• Ensures that patient results are not reported until corrective action has been taken and the test system is functioning properly.

• Evaluates the competency of all Testing Personnel and assures that staff members maintain their competency to perform test procedures and test results promptly and accurately.

• Ensures enrollment and participation in a proficiency testing program commensurate with the testing services provided, and oversees necessary remedial action when necessary.

• Ensures that all point-of-care testing sites are performing testing according to written procedures, and are in compliance with all federal, state, and accreditation requirements.

Site Medical Director:

• Ensures competent testing personnel with credentials that meet CLIA’88, The Joint Commission and the State of Maryland standards perform testing.

• Provides and ensures documentation of initial training and continuing education of testing personnel.

• Provides consultation as to the appropriateness of the testing ordered and interpretation of results.

• Responsible for seeing that all testing requirements are carried out in accordance with federal, state and accreditation regulations.

• Must appoint a Site Coordinator with supervisory authority over the testing personnel.

• Ensures that the established quality control and quality management programs are maintained to assure the quality of laboratory testing provided and to identify failures as they occur.

• Ensures that acceptable levels of analytical performance for each test system are maintained.
Responsibilities
(continued)

**Site Medical Director:**
(continued)

- Ensures that all necessary remedial actions are taken and documented whenever significant deviations from established performance specifications are identified and that patient test results are reported only when the system is functioning properly.

- Communicates and consults with Site Coordinator and testing personnel on a regular basis.

**Site Coordinator:**

- Ensures functional communication between the Point-of-Care Testing Coordinator, Testing Personnel and Site Medical Director.

- Ensures Testing Personnel’s adherence to laboratory procedures and quality of laboratory testing by ensuring compliance with the QA/QC guidelines of CLIA’88, The Joint Commission and the State of Maryland laboratory regulations.

- Maintains all testing procedures and policies performed at the site in a Laboratory Procedure Manual that must be readily available to all testing personnel.

- Maintains records of Testing Personnel to include education, licensure or certifications, technical training, in-service training, competency testing and testing experience.

- Maintains records for at least two years of all patient logs, QC records, proficiency testing, and retired procedures.

- Meets and/or communicates periodically with the Point-of-Care Coordinator to address any quality assurance issues.

- Maintains records of quality assurance activities, staff meetings in which quality assurance is discussed, problems and resolutions or corrective actions for quality control, proficiency testing, employee competency testing, staff training and result reporting.

- Ensures Quality Control is performed according to test procedure by reviewing Quality Control records minimally once a week, preferably each day of testing.

- Ensures that corrective action is taken whenever quality control limits are exceeded.
Responsibilities (continued)

Site Coordinator:
(continued):

- Provides or makes accessible all Quality Control records and quality assurance documentation to the Point-of-Care Testing Coordinator for review and signature.

- Ensures that all counseling and laboratory testing training sessions are completed for new Testing Personnel prior to any contact or performance of test procedure on patients.

- Coordinates external proficiency test performance and reports the results within the time frame specified by the proficiency test organization.

- Follows up on all unacceptable proficiency testing performance with corrective action documentation. This must be done in consultation with a Point-of-Care Testing Coordinator or a representative from the Department of Pathology CQI Office.

- Maintains a safe working environment for all personnel and patients.

- Ensures that all equipment is maintained and operable. Keeps records of all applicable service, function checks, calibrations, and temperature recordings and retains these records for at least two years.

- Performs thermometer checks annually and timer checks every six months to ensure accuracy of equipment.

- Maintains inventory control.

- Maintains an Organizational Chart document which lists the current Site Medical Director, Site Coordinator, and all currently trained and competent Testing Personnel. This document must be kept up-to-date to reflect all personnel changes.

- Maintains a list identifying staff members who perform laboratory testing that includes their signature, initials, counselor number and employment dates.

Testing Personnel:

- Responsible for specimen processing, test performance, result reporting according to laboratory guidelines and procedures.

- Only testing personnel who have completed a defined training program and can demonstrate competence will perform Rapid HIV testing.

- Demonstrates competency twice a year by successfully performing three levels of quality control and one of the following: testing an unknown specimen, written test or having a supervisor or qualified delegate observe routine work.
Responsibilities (continued)

Testing Personnel:
(continued):

- Properly performs Quality Control and patient testing.
- Properly stores Rapid HIV test kits and Quality Control solutions.
- Records “opened date” on Rapid HIV test kit boxes.
- Records “opened date” and “new expiration date” on the OraQuick ADVANCE® QC bottles.
- Records the temperature readings for the test kit storage area, refrigerator where the controls are stored and testing area daily.
- Documents all Quality Control results (both acceptable and failed QC), date, time, lot numbers, expiration dates, internal procedural control results, problems and corrective actions in the Rapid HIV QC log sheet.
- Maintains a log of patient test results.
- Documents the date and time test performed, patient’s name and medical history number or unique identifying number, test kit lot number and expiration date, test start and end time, internal procedural control results, test result, documentation of whether confirmatory testing is required, documentation of when confirmatory specimen was sent, confirmatory test result (when available), the action taken if result is “Invalid” and the identity of the individual who performed the test.
- Ensures test results are entered into the patient’s permanent record.
- Maintains records that demonstrate that proficiency testing samples are tested in the same manner as patient samples, i.e., logs proficiency testing sample results on the patient test result log sheet with the day’s run following routine QA/QC procedures.
- Follows established corrective action guidelines and procedures whenever test systems are not within the laboratory’s (or manufacturer’s) acceptable limits of performance.
- Is capable of identifying problems that may adversely affect test performance or reporting of test results and either corrects the problem(s) immediately or notifies the Site Coordinator, Site Medical Director or Point-of-Care Testing Coordinator.
- Follows Standard Precautions
Responsibilities (continued) HIV Counselors:

- Responsibilities include the same as those listed under Testing Personnel if performing Rapid HIV laboratory testing.


- Obtains patient information needed to fill in the required State of Maryland forms, including patient’s informed consent form prior to collection of specimens for HIV testing.

- Provides patient with the “Subject Information” pamphlet provided with the Rapid HIV test kit before collecting specimen.

- Follows CDC guidelines to inform the patient of his/her test result and its interpretation, e.g., must inform patient that the Rapid HIV test result is a “presumptive positive” and that a confirmatory test will be needed to confirm HIV infection.

- Provides appropriate referrals during post-test counseling for all patients per CDC guidelines found in the CTR Policies and Procedures Manual and documented on the Post-test Counseling Form.

- Maintains inventory of required State of Maryland forms and insurance forms.

Preliminary Requirements For Sites Offering Rapid HIV Testing

Each site must contact the Department of Pathology’s CQI Office to inform them of its intent to perform Rapid HIV testing. The Department of Pathology is responsible for all laboratory testing performed within the Johns Hopkins Medical Institutions.

Each site offering testing must have a CLIA Certificate of Waiver if performing only the Rapid HIV-1/2 test or the Rapid HIV-1/2 test and other waived tests, or be included under an organization with a CLIA certificate.

Training

HIV Counselors using Rapid HIV-1/2 Antibody Test Kits must attend the State of Maryland IDEHA sponsored (or approved) Level I HIV Counselor training program.

Counselors must have an assigned State of Maryland 4-digit counselor number.

Testing Personnel must complete a State of Maryland IDEHA sponsored (or approved) training program on the OraQuick® ADVANCE Rapid HIV and/or Clearview COMPLETE HIV-1/2 test procedures.

All training must be completed prior to reporting patient test results.
Training (continued) Training must be documented for each testing person; training certificates or training checklists are ways to satisfy this documentation requirement.

Testing Personnel Training Program should include the following components:

- How to perform the test, including procedures performed before, during, and after testing;
- How testing is integrated into the overall counseling and testing program;
- The importance of QA and the components of the quality management plan; and
- The use and importance of Standard Precautions/ biohazard safety.

The Training Method for Testing Personnel should minimally include the following activities:

- Reading the manufacturer’s instructions for performing the test;
- Observing a trained individual performing the test or viewing a video of a trained individual performing the test;
- Practicing the performance of the test with positive and negative controls;
- Practicing the specimen collection procedure(s); and
- Reviewing the procedures and forms on how to document the testing.

Competency Laboratory regulations require that a supervisor or qualified trainer assess and document the competency of testing personnel for each task for which the individual is responsible:

- Before the individual is permitted to perform testing without assistance for the first time;
- At least every six months; and
- When procedures or test systems change.

Testing Personnel Competency for the Rapid HIV-1/2 Antibody Test will be assessed twice a year by two methods:

- Successful performance of quality control, and
- One of the following:
  - Written test;
  - Testing an unknown specimen; or
  - Having the supervisor or qualified delegate periodically observe routine work.
Facility Requirements

The testing area should be a separate area where equipment and supplies along with the testing equipment will be located.

The testing area is to be maintained in a state of cleanliness, order and efficiency in a manner conducive to productivity.

Ambient temperature and humidity must be controlled during all seasons to minimize effects on reagents and test systems.

Storage must be convenient to the testing area, sufficient for operational need and provide an environment which is appropriate for all stored materials.

Facilities for hand washing and an eye wash station must be available in or immediately adjacent to the testing area.

Safety precautions must be established, posted, and observed to ensure protection from physical, chemical, biochemical, electrical and biohazardous hazards.

Patients are not permitted in the testing area.

Continuous temperature monitoring of the testing area, test kit storage area, and the refrigerator used to store the controls is required. This can be accomplished by using a min-max thermometer and/or using a wireless remote temperature monitoring system provided by a contracted service. (Appendix A)

Workspace area where testing is performed should be level.

Adequate lighting is required in the workspace area where test results are read and interpreted.

Laboratory Equipment

Laboratory equipment, including refrigerators, are monitored under a preventive maintenance program.

Equipment will not be used unless it is in a safe and reliable operating state.

Electrical equipment will be installed, connected and grounded according to manufacturer’s instructions.

Maintenance schedules are established based on manufacturer’s operating manuals.

Refrigerator temperatures are monitored daily with a min-max calibrated thermometer and recorded on a temperature log and/or by using a wireless remote temperature monitoring system provided by a contracted service.

Thermometers are checked annually against a NBS-traceable certified thermometer to establish accuracy, and when initially placed into service.
Laboratory Equipment
(continued)

Timers are checked minimally every six months against a reference timer traceable to the Atomic Clock to establish accuracy, and when initially placed into service.

NOTE: Calibration of timers and thermometers can be provided by an outside calibration/maintenance organization. A list of all approved companies can be obtained from the Department of Pathology CQI Office.

Equipment will be regularly cleaned by testing personnel as per manufacturer’s recommendations.

All records of preventive maintenance and calibration checks will be documented in an Equipment Maintenance Log Book or equivalent.

All records of corrective actions taken and repairs are documented in the specific equipment’s maintenance log or suitable ledger maintained by the testing site personnel.

Equipment monitoring records are periodically reviewed, dated and signed by the Site Coordinator and POCT Coordinator.

Records of major repairs, parts replacement, and annual maintenance are retained for the life of the instrument or equipment.

Performance testing and function check records are retained for a minimum of 2 years.

Laboratory Reagents and Controls

To assure the quality of test results produced by the Rapid HIV-1/2 Antibody test kits (reagent), the following guidelines are to be followed:

• Reagents and controls used in the Rapid HIV testing program will be of the appropriate quality for the intended use.

• All reagents and controls shall be marked with date of receipt.

• All reagents and controls shall be marked with date opened.

• All reagents and controls shall be labeled with expiration date.

• All reagents and controls shall be marked with a new expiration date if opening the container changes the expiration date, storage requirements, etc.

• Expired reagents or controls may never be used for clinical testing.

• All new lot numbers or shipments of reagent or controls are to be validated prior to being placed into service for patient testing.

• All reagents and controls shall be properly stored according to manufacturer’s instructions.
Laboratory Reagents and Controls  
(continued)

- Reagent and control shelf life shall be strictly observed.
- Components of reagent kits of different lot numbers are not interchangeable.
- Material Safety Data Sheets (MSDS) for all reagent and controls are maintained on the Department of Pathology POCT Program’s Website and are easily accessible to testing personnel.

Procedures

Procedures or step-by-step written instructions must be made available to all staff performing testing. This will ensure that personnel know how to perform specific tasks, and testing success is not left to chance.

Test procedures are electronically available on Hopkins Policies Online: Pathology Volume I, as well as the Department of Pathology POCT Program’s Website.

The manufacturer’s instructions must be followed when performing testing.

All work will be accomplished according to a written procedure selected, developed and optimized for each situation in advance of the actual work. Test procedures used will be equivalent to or exceed requirements recognized by existing state and federal regulations. Test procedures will include the following criteria as applicable:

- Specimen collection, Handling and Rejection criteria
- Appropriate criteria for specimen storage and preservation to ensure specimen integrity until testing is completed.
- Safety concerns unique to a particular procedure.
- Quality Control and Calibration requirements
- Failed Quality Control corrective action guidelines
- Patient Test Procedure
- Interpretation of Results; includes reference ranges, how to report results outside reportable range and critical action values
- Limitations of test method
- Criteria for the course of action to be taken in the event that a test system becomes inoperable.
Procedures (continued)

• Criteria for referral of specimens, including procedures for specimen submission and handling.

• References

Test procedures are approved, dated and signed when implemented and every 2 years thereafter by the Director of the Point-of-Care Testing Program or designee.

All changes in the test procedures must also be approved, signed and dated by the Director of the Point-of-Care Testing Program or designee.

Procedures must be re-approved, signed and dated if the directorship of the POCT Program changes.

When a test procedure is discontinued, a copy of the procedure with the dates of initial use and discontinuance must be retained for two years.

In addition to the technical Test Procedure that must be readily available to testing personnel, the Johns Hopkins Safety Manual and the Quality Management Plan for Point-of-Care Rapid HIV-1/2 Antibody Testing must also be available for all testing personnel to consult.

The key procedures from the Johns Hopkins Safety Manual that are relevant to Rapid HIV testing are the following:

• Policy Number HSE 501: Bloodborne Pathogen Exposure Control Plan
• Policy Number HSE 805: Laboratory Waste Disposal

Specimen Identification and Integrity

Analysis of specimens for diagnostic, therapeutic or clinical management requires that the specimen must be unequivocally identifiable, adequate and reflective of the clinical condition in question. If a specimen does not meet such criteria, it should not be tested as the data is misleading and may result in inappropriate treatment or management of the patient.

Regardless of where a specimen is tested, at the site of collection or an off-site location, e.g., clinical laboratory, the following conditions always apply:

• The patient needs to be properly identified using a minimum of two identifiers (neither to be the room location) prior to collecting the specimen, e.g., ask the patient to state his/her name and birth date. Accompanying requisitions and paperwork are verified for correct patient information.

• Patients must receive the “Subject Information” pamphlet and pre-test counseling prior to specimen collection, and appropriate counseling when test results are provided. (Appendix B)
Specimen Identification and Integrity (continued)

- For HIV testing, an informed consent must be obtained from the patient before any specimen collection or testing can be performed. Informed consent must include information that the individual can refuse the HIV test without jeopardizing their medical care.

- Specimen must be appropriate for the intended analysis as specified in the Test Procedure.

- The specimen must be collected in a manner as specified by the Test Procedure.

- The specimen must be free of contaminants (e.g., dirt, soap, alcohol, etc.)

- The specimen must be tested as soon as possible after collection and within the time frame specified in the Test Procedure.

- For specimens that are not tested directly, but must be transported to another site for testing, as for confirmation testing, the following conditions shall also apply:
  - The specimen must be collected in an appropriate vacutainer tube/container as specified on the Pathology requisition or in the Department of Pathology Online Customer Service Handbook.
  - The specimen is transported to the laboratory or testing area under environmental conditions appropriate to preserve and protect as specified in the Test Procedure or the Department of Pathology Online Customer Service Handbook.
  - A tracking system must be used to enable the submitting facility to identify where, when and to whom the specimen was sent, and whether results have been returned and charted in a timely manner. (Appendix C)
  - The specimen must be unequivocally identified with a minimum of two patient identifiers (patient name and medical history number). Specimen labels must be affixed to the vacutainer tube or container that directly contains the specimen, not on the specimen bags/boxes/wrappings that facilitate transport.
  - Unlabeled or mismatched (container label information does not match order information) specimens will be rejected, without testing.
  - At minimum, the test order should contain the following information:
    - Patient name and medical history number
    - Patient’s sex and age or date of birth
    - Specimen source, when appropriate
    - Date and time of specimen collection
Specimen Identification and Integrity (continued)

♦ Test(s) requested
♦ Requesting Provider’s name and ID number
♦ Any other information required for test performance, result interpretation, results reporting as specified in the Department of Pathology Online Customer Service Handbook.

• The receiving laboratory retains the right to reject any specimen which is less than unequivocally identified and submitted without all of the testing information needed.

• It is the submitter’s responsibility to assure that all requested information is legible, complete and accurate.

• In order to maintain specimen identification through the analytical and post-analytical phases of performing the Rapid HIV test, the Test Device, the Developer Solution Vial/Test Stand, and the documents for recording results are labeled with a minimum of two patient identifiers and/or a unique identifying number (e.g., an accession number that can be traced back to two patient identifiers) can be used.

Analytical (Test) Method

The Rapid HIV-1/2 Antibody Tests have been validated through the process of method verification. Method verification is a series of exercises that the laboratory undertakes to ensure, and document, that a method is working properly in its laboratory setting and enables the laboratory to make decisions on how to manage the method. The laboratory verifies the manufacturer’s performance specifications and any other relevant claims before initiating patient testing.

If the testing site modifies the manufacturers’ procedures in any way or develops in-house tests, full pre-use method evaluation is required. This method evaluation includes verification and establishment of the following applicable characteristics:

• Accuracy
• Precision
• Analytical sensitivity
• Analytical specificity
• Reportable range of patient results
• Reference range
• Calibration and control procedures
Analytical (Test) Method
(continued)

The laboratory will make the following information available to anyone upon request:

- Testing methodology
- Basis for reference ranges
- Test limitations or interferences
- Sensitivity, specificity and predictive value

Quality Control

Each testing site must establish and maintain a system that ensures accurate reporting of results and optimal specimen integrity and identification throughout the testing process.

- Each testing site must have a written policy indicating the quality control procedure and acceptability criteria. These procedures are commonly part of the individual test procedure.

- Routine quality control performance must be at least as frequent as the manufacturer’s specifications.

- Control material should monitor both the normal and abnormal ranges and correlate with the specimen matrix.

- All control results and remedial actions must be recorded and records kept for a minimum of 2 years.

- Quality control is to be performed only by the trained staff who performs patient testing.

- The performance of quality control is to be rotated among the trained staff who performs patient testing.

Rapid HIV-1/2 Quality Control:

**Internal Procedural Control:** Each device includes a built-in (internal) control. When an appropriate line develops in the CONTROL area of the device, the patient’s specimen has been correctly loaded and traveled through the test strip, indicating a valid test.

**Internal QC Frequency:** These control results are evaluated with every test.

**Internal QC Corrective Action:** If the internal control does not produce the expected result, the test result for the patient is not valid, therefore cannot be reported. The test must be repeated.

External controls are run and evaluated after a second consecutive Invalid result occurs.
External QC Levels: Three levels of quality control materials are used with the Rapid HIV test:

- Negative Control
- HIV-1 Positive Control
- HIV-2 Positive Control

External QC Frequency: The Rapid HIV Kit Controls will be run under the following circumstances:

- Once per day that the test is performed (site dependent)
- Minimally once per week
- When opening a new test kit lot number, prior to being placed into service
- Whenever a new shipment of test kits is received
- By each new staff member prior to performing tests on patients
- If there is a change in testing conditions, e.g., new location, temperature exceeds testing/storage temperature ranges
- Whenever two consecutive “Invalid” results are obtained

External QC Corrective Action: When external quality control results do not give expected results, corrective actions must be taken before any patient test results can be reported. The following actions can be taken:

- Repeat test; if QC fails again then,
- Repeat test using a newly opened control vial; if QC fails again then,
- Repeat test using a Test Device from a newly opened test kit box with the newly opened control vial
- If QC fails again, the current lot of test kits may be bad. Stop Testing! Notify the Site Coordinator and/or Site Medical Director.

All corrective actions taken must be documented on the Rapid HIV QC Log Sheet.

When external controls do not provide the expected results and it has been determined that the test kits are bad or QC failures are unresolved, none of the tests that were run since the last time control results were correct can be considered valid. This means that everyone who was tested since the last time controls ran correctly will need to be called back and retested (unless a confirmatory test was ordered).

Maryland IDEHA Notification: All unresolved QC failures and all Invalid test results are to be reported to the Maryland IDEHA using their Communication and Complaint Log. (Appendix D)
Maryland IDEHA Notification: Invalid test results due to operator error, e.g., test device tipped over during incubation, or results read later than the maximum allowed time, are not to be reported to the Maryland IDEHA.

Reporting Results

Test results can only be released when the quality control results (both internal and external) are acceptable.

All test results must be carefully reviewed and verified before they are reported.

All test results are recorded on the Patient Test Result Log Sheet, or equivalent form, that requires input of the following information: date and time test performed, patient’s name and medical history number or unique identifying number, test kit lot number and expiration date, test start and end time, internal procedural control results, test result, documentation of whether confirmatory testing is required, documentation of when confirmatory specimen was sent, confirmatory test result (when available), the action taken if result is “Invalid” and the identity of the individual who performed the test.

All test results must be entered into the patient’s permanent record.

- Results must be identified as a Point-of-Care test
- The performance of the Internal Procedural Control must be indicated next to the result, e.g. record Internal QC okay or place a checkmark (√) next to the result.

Testing sites must complete the Maryland HIV Counseling and Testing Report form (bubble sheet) (Appendix E) for each patient and submit the completed form to the Maryland IDEHA.

Confirmatory Testing

Whenever the Rapid HIV-1/2 test result is reactive (preliminary positive), a confirmatory test must be performed by the Western blot assay to confirm that the person being tested is infected with HIV. The confirmatory test specimen is sent to the JHH HIV Specialty Lab.

- Each testing site must have established procedures for referral of either test specimens or persons being tested for confirmatory testing when Rapid HIV-1/2 results are reactive.
- A log must be maintained for tracking confirmatory testing and referral of patients (Appendix C).
- If specimens are collected on-site, the site must establish procedures describing how to collect, label, process, store and document specimen transfer; transport the confirmatory test specimens to the site(s) where they will be tested; and obtain the confirmatory results to give to the patients.
Handling Result Discrepancies

Most confirmatory test results will be positive; however, some may be negative or indeterminate.

If the confirmatory test result is negative, the confirmatory test should be repeated with a new specimen in one month to rule out specimen mix-up.

If the confirmatory test results are indeterminate, the person should be advised to return for repeat testing in one month.

Testing sites that refer specimens for confirmatory testing should have established procedures describing how to:

- Match the patient’s confirmatory results with the POCT Rapid HIV-1/2 results to find potential discrepancies and to ensure that testing was performed according to procedure.
- Report the test result to the patient
- Obtain any additional specimens needed to resolve potential specimen mix-up and for retesting, as needed.

All discordant results are to be reported to the Maryland IDEHA.

Internal Assessments

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<tr>
<th>QA Activity</th>
<th>Description</th>
<th>Follow-up</th>
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<tbody>
<tr>
<td>Quality Assessments</td>
<td>On a regular basis, the Point-of-Care Testing Coordinator assesses each testing site for compliance with stated procedures, TJC standards and the State of Maryland regulations that includes, but is not limited to: frequency of quality control performance, failed quality control results with documented corrective actions, reagents and controls labeled with opened date, presence of expired reagents, failure to record appropriate temperatures, proper documentation of internal procedural controls with test results, etc.</td>
<td>The Site Coordinator is notified if any corrective measures are warranted. This review identifies opportunities for improvement for the testing site.</td>
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### Table: Internal Assessments (continued)

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<td><strong>Patient Correlations</strong></td>
<td>When the same analyte is tested using different methodologies, instruments, or at different sites, the laboratory must have a system in place to evaluate and correlate the relationship between, or among, the results at least once every six months. For HIV testing, this is accomplished by correlating the confirmatory test (Western Blot) to the Rapid HIV-1/2 Antibody Test results.</td>
<td>All discrepancies require follow-up.  &lt;br&gt; All discordant results are to be reported to the Maryland IDEHA</td>
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<tr>
<td><strong>Environmental Monitoring Rounds</strong></td>
<td>Enviromental Monitoring Rounds are conducted by the Johns Hopkins Department of Health, Safety and Environment twice a year (clinical areas) to assess compliance with the Institution’s safety policies, as well as federal, state and local safety regulations. These surveys are unannounced.</td>
<td>A corrective action plan is required to be submitted to the Department of Health, Safety and Environment when deficiencies are identified.</td>
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<tr>
<td><strong>Mock TJC Surveys</strong></td>
<td>The Department of Pathology Continuous Quality Improvement Office periodically conducts mock TJC surveys of testing sites to assess compliance with the current TJC standards.</td>
<td>Corrective action plans must be submitted to the CQI Office when areas of improvement have been identified.</td>
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External Assessments

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<tr>
<td>Proficiency Testing</td>
<td>Each testing site must participate in a CLIA-approved proficiency testing program for Rapid HIV testing. The site will receive commercially prepared survey specimens to analyze. The specimens must be tested with the site’s regular patient workload by personnel who routinely perform the testing, using the site’s routine test method. The results must be submitted to the proficiency testing organization within a defined time period. These results are then evaluated by the proficiency testing organization who determines the acceptability of the results. The Site Medical Director and the Site Coordinator must review, sign, and date the proficiency testing results summary report. The proficiency testing result summary reports and corrective actions are retained for a minimum of 2 years.</td>
<td>Corrective action is taken for any unacceptable results. The Investigation and Remedial Action on Unacceptable Proficiency Testing form (Appendix F) is completed and sent to the Maryland IDEHA.</td>
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<tr>
<td>TJC Accreditation Surveys</td>
<td>Point-of-Care Testing is reviewed during the TJC Hospital Accreditation Survey that occurs every three years. Each testing site has the potential for an on-site review. These surveys are unannounced.</td>
<td>Corrective action plans must be submitted if any deficiencies are identified.</td>
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<tr>
<td>State of Maryland</td>
<td>Unannounced on-site surveys may also be conducted by the State of Maryland when there is a complaint to investigate or to periodically assess compliance with state regulations.</td>
<td>Corrective action plans must be submitted if any deficiencies are identified.</td>
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Performance Improvement

Each testing site must have an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified. This is very site specific and deals with those issues that are of particular importance to the site. The Site Medical Director, together with the Site Coordinator, develop the ongoing quality assurance monitors.
Removal of Testing from POCT Site

Testing may be removed from a site, if the site repeatedly fails to take corrective action, despite efforts by the POCT Program Office to assist them, and all courses of action have been exhausted.

Testing may also be removed from a site if the site is unsuccessful in proficiency testing performance for the same analyte in two consecutive testing events or two out of three consecutive testing events.

Communications

Whenever an error or problem results in faulty communications of laboratory results, or there is an inquiry or complaint, the incident must be documented. The documentation should indicate the problem, personnel involved, and final resolution. The Communication and Complaint Log (Appendix D) is used to document these issues.

Patient Safety Events

Any event that involves patient safety, actual or potential, is reported in Patient Safety Net (PSN), the Institution’s electronic documentation system. This includes visitor events.

Records

Records are generated by capturing process or procedure output data on forms. A completed form is a record of activities performed. Records are the heart of any Quality Management program because they document every aspect of laboratory activities. The attitude taken by most accrediting and inspecting agencies is that “If you did not document it, then you did not do it”.

- Data will be recorded on log sheets using permanent ink. Pencils, correction fluid, and tape are not permitted. If an error is made, simply draw a single line through the erroneous data and write the correct data above or beside the mistake along with your initials and the date.

- Dates are to be recorded in the MM/DD/YY format. The year must be included when recording the date due to the length of time for record retention.

- A list identifying staff members who perform laboratory testing is to be maintained that includes their signature, initials, counselor number and employment dates.

- Refrain from using ditto marks or arrows to replicate information; each space is required to be filled-in with the requested information.

- Data recorded on log sheets must be legible and complete.

- It is the responsibility of the testing personnel to keep all records current.
Records (continued)

- Unauthorized changes to, loss of, or destruction of records is prohibited.

- In view of the possible legal use of some of the data, all records shall be maintained in such a way as to maintain credibility at all times.

- Records pertaining to laboratory testing are to be retained for a minimum of two years.

- The Site Coordinator is responsible for reviewing records minimally once a week, preferably each day of testing, to
  - determine that the expected outcomes/results were obtained, and
  - detect and identify problems with the procedure, outcomes or results before the product or results are released.

- In the patient’s medical record, documentation that the patient received pretest counseling and was provided informed consent is required. Documentation of consent can be done on the provider’s or facility’s General Consent to health care, on a separate written form, or in the medical record progress notes. Patients do not need to sign a separate written form.

Appendices

Appendix A: POC1-012F7-Temperature Log
Appendix B: POC1-012F6-Subject Information Pamphlet
Appendix C: POC1-012F5-Rapid HIV-1/2 Antibody Test Patient Confirmation and Referral Log
Appendix D: POC1-012F1-Communication and Complaint Log
Appendix E: POC1-012F4-Maryland HIV Counseling and Testing Report
Appendix F: POC1-012F3-Investigation and Remedial Action on Unacceptable Proficiency Testing
Appendix A: POC1-012F7 – Temperature Log
POC1-012F7a: TEMPERATURE LOG
(OraQuick® ADVANCE Rapid HIV-1/2 Antibody Test)

☐ Test Kit Storage Room
Location: ____________

☐ Control Kit Storage (Refrigerator)
Location: ____________
Refrigerator Serial #: ____________

☐ Testing Room
Location: ____________

Acceptable Temperature Range:
Test Kit Storage: 2°C to 27°C
35°F to 80°F

Control Kit Storage: 2°C to 8°C
35°F to 46°F

Testing Room: 15°C to 37°C
59°F to 99°F

Month/Year: __________________________

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<th>Day</th>
<th>Temp. (°C) MIN</th>
<th>Temp. (°C) MAX.</th>
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Comment/Action Codes:
1. Inventoried/stocked/removed supplies
2. Removed overstock; ensured refrig. fan not blocked
3. Adjusted thermostat
4. Ensured Room air intake/supply ducts not blocked
5. Called Maintenance- supplies/testing moved to: _____.
6. Continue to monitor

Revision: 2/2011
POC1-012F7b: TEMPERATURE LOG  
(Clearview COMPLETE HIV-1/2 Antibody Test)

☐ Test Kit Storage Room  
Location: ____________  
Refrigerator Serial #: ___________

☐ Control Kit Storage (Refrigerator)  
Location: ____________  
Refrigerator Serial #: ___________

☐ Testing Room  
Location: ____________

Acceptable Temperature Range:
Test Kit Storage: 8°C to 30°C  
46°F to 86°F  
Control Kit Storage: 2°C to 8°C  
36°F to 46°F  
Testing Room: 18°C to 30°C  
64°F to 86°F  

Month/Year: __________________________

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Comment/Action Codes:
1. Inventoried/stocked/removed supplies
2. Removed overstock; ensured refrig. fan not blocked
3. Adjusted thermostat
4. Ensured Room air intake/supply ducts not blocked
5. Called Maintenance- supplies/testing moved to: _____.
6. Continue to monitor

Revision: 2/2011
Appendix B: POC1-012F6-Subject Information Pamphlet
What can I get more information?
If you have any questions, ask your healthcare provider. You can also call the National AIDS Hotline (1-800-342-AIDS) to talk with an HIV specialist. They can give you quick, private answers at any time, day or night. Your local health department is another place to go for information. An AIDS service organization near you can also be a good source for information, education, and help.

LD6nde puedo obtener mas información?
Si tiene preguntas, hable con su proveedor médico. también puede llamar a la Línea Directa Nacional del SIDA (National AIDS Hotline) al teléfono 1-800-342-AIDS (1-800-342-2437) para hablar con uno de los especialistas en el VIH. Ellos pueden darle respuestas rápidas y privadas en cualquier momento, día o noche. El departamento de salud de su localidad es otro sitio al que puede acudir para obtener información. Una organización de servicio para personas con SIDA que se encuentre cerca de su domicilio también puede ser una buena fuente de información, educación y ayuda.

Where should I know before I get tested?
Your healthcare provider is the best person to answer your questions about HIV, the OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test, and other testing options. You have a choice of the type of test to use. When you are tested for HIV, a specimen will be collected and checked for HIV antibodies. The presence of HIV antibodies in your body means that you have been infected with the virus that causes AIDS.

LDénde debo saber antes de que me hagan la prueba?
Su proveedor médico es la persona que mejor puede responder a sus preguntas sobre el VIH, la prueba de detección de anticuerpos OraQuick ADVANCE® Rapid HIV-1/2 y otras pruebas alternativas. Usted decide qué tipo de prueba desea que le hagan. Cuando le hacen la prueba de VIH, se le toma una muestra que se analiza para detectar la presencia de anticuerpos contra el VIH. La presencia de anticuerpos contra el VIH en su cuerpo significa que usted está infectado con el virus que causa el SIDA.

INFORMACIÓN PARA EL PACIENTE
Lo que debe saber acerca del VIH y OraQuick ADVANCE®
Prueba de detección de anticuerpos Rapid HIV-1/2 antes de que le hagan la prueba

¿Qué debo saber antes de que me hagan la prueba?
Su proveedor médico es la persona que mejor puede responder a sus preguntas sobre el VIH, la prueba de detección de anticuerpos OraQuick ADVANCE® Rapid HIV-1/2 y otras pruebas alternativas. Usted decide qué tipo de prueba desea que le hagan. Cuando le hacen la prueba de VIH, se le toma una muestra que se analiza para detectar la presencia de anticuerpos contra el VIH. La presencia de anticuerpos contra el VIH en su cuerpo significa que usted está infectado con el virus que causa el SIDA.

Debe saber que la presencia de anticuerpos contra el VIH se puede detectar de varias maneras. Pida a su proveedor médico la información que necesita para tomar buenas decisiones. Algunas de las preguntas que se contestan en este folleto son:

- ¿Qué son el VIH y el SIDA?
- ¿Cómo se contagian las personas con el VIH?
- ¿Cómo puedo evitar contagiarme?
- ¿Por qué debo hacerme una prueba?
- ¿Qué es la prueba de detección de anticuerpos OraQuick ADVANCE® Rapid HIV-1/2 y cómo se hace?
- ¿Qué significa un resultado preliminar positivo?
- ¿Qué significa un resultado negativo?
- ¿Cómo puedo obtener más información?

What should I know before I get tested?
Your healthcare provider is the best person to answer your questions about HIV, the OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test, and other testing options. You have a choice of the type of test to use. When you are tested for HIV, a specimen will be collected and checked for HIV antibodies. The presence of HIV antibodies in your body means that you have been infected with the virus that causes AIDS.

Should I know before I get tested?
Your healthcare provider is the best person to answer your questions about HIV, the OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test, and other testing options. You have a choice of the type of test to use. When you are tested for HIV, a specimen will be collected and checked for HIV antibodies. The presence of HIV antibodies in your body means that you have been infected with the virus that causes AIDS.

What are HIV and AIDS?
HIV is the human immunodeficiency virus. The virus that causes AIDS (acquired immunodeficiency syndrome) is possible for a person to have the virus for months or years before any signs of illness appear. The virus weakens the body's ability to fight off infections. As a result, people with AIDS develop serious infections and cancers. These illnesses make them very sick and can eventually kill them.

How does someone get HIV?
HIV spreads through contact with blood, semen, vaginal fluids, or breast milk from infected people. Contact can come from unsafe sex. It can also come from sharing used needles and syringes. Infected women can pass the virus to their babies during pregnancy, childbirth, and breastfeeding. It is also possible to become infected with HIV through a blood transfusion, although this is now very rare.

People do not become infected with HIV through everyday casual contact with people at school, work, home, or anywhere else. The virus is not spread from contact with sweat, tears, saliva, or a casual kiss from an infected person (deep, or "French" kissing is not advised). Nor can people become infected from contact with forks, cups, clothes, phones, toothbrushes, or other things used by someone who is infected with HIV. People do not become infected from eating food prepared by an HIV-infected person. People have not become infected with HIV through insect bites.

¿Qué son el VIH y el SIDA?
El VIH es el virus de inmunodeficiencia humana. El VIH es el virus que causa el SIDA (síndrome de inmunodeficiencia adquirida). Es posible que una persona tenga el virus durante meses o años antes de que presente algún síntoma de la enfermedad. El virus debilita la capacidad del cuerpo para combatir infecciones. Como resultado, las personas con SIDA desarrollan infecciones graves y cánceres. Estas enfermedades les enferman gravemente y eventualmente pueden matarlas.

¿Cómo se contagian las personas con el VIH?
El VIH se transmite a través del contacto con la sangre, el semen, los fluidos vaginales o la leche materna de las personas infectadas. El contacto puede originarse de las prácticas sexuales sin protección. También puede prevenir el compartir agujas y jeringas usadas. Las mujeres infectadas pueden pasar el virus a sus bebés durante el embarazo, el parto y la lactancia. También es posible infectarse con el VIH a través de las transfusiones sanguíneas, aunque en la actualidad esto es muy raro.

No es posible infectarse con el VIH a través del contacto casual cotidiano con las personas en la escuela, el trabajo, el hogar u otro lugar. El virus no se transmite a través del contacto con sudor, lágrimas, saliva o el beso casual de una persona infectada (no se recomiendan los besos profundos o con la lengua). Tampoco es posible infectarse con tenedores, tazas, ropa, teléfonos, asientos de inodoro o con otras cosas usadas por una persona infectada con el VIH. No es posible infectarse por comer la comida preparada por una persona infectada con el VIH. No se han infectado personas con el VIH a través de las picaduras de insectos.
How can I avoid becoming infected?
The best way to avoid getting HIV is to avoid activities that would allow the virus to be passed to you. By following these suggestions, you will lower your risk of getting HIV:

- The only way to avoid sexual exposure to HIV is to have sex with an uninfected partner or to abstain.
- If you are not certain that your sex partner is uninfected, you should use a latex condom correctly every time you have sex.
- Do not share needles or syringes.
- Why should I get tested?
  You cannot generally tell by looking at someone whether he or she has an HIV infection. A person can be infected with HIV and not know it. The virus may take time to show its effects. A person can have HIV for ten years or more before the symptoms of AIDS appear. The only way to be certain that you are not infected is to get an HIV test.

It is important to find out if you are infected with HIV so that you do not infect someone else. If you know you are infected with HIV, you can avoid any activity that may pass it on.

It is also important to find out if you are infected with HIV so that you can receive good medical care. There are medicines that can help keep you healthy even though you are infected with the HIV virus.

What are my options for HIV testing?
OraQuick ADVANCE® provides a rapid HIV test result (in as little as 20 minutes) and in some settings a result is needed quickly, such as in hospital emergency rooms. However, in settings where a rapid HIV test is not needed, alternative tests can be done. You also have a choice of having another type of test that would require you to wait about a week for your results. This type of test can be done using a sample of blood taken from your vein, a sample of oral fluid taken from your mouth, or a sample of urine.

What is the OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test and how is it done?
The OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test is used to see if a sample of your oral fluid or blood contains HIV antibodies. If you decide to have an OraQuick ADVANCE® test, your healthcare provider will collect an oral fluid sample or take a small drop of blood from your finger, or draw blood from your vein, run the test, and give the results to you during the same visit. The OraQuick ADVANCE® test is very accurate. However, additional testing is necessary to confirm a preliminary positive result.

Complete information about the OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test device is available from your testing counselor or healthcare provider.

What does a PRELIMINARY POSITIVE result mean?
A PRELIMINARY POSITIVE result suggests that antibodies to HIV may be present in your blood or oral fluid. If you receive a PRELIMINARY POSITIVE result on the test, you will need to have another test to confirm the OraQuick ADVANCE® test result. You will also be encouraged to take precautions to avoid any chance of spreading HIV until your test result is confirmed.

If you are found to be infected, you may benefit from special medical care. New treatments can help keep you healthy, even though you are infected with HIV. See a doctor, even if you do not feel sick. A doctor can help you to live longer. Other tests can tell you how strong your immune system is and what treatments might be best for you. Some people stay healthy for a long time with HIV. Others may become ill more rapidly. Be careful not to pass HIV on to others.

What does a NEGATIVE result mean?
A NEGATIVE result means that this test did not detect HIV antibodies in your blood or oral fluid. However, in some cases HIV infection cannot be ruled out completely. If you recently (within 3 months) had any of the contacts described in the "How does someone get HIV?" section of this pamphlet it is still possible that you are infected with HIV. This is because your body can take several months after you are infected to make HIV antibodies. If you became infected only recently, there may not have been enough time to develop antibodies that can be detected by the test. You should consider getting tested again in three to six months to be sure you are not infected. If you had none of the contacts that transmit HIV in the three months before your test, a negative test result means you were not infected with HIV at the time of testing. Ask your healthcare provider to help you understand what your result means for you.

¿Cómo puedo evitar contagarme?
La mejor manera de prevenir el contagio es evitar aquellas actividades que permitieran el paso del virus a su cuerpo. Si sigue sus recomendaciones, reducirá su riesgo de contagio con el VIH.

- La única manera de evitar la exposición al VIH a través del sexo es tener relaciones sexuales con un compañero que no esté infectado o abstenerse.
- Si no tiene la certeza de que su compañero sexual no está infectado, debe usar correctamente un condón el próximo contacto.
- No comparta agujas ni jeringas.

¿Por qué debo hacer una prueba?
Generalmente no es posible determinar si una persona está infectada con el VIH sólo con mirarla. Una persona puede estar infectada y no saberlo. El virus puede tardar tiempo para causar su efecto. Una persona puede tener el VIH durante diez o más años antes de que se manifiesten los síntomas del SIDA. La única manera de tener la certeza de que no está infectado es hacerse una prueba de detección del VIH.

Es importante que sepa si está infectado con el VIH para que no infecte a otras personas. Si usted sabe que está infectado con el VIH, puede evitar toda actividad que pueda diseminarlo.

También es importante que sepa si está infectado con el VIH para que reciba una atención médica. Hay medicamentos que pueden ayudarle a mantenerse sano aunque esté infectado con el VIH.

¿Cuáles son mis opciones respecto a las pruebas de detección del VIH?
OraQuick ADVANCE® es una prueba de detección del VIH que da resultados rápidos (puede ser apenas 20 minutos), y en algunas circunstancias el resultado se necesita rápidamente, como por ejemplo en las salas de emergencia de los hospitales. Sin embargo, en los lugares en los que no sea necesario una prueba rápida de detección del VIH, se pueden hacer pruebas alternativas. También tiene la opción de hacerse otro tipo de prueba en la que requerirá esperar aproximadamente una semana para obtener los resultados. Este tipo de prueba se puede hacer en una muestra de sangre obtenida de su vena, una muestra de fluido oral tomada de su boca o una muestra de orina.

¿Qué es la prueba para detección de anticuerpos OraQuick ADVANCE® Rapid HIV-1/2 y cómo se lleva a cabo?
La prueba para detección de anticuerpos OraQuick ADVANCE® Rapid HIV-1/2 se usa para determinar si una muestra de fluido oral o de sangre contiene anticuerpos anti VIH. Si usted decide hacerse una prueba, su proveedor de atención de la salud obtendrá una muestra de su fluido oral, o le sacará una pequeña gota de sangre de su dedo, o le tomará una muestra de sangre de una vaina. Llevará a cabo la prueba y le dará el resultado durante el mismo día. La prueba OraQuick ADVANCE® es muy precisa. Sin embargo, en el caso de que el resultado preliminar sea positivo, se requerirán otras pruebas para confirmarlo.

Su asesor de pruebas o su proveedor médico tiene información completa sobre la prueba para detección de anticuerpos OraQuick ADVANCE® Rapid HIV-1/2.
SUBJECT INFORMATION NOTICE

It is very important for you to read this brochure before you are tested for HIV. It will provide you with the following information:

- What should you know before you are tested for HIV?
- What should you know about HIV and AIDS?
- How can you become infected with HIV?
- How can you avoid HIV infection?
- Why should you get an HIV test?
- What should you know about your options for HIV testing?
- What should you know about the Clearview COMPLETE HIV 1/2 assay Rapid Tests and how they are done?
- What should you know about your test results?
- Where can you get more information about HIV and AIDS?

WHAT SHOULD YOU KNOW BEFORE YOU ARE TESTED FOR HIV?

Read this brochure carefully. If you have any further questions, do not understand something, make sure that you ask your healthcare provider to explain it to you. Your healthcare provider is the best person to answer your questions about HIV, the Clearview COMPLETE HIV 1/2 assay, and other testing options that are available to you. You have a choice of the type of test to be used. Depending on what type of HIV test you choose, an appropriate sample will be taken and checked for HIV antibodies. If HIV antibodies are found in your body, that means that you have been infected with HIV, which is the virus that causes AIDS.

WHAT SHOULD YOU KNOW ABOUT HIV AND AIDS?

HIV stands for Human Immunodeficiency Virus. HIV causes AIDS (Acquired Immunodeficiency Syndrome). Many people are infected with HIV and do not have any sign of illness for many months or years. When a person becomes infected with HIV, the virus begins to attack his or her immune system, which is the body's defense against illness. As a result, that person becomes ill more and more often. When his or her body loses the ability to fight diseases, that person is said to have AIDS. People with AIDS become very sick with serious illnesses and cancers, and often will die from these illnesses.

HOW CAN YOU BECOME INFECTED WITH HIV?

HIV is passed on through contact with blood, semen, vaginal fluids, or the breast milk of an infected person. Contact can come from unsafe sex. It can also come from exposure to blood through the sharing of used syringes or needles. Infected women can pass the virus to their babies during pregnancy, childbirth, and breastfeeding. It is also possible to become infected with HIV through a blood transfusion, although this is now very rare. People do not become infected with HIV through everyday casual contact with people at school, work, home, or anywhere else. The virus is not spread from contact with sweat, tears, saliva, or a casual kiss from an infected person (deep, or "French" kissing is not advised). Nor can people become infected from contact with forks, cups, clothes, phones, toilet seats, or other things used by someone who is infected with HIV. People do not become infected from eating food prepared by an HIV-infected person. People have not become infected with HIV through insect bites.

HOW CAN YOU AVOID HIV INFECTION?

The best way to avoid getting HIV is to avoid activities that would allow the virus to be passed to you. You can reduce the risk of becoming infected with HIV by the following:

- The only way to avoid sexual exposure to HIV is to have sex with an uninfected partner or to abstain.
- If you are not certain that your sex partner is uninfected, you should use a latex condom correctly every time you have sex.
- Do not share needles or syringes.
INFORMATION YOU SHOULD KNOW ABOUT HIV AND THE CLEARVIEW® COMPLETE HIV 1/2 ASSAY

WHY SHOULD YOU GET AN HIV TEST?
You may have been infected with HIV and not know it. It can take many years before someone infected with HIV develops AIDS. There are no visible signs to tell you if you have been infected with HIV. The only way to be confident that you are not infected with HIV is to get an HIV test. If you learn that you are infected with HIV, you can take steps to avoid activities that will pass it on to others. It is important to find out if you are infected with HIV so that you can receive good medical care. Although there is presently no cure for AIDS, there are new treatments and medications for HIV infection that can help you live a longer and healthier life.

WHAT SHOULD YOU KNOW ABOUT YOUR OPTIONS FOR HIV TESTING?
The Clearview COMPLETE HIV 1/2 assay can give you a rapid HIV test result in 15 to 20 minutes. A rapid test is ideal for those situations where speed is critical, such as in an emergency room. There are other HIV tests available, if the test results are not needed right away. These tests may use a sample of your blood, fluid from your mouth, or a urine sample, but the result may not be available for 1-2 weeks.

WHAT SHOULD YOU KNOW ABOUT THE CLEARVIEW COMPLETE HIV 1/2 ASSAY AND HOW IT IS DONE?
The Clearview COMPLETE HIV 1/2 assays are fast and accurate tests that provide easy-to-read test results in 15 to 20 minutes. The Clearview COMPLETE HIV 1/2 assay is used to look for antibodies in a sample of your blood. Once you decide to use the Clearview COMPLETE HIV 1/2 assay, your healthcare provider will either prick your finger and take a drop of blood or take a tube of blood from your vein and perform the test while you wait. He or she will give you the test results during the same visit. The Clearview COMPLETE HIV 1/2 assay is very accurate; however, additional testing is necessary to confirm a reactive result. For more detail, you can ask your healthcare provider to give you complete information about the Clearview COMPLETE HIV 1/2 assay.

WHAT SHOULD YOU KNOW ABOUT YOUR TEST RESULTS AFTER HAVING THE CLEARVIEW COMPLETE HIV 1/2 ASSAY?
A Negative result means that HIV antibodies were not detected in your blood at the time of testing. However, this does not completely rule out the possibility of infection with HIV. If, in the last 3 months, you have had any of the contacts described in the "How can you become infected with HIV?" section above, there is a possibility that you may still be infected with HIV. HIV antibodies may not appear until a few months after infection with the virus. A very recent infection may not produce enough antibodies to be detected by this test. Ask your healthcare provider if you should consider getting tested again in the next 3 to 6 months to be sure that you are not infected. However, if you are certain that you have not had any of the contacts that could transmit HIV in the 3 months before your HIV test, a Negative test result means you were not infected with HIV at the time of testing. Ask your healthcare provider to help you understand what your test results mean for you.

A Preliminary Positive test result suggests that your blood may contain HIV antibodies. This result, however, must be confirmed by another test. If you have participated in an HIV vaccine study, you should inform the person giving you the test. Until your HIV test is confirmed, you should be careful to avoid activities that might spread HIV. If your test result is confirmed positive (HIV-infected), new treatments can help you maintain your health. Some people who test positive for HIV infection stay healthy for many years. Even if you become ill, there are medications that can help to slow down the virus and maintain your immune system. You should tell your doctor that you are HIV positive, so that he or she can watch your health closely. You must take steps to protect others by practicing safe sex and by informing your past and present partners about your HIV test result.

WHERE CAN YOU GET MORE INFORMATION ABOUT HIV AND AIDS?
If you have any questions or want additional information, ask your healthcare provider or contact your local health department. You can also call the National AIDS Hotline at 1-800-CDC-INFO (1-800-232-4636) to talk with an HIV specialist. They can give you quick, private answers at any time, day or night. Other AIDS service organizations near you can also provide information, education, and the help you may need.

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Appendix C: POC1-012F5 – Rapid HIV-1/2 Antibody Test
Patient Confirmation and Referral Log
# Patient Confirmation and Referral Log

### Site Location: 

<table>
<thead>
<tr>
<th>Name</th>
<th>Rapid HIV Test Date</th>
<th>Result: Oral Fluid R/NR/I</th>
<th>Confirm. Blood Collected? (Y/N)</th>
<th>Result: EIA R/NR</th>
<th>Result: WB P/N/I</th>
<th>All tests concordant? Y/N</th>
<th>If any discordancy, Pt Notified and advised to return to Moore Clinic (on Call 1,2,3) or referred to DIS</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td></td>
<td></td>
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<td></td>
<td>Call 1: Y N Call 3: Y N Call 2: Y N DIS referral: Y N</td>
</tr>
<tr>
<td>2.</td>
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<td></td>
<td>Call 1: Y N Call 3: Y N Call 2: Y N DIS referral: Y N</td>
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<td>3.</td>
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<td>Call 1: Y N Call 3: Y N Call 2: Y N DIS referral: Y N</td>
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<td>4.</td>
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<td>Call 1: Y N Call 3: Y N Call 2: Y N DIS referral: Y N</td>
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<td>Call 1: Y N Call 3: Y N Call 2: Y N DIS referral: Y N</td>
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<td>6.</td>
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<td>Call 1: Y N Call 3: Y N Call 2: Y N DIS referral: Y N</td>
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<td>7.</td>
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<td>Call 1: Y N Call 3: Y N Call 2: Y N DIS referral: Y N</td>
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<tr>
<td>8.</td>
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<td></td>
<td></td>
<td>Call 1: Y N Call 3: Y N Call 2: Y N DIS referral: Y N</td>
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</tbody>
</table>

## Quality Assurance Review

<table>
<thead>
<tr>
<th>Date</th>
<th>Problem</th>
<th>Correction Needed?</th>
<th>Correction Taken</th>
<th>Counselor #</th>
<th>Reviewed By</th>
</tr>
</thead>
<tbody>
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</table>

**Revision: 2/2011**

Test Result for Oral Fluid is recorded as: R=Reactive, NR=Non-reactive, I=Invalid
Test Result for EIA is recorded as: R=Reactive, NR=Non-reactive
Test Result for WB is recorded as: P=Positive, N=Negative, I=Indeterminate
POC1-012F5b – Clearview COMPLETE Rapid HIV-1/2
Patient Confirmation and Referral Log

Site Location: ____________________________________

<table>
<thead>
<tr>
<th>Name</th>
<th>Rapid HIV Test Date</th>
<th>Result: Fingerstick R/NR/I</th>
<th>Confirm. Blood Collected? (Y/N)</th>
<th>Result: EIA R/NR</th>
<th>Result: WB P/N/I</th>
<th>All tests concordant? Y/N</th>
<th>If any discordancy, Pt Notified and advised to return to Moore Clinic (on Call 1,2,3) or referred to DIS</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
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<td></td>
<td></td>
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<td>Call 1: Y N Call 2: Y N DIS referral: Y N</td>
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<tr>
<td>2.</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>Call 1: Y N Call 2: Y N DIS referral: Y N</td>
</tr>
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<td>3.</td>
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<td></td>
<td>Call 1: Y N Call 2: Y N DIS referral: Y N</td>
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<tr>
<td>4.</td>
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<td></td>
<td>Call 1: Y N Call 2: Y N DIS referral: Y N</td>
</tr>
<tr>
<td>5.</td>
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<td></td>
<td>Call 1: Y N Call 2: Y N DIS referral: Y N</td>
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<tr>
<td>6.</td>
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<td>Call 1: Y N Call 2: Y N DIS referral: Y N</td>
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<td>7.</td>
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<td></td>
<td>Call 1: Y N Call 2: Y N DIS referral: Y N</td>
</tr>
<tr>
<td>8.</td>
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<td></td>
<td></td>
<td>Call 1: Y N Call 2: Y N DIS referral: Y N</td>
</tr>
</tbody>
</table>

Quality Assurance Review

<table>
<thead>
<tr>
<th>Date</th>
<th>Problem</th>
<th>Correction Needed?</th>
<th>Correction Taken</th>
<th>Counselor #</th>
<th>Reviewed By:</th>
</tr>
</thead>
<tbody>
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</tr>
</tbody>
</table>

Revision: 2/2011

Test Result for Fingerstick is recorded as: R=Reactive, NR=Non-reactive, I=Invalid
Test Result for EIA is recorded as: R= Reactive, NR= Non-reactive
Test Result for WB is recorded as: P=Positive, N=Negative, I=Indeterminate
Appendix D: POC1-012F1 - Communication and Complaint Log
### Local Health Department
#### Communication and Complaint Log

<table>
<thead>
<tr>
<th>Health Department:</th>
<th>Time:</th>
<th>Initiated By:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date Reported:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Source of Communication/Complaint:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date of Occurrence:</td>
<td>Time:</td>
<td></td>
</tr>
<tr>
<td>Narrative of Event (If necessary):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Immediate Corrective Action Taken:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Does the written procedure cover how to deal with this event?**

- Yes
- No*       Not Applicable

*If No - Procedure must be updated within fifteen days from date of event.

**If Yes - Was the written procedure followed?**

- Yes
- No

**If No - Why not? Elaborate Below**

**Follow Up Activities Required?**

- Yes
- No

**If Yes - Indicate what and date to be completed below.**

<table>
<thead>
<tr>
<th>Who Completed - Signature</th>
<th>Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signature</td>
<td>Date:</td>
</tr>
</tbody>
</table>

Upon Completion – Contact a CTR Team Member IMMEDIATELY. This Record Must be Kept for Two Years.
Appendix E: POC1-012F4 – Maryland HIV Counseling and Testing Report
Prior to beginning the HIV testing encounter, complete all HIV testing consent requirements in accordance with current Maryland statutes and regulations.

Instructions for Completion

Use ONLY a pencil or a pen with blue or black ink. DO NOT use red ink.

DO NOT fold, staple or wrinkle the forms.

DO NOT make any stray marks on the forms.

Each page has a top sheet and a carbon copy sheet. The top sheet is the only sheet that will be scanned. Keep the bottom carbon copy for record keeping purposes.

Carefully separate the sheets at the perforations. If the form tears, it may not be scannable.

Text Boxes

Text boxes are used to record handwritten information (e.g. codes, names, dates).

These boxes are read using character recognition scanning software. Our ability to read and interpret the information on this form depends on the quality of the hand-written characters.

When writing letters or numbers in the boxes:
- PRINT neatly. DO NOT use cursive.
- Put only 1 letter or number per box.
- Use all CAPITAL letters.
- DO NOT have any part of the number or letter go outside of the box.

Please write all letters and numbers as shown below.

\[ \text{ABCDEFGHIJKLMNOPQRSTUVWXYZ} \quad \text{1234567890} \]

Bubbles

Bubbles or ovals are used to select the options that are applicable to the client.

Do not mark more than one bubble unless the question clearly states “Mark All That Apply.”

Shade Ovals Like This \[ \bullet \] NOT Like This \[ \times \]

Form Number

DO NOT mark or cover the form number located in two places on the bottom of each page. This number is the testing encounter number that links the form pages together and the form to any lab samples, logs or other forms.

Labels

The last page of the booklet contains labels with the HIV testing encounter number. These labels can be used for lab samples, logs, referral forms, charts and other records.

DO NOT place these or any other labels anywhere on the scannable form.

A mailing label is also provided for use when submitting data. Send all data to this address.
# MARYLAND HIV TESTING ENCOUNTER
## Part A – Client Information

### DEMOGRAPHIC INFORMATION

<table>
<thead>
<tr>
<th>Category</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of Birth</td>
<td>Month Day Year</td>
</tr>
<tr>
<td>Social Security Number Last 4 Digits</td>
<td></td>
</tr>
<tr>
<td>Gender Assigned at Birth</td>
<td>Male, Female</td>
</tr>
<tr>
<td>Current Gender Identity</td>
<td>Male, Female, Transgender, Transgender – M to F, Transgender – F to M</td>
</tr>
<tr>
<td>Pregnant? (Females only)</td>
<td>Yes, No, Don’t Know</td>
</tr>
<tr>
<td>If pregnant, in prenatal care?</td>
<td>Yes, Don’t Know</td>
</tr>
<tr>
<td>Special Populations</td>
<td>Deaf / Hard of Hearing, Blind / Vision Impaired</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Category</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethnicity</td>
<td>Hispanic, Not Hispanic, Don’t know, Declined</td>
</tr>
<tr>
<td>Race (Mark all that apply)</td>
<td>American Indian or Alaska Native, Asian, Black or African American,</td>
</tr>
<tr>
<td></td>
<td>Native Hawaiian or Other Pacific Islander, White, Don’t Know, Declined</td>
</tr>
<tr>
<td>Country of Origin</td>
<td>United States, El Salvador, Mexico, Guatemala, Honduras, Other</td>
</tr>
<tr>
<td>Length of time living in the United States</td>
<td>Less than 1 year, 1 to 5 years, 6 to 10 years, 10+ years, Declined</td>
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<tr>
<td>Primary Language</td>
<td>English, Spanish, Other, see codes</td>
</tr>
</tbody>
</table>

### RESIDENCY INFORMATION

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<tr>
<th>Category</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Client ZIP Code</td>
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</tr>
<tr>
<td>County Code</td>
<td></td>
</tr>
<tr>
<td>State Code</td>
<td></td>
</tr>
<tr>
<td>Recent Housing Status</td>
<td>Permanent Housing, Transitional Housing, Jail/Prison/Detention Center,</td>
</tr>
<tr>
<td></td>
<td>Residential Treatment, Street/Outdoors, Shelter, Other, Declined</td>
</tr>
</tbody>
</table>

### HIV TESTING HISTORY

<table>
<thead>
<tr>
<th>Category</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Previous HIV Test</td>
<td>Yes, No, Don’t Know</td>
</tr>
<tr>
<td>Self-Reported HIV Test Result</td>
<td>Positive (confirmed), Preliminary Positive, Negative, Indeterminate,</td>
</tr>
<tr>
<td></td>
<td>Don’t Know, Declined</td>
</tr>
<tr>
<td>Date of Last HIV Test</td>
<td>Month Year</td>
</tr>
<tr>
<td>Total Number of HIV Tests In Past 2 Years</td>
<td>Include Current Test, see codes</td>
</tr>
</tbody>
</table>

### CLIENT RISK FACTORS – MARK ALL THAT APPLY

<table>
<thead>
<tr>
<th>Category</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Past Since 12 mos. 1978</td>
<td></td>
</tr>
<tr>
<td>Sex (vaginal or anal) with male</td>
<td></td>
</tr>
<tr>
<td>Sex (vaginal or anal) with female</td>
<td></td>
</tr>
<tr>
<td>Sex (vaginal or anal) with</td>
<td></td>
</tr>
<tr>
<td>transgender</td>
<td></td>
</tr>
<tr>
<td>Sex (oral) with male</td>
<td></td>
</tr>
<tr>
<td>Sex (oral) with female</td>
<td></td>
</tr>
<tr>
<td>Sex (oral) with</td>
<td></td>
</tr>
<tr>
<td>transgender</td>
<td></td>
</tr>
<tr>
<td>Injection Drug Use</td>
<td></td>
</tr>
<tr>
<td>Other Risk</td>
<td></td>
</tr>
<tr>
<td>No risk identified</td>
<td></td>
</tr>
<tr>
<td>Declined</td>
<td></td>
</tr>
<tr>
<td>Client was not asked</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Category</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Past Since 12 mos. 1978</td>
<td></td>
</tr>
<tr>
<td>Complete additional risk factors for VAGINAL OR ANAL SEX ONLY</td>
<td></td>
</tr>
<tr>
<td>Sex with person who is HIV positive</td>
<td></td>
</tr>
<tr>
<td>Sex with person who is an IDU</td>
<td></td>
</tr>
<tr>
<td>Sex with person who is an MSM (female clients only)</td>
<td></td>
</tr>
<tr>
<td>Sex with anonymous partner</td>
<td></td>
</tr>
<tr>
<td>Sex in exchange for drugs, money or something they needed</td>
<td></td>
</tr>
<tr>
<td>Sex with person who exchanges sex for drugs / money</td>
<td></td>
</tr>
<tr>
<td>Sex without using a condom</td>
<td></td>
</tr>
<tr>
<td>Recent STD diagnosis (not HIV)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Category</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>If injected in the past 12 months, did the client share injection equipment (needles, works)?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Yes, No</td>
</tr>
<tr>
<td>If shared, was injection equipment cleaned with bleach before use?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Yes, No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Category</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Which drugs has the client used in the past 12 months?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Amphetamine, meth, speed, crystal, etc., Club drugs (e.g. GHB, ketamine), Hallucinogens (e.g. LSD, PCP), Other</td>
</tr>
</tbody>
</table>
**MARYLAND HIV TESTING ENCOUNTER**

**Part B - Content and Results of HIV Testing Encounter**

<table>
<thead>
<tr>
<th>Site Number</th>
<th>ZIP Code Where Test Performed</th>
<th>HIV TEST #1</th>
<th>HIV TEST #2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pre-Test Session Date</th>
<th>Pre-Test Session Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Month</td>
<td>Day</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Counselor Number</th>
<th>If number less than 5 digits, add leading zeros.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test Election</th>
<th>Test Technology</th>
<th>Lab Used for Conventional Sample</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tested Anonymously</td>
<td>Rapid</td>
<td>DHMH/State Lab</td>
</tr>
<tr>
<td>Tested Confidentially</td>
<td>Conventional</td>
<td>BCHD Lab</td>
</tr>
<tr>
<td>Declined Testing</td>
<td>Other</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Blood – Venipuncture</th>
<th>Blood – Finger Stick</th>
<th>Oral Fluid</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Post-Test Session Date</th>
<th>Post-Test Session Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Month</td>
<td>Day</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Counselor Number</th>
<th>If number less than 5 digits, add leading zeros.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test Result</th>
<th>Positive/Reactive</th>
<th>Negative</th>
<th>Indeterminate/Invalid</th>
<th>No Result</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Positive/Reactive</td>
<td>Negative</td>
<td>Indeterminate/Invalid</td>
<td>No Result</td>
</tr>
<tr>
<td></td>
<td>Positive/Reactive</td>
<td>Negative</td>
<td>Indeterminate/Invalid</td>
<td>No Result</td>
</tr>
<tr>
<td></td>
<td>Positive/Reactive</td>
<td>Negative</td>
<td>Indeterminate/Invalid</td>
<td>No Result</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Result provided?</th>
<th>If results not provided, why?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>Declined notification</td>
</tr>
<tr>
<td>No</td>
<td>Did not return/Could not locate</td>
</tr>
<tr>
<td></td>
<td>Obtained results from another agency</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>If rapid reactive, did the client provide confirmatory sample?</th>
<th>NAAT Testing Results: (Mark all that apply)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>Positive NAAT result received from laboratory</td>
</tr>
<tr>
<td>No</td>
<td>Positive NAAT result delivered to client</td>
</tr>
</tbody>
</table>

| NAAT Testing Results: (Mark all that apply) | |
|--------------------------------------------| |
| Positive NAAT result received from laboratory | |
| Positive NAAT result delivered to client | |

<table>
<thead>
<tr>
<th>Was a risk reduction plan developed with the client?</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Other testing provided during this encounter: (Mark all that apply)</th>
<th>Pregnancy</th>
<th>Syphilis</th>
<th>Hepatitis B</th>
<th>Gonorrhea</th>
<th>Hepatitis C</th>
<th>Chlamydia</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Counselor Notes:</th>
<th>10180416</th>
<th>10180416</th>
</tr>
</thead>
</table>
MARYLAND HIV TESTING ENCOUNTER
Part C – Section For HIV-Positive Clients Only

REFERRAL AND LINKAGE TO CARE INFORMATION

Was the client referred to HIV medical care?

- Yes
- No

If not referred to HIV medical care, why?

- Client already in care
- Client declined care

Where was the client referred?

Did the client attend the first appointment?

- Yes
- No
- Don't Know

Was the client referred to HIV Partner Services (formerly PCRS)?

- Yes
- No

Was the client referred to prenatal care?

- Yes
- No - client declined

Where was the client referred?

Did the client attend the first appointment?

- Yes
- No
- Don't Know

Was the client referred to HIV prevention services?

- Yes
- No

EXTERNAL REFERRAL FOR CONFIRMATORY TESTING OF PRELIMINARY POSITIVES

If preliminary positive client was referred for confirmatory testing, did client receive confirmatory test result?

- Yes
- No
- Don't Know

HIV INCIDENCE QUESTIONS – CONFIRMED POSITIVES ONLY

Date of Client’s Last Negative HIV Test

Month

Day

Year

Has the client EVER taken antiretroviral medication?

- Yes
- No
- Don’t Know

Has the client taken antiretroviral medication in the past 6 months?

- Yes
- No
- Don’t Know

Is the client currently taking antiretroviral medication?

- Yes
- No
- Don’t Know

HIV REPORTING INFORMATION

Client First Name

Client Middle Name

Client Last Name

Client Suffix (e.g. III, Jr.)

Counselor Notes:

10180416
Appendix F: POC1-012F3 - Investigation and Remedial Action on Unacceptable Proficiency Testing
**Investigation and Remedial Action on Unacceptable Proficiency Testing**

<table>
<thead>
<tr>
<th>Date of Investigation: _________</th>
<th>Local Health Department: __________________________</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prepared by: ____________________</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>PT Set Identification:</strong></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th><strong>Date Received:</strong></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th><strong>Unacceptable (reported) result:</strong></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th><strong>Acceptable result/range:</strong></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th><strong>Previous trends/unacceptable results for this analysis/test?</strong></th>
</tr>
</thead>
</table>

- No - skip to next section
- Yes - Corrective action/investigation noted:

<table>
<thead>
<tr>
<th><strong>Day of testing - quality control results reviewed:</strong></th>
</tr>
</thead>
</table>

- Yes
- Acceptable
- Not Acceptable
- Indicate corrective action:

<table>
<thead>
<tr>
<th><strong>Clerical/Transcription Review:</strong></th>
</tr>
</thead>
</table>

- Acceptable
- Not Acceptable
- Indicate corrective action:

<table>
<thead>
<tr>
<th><strong>Was patient data affected?</strong></th>
</tr>
</thead>
</table>

- No - skip to next section
- Yes - Indicate corrective action taken:

<table>
<thead>
<tr>
<th><strong>Classification of Problem:</strong></th>
</tr>
</thead>
</table>

- Clerical
- Technical
- Methodology
- Problem with PT material
- Problem with PT evaluation
- No explanation

<table>
<thead>
<tr>
<th><strong>Conclusions:</strong></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th><strong>Corrective actions/system changes(s) to prevent recurrence:</strong></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th><strong>Supervisor/Date:</strong></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th><strong>Laboratory Director/Date:</strong></th>
</tr>
</thead>
</table>

**Upon Completion - This Record Must be Maintained For Two Years**
Title: Quality Management Plan for Point-of-Care Rapid HIV-1/2 Antibody Testing

Author: Sandra Humbertson, MT(ASCP)  
Signature:  
Date: 11/3/05

POCT Director: William Clarke, PhD.  
Signature:  
Date: 12/21/05

Issued:  
Signature:  
Date: 1/3/06

Effective:  
Signature:  
Date: 2/1/06

Revision Level  Reviewed By:  Review Date
11/22/06  William Clarke, Ph.D.  1/2/07
2/26/09  William Clarke, Ph.D.  3/2/09
7/1/10  William Clarke, Ph.D.  6/17/2010
2/15/11  William Clarke

Distribution List

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<th>SITE</th>
<th>Location</th>
<th># of Copies</th>
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<tbody>
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<td>POCT Website</td>
<td></td>
<td></td>
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</tbody>
</table>