

*Revised & approved.*  
*[Signature]*  
4/1/15

# NJ RAPID HIV TESTING SUPPORT PROGRAM POLICY MANUAL

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## *PROGRAM OVERVIEW*

### Program Description:

Point of Care testing may seem, on its face, simple and 'fool proof', but in a study conducted by HCFA in Colorado and Ohio, quality problems were identified in more than 50% of Certificate of Waiver labs surveyed. It revealed "glaring quality control problems" and urged the FDA to provide more governmental oversight of these laboratories. The HCFA study cited the following performance problems:

- Obsolete instructions
- Lack of instructions
- Incorrect instructions
- Failing to perform quality control as required by the manufacturer

The laboratories risk intervention by both federal and state authorities if clinical testing is performed in violation of CLIA and NJ Department of Health and Senior Services requirements. Please note that a CLIA certificate does not substitute for licensure by the State.

To assist personnel who wish to perform clinical laboratory procedures on-site, the Robert Wood Johnson Medical School, statewide Rapid HIV Testing Support Program, has adopted a POCT program designed:

- To provide quality care to our patients and clients;
- To meet the standards of quality review organizations;
- To ensure that RWJMS maintains required compliance with state and federal regulations regarding laboratory oversight;
- To provide consistency of test offerings at all clinical sites participating in the program;
- To achieve economies of scale in the acquisition of reagents and instrumentation within the group;
- To ensure the highest quality of test performance to all patients.

Under this program, rapid HIV testing services (Qualitative HIV 1 & 2 Antibodies) can be provided at any RWJMS sponsored site, so long as the required training, proficiency testing, quality control and validation procedures are performed. The Department of Pathology and Laboratory Medicine will oversee this program and provide Bioanalytical Laboratory Directorship (BLD) and all necessary state and federal licensing for these sites. The implementation of the program will include administrative functions and clinical oversight responsibilities handled by the Rapid HIV Testing Support Program under the auspices of the Department of Pathology and Laboratory Medicine.

This program will:

- Provide each participating unit with standardized procedures which can be performed at a licensed facility so long as the requirements for training, competency assessment, quality control and periodic review are maintained within the facility.
- Provide training and recertification to all staff performing rapid HIV testing.
- Centralize inventory so that common reagents are used throughout the state, to provide validation of this inventory and to minimize lot to lot variability.
- Provide resource support to insure testing quality including a standardized procedure for reporting testing exceptions and problem resolution.
- Submit and maintain clinical laboratory licensure for any RWJMS site providing rapid HIV testing.
- Provide monitoring and initial review of testing records and ongoing proficiency.
- Provide monthly visits to each clinical facility to review compliance efforts with state and federal regulations regarding clinical laboratories.

### Program Participation:

To participate in rapid HIV testing under UMDNJ-RWJMS sponsorship, the following is required:

1. Execution of a Professional Services Agreement (PSA) between UMDNJ-RWJMS and the organization requesting testing. This document legally delineates the responsibilities and requirements of both parties. Following a physical inspection of the facility, the Department of Pathology and Laboratory Medicine will arrange for licensure of the facility.
2. Upon completion of the PSA, the Department of Pathology and Laboratory Medicine will begin the process for licensure to include: a physical inspection of the site and training of site staff to all the policies and procedures for providing rapid HIV testing, proficiency testing, and license application preparation. During this process the Department will:
  - a. Provide each site with Rapid HIV Testing procedure manuals and log sheets.
  - b. Provide for staff training, retraining and staff support to operationalize site.
  - c. Review competency assessment of staff, including review of on-going proficiency testing under an appropriate program and direct observation.
  - d. Provide all necessary supplies and reagents necessary to perform rapid HIV testing.
  - e. Adherence to Rapid HIV Testing Support Program Procedures: Continued participation in the Rapid HIV Testing Support Point of Care program requires that these procedures be performed in accordance with the instructions described in our manual including those related to quality control, record keeping, proficiency testing and competency assessment. Monthly inspections of all sites will occur.
  - f. Submit all license application materials with appropriate fees to the Clinical Laboratory Improvement Service (CLIS) at the New Jersey Department of Health and Senior Services.

**Obtaining Necessary Supplies:**

Supplies, including test and control reagents, may be requested by forwarding a supply request to the Rapid HIV Testing Support Program via fax at 732-235-9012. Supplies obtained by the Rapid HIV Testing Support Program on behalf of participating sites will be validated prior to distribution.

**Rapid HIV Testing Support Program Contact Information**

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### **General Guidelines:**

#### **Goal:**

The clinical goals of Robert Wood Johnson Medical School are to provide optimal laboratory services to patients and reference clients. To provide such service, it is essential that the quality of results be assured. Proper use of Rapid HIV testing can provide clinical diagnostic information in a timely manner at the time of patient care and can reduce the volume of blood needed for laboratory testing. Quality assurance/performance improvement guidelines for rapid HIV point of care testing are a necessary step in providing standardized testing procedures and complying with the laboratory accrediting requirements of the New Jersey Department of Health and Human Services, the Federal Drug Administration, and the College of American Pathologists.

#### **Policy:**

Properly trained and certified personnel may perform testing outside the laboratory, under the authority and licensure of a NJ licensed bioanalytical laboratory director.

In order to assure the clinical reliability of results obtained from such testing and to comply with federal and state regulations, the following guidelines must be followed. These guidelines will be used to establish specific procedures for each ancillary testing site.

For rapid HIV testing to be performed at each practice site, a procedure specific to the specific rapid test used and type of site where performed has been developed. These procedures will be modified as needed. Failure to follow the procedures outlined will result in cessation of permission to perform ancillary testing.

#### **Quality Control:**

Following proper quality control procedures is essential. Lack of quality control can result in serious misinterpretations of test results.

All test procedures require that a fixed number of quality control (QC) samples be run at pre-determined intervals. QC samples are samples which contain a known concentration of the analyte being measured. If the result of the QC sample is not within its expected range, it is an indication that patient samples would give erroneous results. **If QC results are out-of-range, patient or client samples may not be run!**

The ancillary testing site is responsible for the proper storage and replacement of acceptable quality control materials as specified by the test procedure or the QC manufacturer. An inventory of QC materials will be maintained by the Rapid HIV Testing Support Program. All supplies should be ordered from the Rapid Testing Support Program using forms provided in this manual.

- *Frequency:* The frequency of QC testing depends on the test being performed. For rapid HIV testing, the frequency is delineated in the policy.
- *Number:* QC run for Rapid HIV 1/2 testing consists of one positive HIV 1, one positive HIV 2 and one negative sample. QC run for Rapid HIV 1 testing consists of one positive HIV 1 and one negative sample.
- *Expected values:* If the positive results and the negative result are not achieved, the program coordinator is available to help with interpreting the results of QC samples and to advise whether patient testing may proceed (see contact sheet in this manual). In the absence of the site's program coordinator, any staff listed can be contacted for assistance.
- *Record keeping:* Results of all QC samples must be logged onto appropriate record sheets that will be kept at each testing area, and must indicate who performed the testing. These may be reviewed at any time by the HIV Rapid Testing Support Program coordinator, laboratory supervisors or representatives from regulatory agencies. They must be sent to the Rapid HIV Testing Support Program monthly, and will be kept for at least two years in the Rapid HIV Testing Support Program office.

**Testing:**

The test procedure will describe the steps necessary to perform testing. It will also include information about proper specimen collection.

**Recordkeeping:**

Results of all patient/client tests must be permanently recorded. The record must allow for a review of which patients were tested. This would allow tracking of those patients in case a problem occurs, such as a reagent recall by the manufacturer or testing problems discovered at the site. To do this, all results must be entered on the log sheet located at each site and in the patient file. The date and time the specimen was collected (and the date and time of analysis if there is a significant delay) must be recorded along with the identity of the person performing the test. These records are to be sent to the HIV Rapid Testing Support Program monthly and must be retained for at least two years.

**Operator Proficiency:**

Each person running the test must be trained according to HIV Rapid Testing Support program policy. Training will be provided by the Rapid HIV Testing Support Program staff. The Rapid HIV Testing Support program staff must be notified of all new hires, terminations or resignations. In general, operator proficiency is certified initially for six months. A re-certification process is then completed with subsequent certification for periods of one (1) year.

Recertification: Recertification of individuals performing testing will be established by direct observation, testing and/or documentation of having obtained proper results on daily quality control (QC) samples and proficiency test (PT) specimens provided. Staff from the Rapid Testing Support Program will monitor compliance with these activities. Correct QC results must be performed in accordance with specific procedures, or certification will lapse.

**Proficiency Testing:**

Periodically, unknown samples will be given to each rapid HIV testing site to be run. These samples are purchased from outside regulatory agencies to evaluate the accuracy of the results obtained by the site. These “proficiency testing” samples must be run as patient samples are run, after proper maintenance and quality control procedures have been completed. PT samples may not be transferred to or discussed with another testing site or lab during the testing period. The results will be reported back to the testing agency for evaluation. These proficiencies are required in order to maintain NJ licensure. Failure to perform adequately on proficiency testing challenges can result in loss of the laboratory’s license.

**Competency Assessment:**

At the discretion of the laboratory director, a program for on-going competency assessment may be established. In some instances this will involve mandatory testing of unknown specimens at a frequency sufficient to insure continued successful operator performance.

**Quality Assurance Indicators:**

A series of quality assurance indicators will be established and updated on a regular basis. These indicators will be selected so as to provide monitoring of compliance with the quality procedures of the Rapid HIV Testing Support Program, including: quality control, temperature monitoring, proficiency test results, discordants, patient/client recordkeeping, and operator competency. Findings of these monitors will be evaluated by the director, and will be forwarded to the appropriate committees or boards responsible for the laboratory’s operations.

**Delegation of Authority:**

Drs. Evan Cadoff, Eugene Martin and Gratian Salaru shall have authority with regard to all policies, procedures and practices of the laboratory in the absence of, or in addition to, the licensed lab director, Dr. Parisa Javidian. This authority shall include, but it not limited to, approving revisions to procedures, enforcing the procedures, and reviewing records—including personnel, patient testing, quality control, and proficiency test records, and any other data that may periodically need to be reviewed.

Written by:	<u>POCT Committee</u>	Date:	<u>01/15/02</u>
Approved by:	<u>Evan Cadoff, M.D.</u>	Date:	<u>01/15/02</u>
Revised by:	<u>Patricia A Ribeiro, MT(ASCP)</u>	Date:	<u>4/12/13</u>
Reviewed by:	<u>Joanne Corbo, MBA, MT (ASCP)</u>	Date:	<u>10/2/13</u>
Approved by:	<u>Gratian Salaru, M.D.</u>	Date:	<u>10/2/13</u>
Updated by:	<u>Franchesca Jackson, BS</u>	Date:	<u>10/1/14</u>

**OPERATOR CERTIFICATION**

**Purpose**

Each person running the test must be trained according to the NJ Rapid HIV Testing Support Program policy. Training will be provided by the NJ Rapid HIV Testing Support Program trainers. The NJ Rapid HIV Testing Support Program must be notified of all new hires or resignations.

Recertification of individuals performing testing is performed six (6) months after the initial certification and annually thereafter via a written test given at the site. The individual's technique will also be reviewed by direct observation, review of quality control records and documentation of having obtained proper results on quality control (QC) samples and proficiency test (PT) specimens provided through the NJ Rapid HIV Testing Support Program's clinical coordinator. Correct QC results must be performed in accordance with specific procedures, or certification will lapse. All personnel who are certified and actively testing clients, running controls or proficiencies are required to recertify annually.

**Initial Training**

Initial training of testing personnel shall include:

- Attendance at a NJ Rapid HIV Testing Support Program training session conducted by one of the program's designated trainers.
- Review of general aspects of the NJ Rapid HIV Testing Support Program.
- Review of general aspects of Point of Care laboratory testing
- Successful performance of the tests being trained for using blind samples, under the observation of the trainer.
- Successful completion of a competency exam for the Rapid HIV test.

Annual recertification shall be based on:

- Successful performance of quarterly QC and/or PT samples during the prior year.
- Successful completion of a written or electronic competency assessment exam required 6 months post certification and annually thereafter.
- Successful performance of the test under direct observation by the NJ Rapid HIV Support Program's designated staff member.

Records of certification and re-certification shall be maintained in the NJ Rapid HIV Testing Support Program office.

Written by: Evan Cadoff, M.D.

Date: 05/07/2003

Approved by: Evan Cadoff, M.D.

Date: 05/07/2003

Revised by: Patricia Ribeiro, MT (ASCP)

Date: 05/31/2013

Reviewed by: Joanne Corbo, MBA, MT (ASCP)

Date: 05/31/2013

Approved by: Evan Cadoff, M.D.

Date: 8/6/2013

## *Quality Control Program*

### **Purpose:**

The purpose of the QC program is to monitor the quality of testing performed by Rapid HIV Testing sites and to ensure that problems related to the test systems, reagents or testing procedures are identified and addressed. Quality Control testing is an intrinsic part of any laboratory testing and must be done in order to provide proper patient care and to be in compliance with the standards of the NJ Department of Health and Senior Services and CLIA 88.

### **Elements of the Quality Control Program:**

Quality control is an ongoing process designed to insure that an analytic system is functioning correctly. The basic premise of most quality control systems is that known samples are tested (simultaneously with patient unknowns) and the results compared with expected results. Failure to obtain the expected values is an indication that a problem may exist, and results in a series of actions designed to protect the patient and personnel from treatment based on aberrant and incorrect data.

### **Responsibilities:**

1. It is the responsibility of the each rapid HIV site testing staff to complete quality control as specified in the policy. Patient testing may only be performed if Quality Control results are within the limits specified.
2. Periodically, the Rapid HIV Testing Support staff will inspect sites to ensure that proper procedures are being followed and documented for patient identification, patient preparation, specimen collection, specimen ID, specimen preservation and processing, and result reporting.
3. Quality Control (QC) specimens will be analyzed at a frequency determined by the laboratory director.
4. QC specimens will be analyzed on a rotating basis by all testing personnel within a rapid HIV testing site so that in each calendar quarter, each counselor has run at least one set of QC specimens.
5. It is the responsibility of the rapid HIV testing on-site coordinator to review all rapid HIV quality control on a weekly basis, to assure that testing and troubleshooting is done and documented.
6. The rapid HIV testing on-site coordinator will submit QC data to the Rapid HIV Testing Support Program on a monthly basis for review and central maintenance of records.
7. At his/her discretion, the Bioanalytical Laboratory Director may assign additional duties for the monitoring of performance and the correction of problems identified by the monitoring system to designated staff.

### **Quality Control Failures:**

In the event of a quality control failure, the site should follow the HIV testing protocol and cease client testing until the problem is rectified.

### **Corrective Actions:**

If a QC failure occurs it is essential to determine the cause of the failure.

- The initial step in examining a QC failure is to suspect the quality of the reagents or controls. It is often helpful to utilize a different set of reagent controls as a first step and repeat the procedure. If this fails, the next step would be to use a different lot of reagent test kits, or a box from a different shipment. If a different lot of reagent controls or kits are not available at the site, please contact the Rapid HIV Testing Support program.
- **In the face of a QC failure, cease patient testing until the issue is resolved. Document all corrective action on the back of the testing log sheet.** For example, if you repeat the QC and have obtained the appropriate results, record the new result and indicate whether you repeated the same QC sample from the same reagent control or whether you employed a different reagent control.

**Frequency of Quality Control Samples:**

- As specified in the specific procedure, i.e. weekly.
- When reagent kit storage has been out-of range.
- Each time a new reagent lot number or new test kit lot number is introduced. Central validation of all reagent lots prior to release will be performed for all inventory provided by the Rapid HIV Testing Support Program, so this does not need to be repeated at each site.
- Each time a new delivery or shipment of reagents is received by the Rapid HIV testing site.

**QC Review:**

All QC results must be reviewed on a regular basis.

Each person performing patient testing must first verify that QC was properly performed and documented at the appropriate interval. If QC has not yet been completed, patient testing may not be done. All testing personnel must initiate corrective action if QC results do not fall within the expected ranges.

The HIV rapid testing on-site coordinator will review documentation of QC on a weekly basis. The on-site coordinator is responsible for instituting corrective action for 'out of compliance' procedures. Additional help is available by calling staff at the Rapid HIV Testing Support program.

**Action to Improve Services and to Resolve Problems:**

All problems identified by the monitoring system will be corrected, documented and brought to the attention of the appropriate Rapid HIV Testing Support Program staff.

Written by: POCT Committee Date: 01/15/02

Approved by: Evan Cadoff, M.D. Date: 01/15/02

Reviewed by: Patricia Ribeiro, MT (ASCP) Date: 4/12/13

Reviewed by: Joanne Corbo, MBA,MT(ASCP) Date: 4/12/13

Approved by: Gratian Salaru, M.D. Date: 4/12/13

Approved by: Parisa Javidian, M.D. Date: 4/12/13

## *BLOODBORNE PATHOGENS*

**Purpose:** Exposure Control Plan (ECP) is provided to eliminate or minimize occupational exposure to bloodborne pathogens in accordance with the OSHA bloodborne pathogen standard.

**Responsibilities:** The UMDNJ/RWJMS Laboratory Director is responsible for overseeing the implementation of this ECP. The site coordinator is responsible for ensuring that each employee is trained and disinfectants and/or personal protective equipment are available and used. The Rapid HIV testing coordinator is responsible to have a post exposure control plan. If your facility does not provide one, one must be created and submitted to the Rapid HIV Support team.

**Universal Precautions:** All facilities and their employees will utilize universal precautions as the base of their bloodborne pathogen safety program. Universal precautions is an infection control method which dictates that all human blood and body fluids be treated as if they were infectious for HIV, HBV and other bloodborne pathogens regardless of patient location, age, diagnosis, quantity of blood or other body fluids. Potentially infectious materials include but are not limited to: human blood, body fluid (saliva, urine, vaginal secretions), tissue cultures, and infected culture medium.

**Clinical Significance:** Healthcare workers incur risk of infection and subsequent illness from bloodborne pathogens with each occupational exposure. By following universal precautions, that risk of occupational exposure and subsequent illness will be minimized. Unprotected (unvaccinated) healthcare workers have up to a 12 times greater risk of becoming infected with the Hepatitis B Virus (HBV) than members of the population at large, 2% of which are asymptomatic carriers of that virus. It is estimated that 1 in every 250 Americans is infected with Human Immunodeficiency Virus (HIV) and as many as 88% of these individuals are unaware of their infection and infectious status. These statistics underscore the necessity for adherence to the principles of "Universal Precautions" in which all human blood, blood products and other potentially infectious materials are treated as if they were KNOWN to be infectious.

**Work Practice:** Work practice controls include but are not limited to the following:

- No food or drink shall be kept in the refrigerator, freezer, or testing area where testing or supplies are kept. At non-fixed site (ie, mobile collection sites), food or drink may be placed no less than an arm's length from the testing area.
- Eating, drinking, smoking, applying cosmetics, lip balm, and handling of contact lenses are not permitted where there is a reasonable likelihood of exposure to blood and other body substances. As above, the rule in rapid HIV testing is all items must not be within arm's reach of the testing area.
- All procedures are to be performed in such a way that splashing, spattering, or droplet formation is minimized.
- Wash hands immediately or as soon as possible after removal of gloves. On the mobile vans or satellites that do not have hand washing facilities available, interim hand washing measures, such as antiseptic towelettes, waterless antiseptic soaps, and paper towels may be used but must be followed as soon as possible with hand washing measures

- Wash all body parts as soon as possible after skin contact with blood or other potentially infectious materials occur. Personnel will flush mucous membranes with water immediately following contact with blood or other potentially infectious materials. Report all exposures that require medical treatment to employee services or Emergency Department immediately after exposure.
- Place all specimens of blood or other potentially infectious material in a container which prevents leakage during collection, handling, processing, storage, transport, or shipping.

**Personal Protective Equipment (PPE):** Personal protective equipment protects you against potentially infectious material. Examples of the equipment are gloves, gowns, laboratory coats, face shields or masks, eye protection, and splash shield. All personal protective equipment must be removed and hands washed prior to leaving the laboratory area.

**Gloves:** Gloves are worn whenever it can reasonably be anticipated that there will be contact with blood or other potentially infectious materials or when handling or touching contaminated surfaces. This includes, but is not limited to: performing a fingerstick or venipuncture, opening a tube for any reason, pipetting a sample, or introducing a specimen into an instrument or test system in any way. Disposable gloves are replaced between client testing and as soon as practically possible when they become contaminated, or as soon as feasible if they are torn, punctured, or when their ability to function as a barrier is compromised. Gloves should not be washed or decontaminated for re-use. Gloves should be discarded into regular trash unless saturated with blood or other potentially infectious material.

**Protective Clothing:** Clothing such as lab coats or jackets, aprons, or gowns are worn in occupational exposure situations. The type and characteristics of such protective clothing must be appropriate to the task and degree of exposure anticipated. This includes, but is not limited to: performing a fingerstick or venipuncture, performing a rapid HIV test on an oral or blood sample, or introducing a specimen into an instrument or test system. Lab coats or jackets, aprons, or gowns are replaced as soon as practically possible when they become contaminated or as soon as feasible if they are torn, punctured, or when their ability to function as a barrier is compromised. Disposables should be discarded into regular garbage unless saturated with 30cc or more of blood. The presence of 30cc or more of blood requires disposal in a red biohazard waste bag.

**Eye Protection and Shields:** Face shields or goggles, and masks are worn whenever it can reasonably be anticipated that there will be contact with blood or other potentially infectious materials or when handling or touching contaminated surfaces. This includes performing a fingerstick, performing a rapid HIV test, and drawing a tube of blood or introducing a specimen into an instrument. Face shields, masks, goggles and splash guards are to be decontaminated as soon as practically possible when they become contaminated or as soon as feasible if they are damaged, or when their ability to function as a barrier is compromised. Disposables should be discarded into regular waste.

**Housekeeping:** Work areas are maintained in a clean and sanitary condition. Phones and computer keyboards are not to be touched while the individual is wearing gloves. All equipment, environmental and working surfaces are cleaned and decontaminated after contact with blood or other potentially infectious material.

**Testing Equipment Handling:** Any testing equipment in the lab may accidentally become contaminated with blood or other potentially infectious materials. Follow each individual manufacturer's instructions on how to decontaminate. If decontamination of the equipment or portions of it is not feasible, clearly label the portion of the equipment that remains contaminated and call the manufacturer's hotline to place a service call or for further instructions.

**Cleaning and Disinfecting:** Contamination is described as the presence or the reasonably anticipated presence of blood or other potentially infectious materials on an item or surface. All work areas will be wiped clean with a 1:10 dilution of bleach at the beginning and end of each shift. Any accidental spill of blood or other potentially infectious materials should be disinfected immediately by applying a 1:10 dilution of bleach for 10 minutes to the area and then wiping up. The bench top must be wiped clean with 10% bleach and then 70% ethanol to remove any bleach residue.

### **Regulated Medical Waste:**

**Definition:** Regulated medical waste is liquid waste human blood; products of blood; items saturated and or dripping with human blood that are caked with dried human blood; including serum, plasma, and other blood components, and their container, which were used or intended for use in either patient care, testing and laboratory analysis or the development of pharmaceuticals. Contaminated sharps must be placed in a sharps container marked regulated medical waste.

**For Rapid HIV Testing Sites, used reagent test kits, external controls and sharps are the items considered to be regulated medical waste. All other items are to be disposed as non-regulated medical waste in regular garbage. If any of your PPE is saturated in blood or if the amount of blood or potential infectious material amounts to 30cc or greater, the PPE must be placed in regulated medical waste.**

**Other Regulated Waste Containment:** Regulated waste is placed in containers that are constructed to prevent leakage, appropriately labeled as a biohazard, and can be closed prior to removal. If the regulated waste to be disposed does not fit in a biohazard container, it must be disposed of in a red biohazard bag. Disposal of regulated waste is the responsibility of the facility in accordance with all federal, state and local standards.

### **Biohazard Warning Labeling:**

Labels for biohazard warnings contain the word "BIOHAZARD" and the following symbol:



They are fluorescent orange or orange-red with symbols with lettering in a contrasting color, either as an integral part of the container or affixed to it in such a fashion as to prevent its loss or unintentional removal.

Biohazard warnings are affixed to:

- Containers of regulated waste, refrigerators and freezers containing blood or potentially infectious material.
- All containers used to store, transport or ship blood or other potentially infectious materials, except individual containers of blood or other potentially infectious materials are placed in a labeled container during storage, transport, shipment or disposal.

**General Guidelines:**

- Universal precautions should be used with regard to all blood and body fluids.
- All specimens of blood and body fluids should be placed in a secure, closed, leak-proof container. Care should be taken to avoid contamination of the outside of the container or its label.
- All personnel processing specimens of blood or other body fluid must wear gloves. Protective eyewear or splash guards should be used if mucous membrane contact may be anticipated. Gloves should be changed and hands washed with soap and water after completion of handling specimens.
- Working surfaces should be disinfected using an appropriate disinfectant following work completion.
- Contaminated materials and equipment should be appropriately decontaminated or labeled, and appropriately disposed of.
- Remove protective wear and wash hands upon completion of laboratory duties.

**References:**

- (1) NCCLS, *Clinical Laboratory Technical Procedure Manual-Third Edition; Approved Guideline*. NCCLS document GP2-A3 (ISBN 1-56238). NCCLS Wayne, PA. 1996.
- (2) Berman, Lee, ed., *Infection Control in Health Care*, Current Concept Seminars, Inc., Hollywood, FL 33021
- (4) Fischbach, Frances ed., *A Manual of Laboratory & Diagnostic Tests*, 5th Edition, Lippencott, Philadelphia, PA. 1987.
- (5) Jacobs, D.S., Kasten, Jr., B.L., Demott, W.R., Wolfson, W.L., ed., *Laboratory Test Handbook*, 2<sup>nd</sup> Edition, Lexi-Comp Inc., Stow, OH 44224

Written By: Evan Cadoff, MD/Eugene Martin, PhD Date 2005

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**ANTI-HIV 1 / 2 ANTIBODY SCREENING by ORAQUICK ADVANCE**

No special patient preparation is needed. However, all test subjects should have received the "Subject Information" pamphlet prior to specimen collection.

Fingerstick blood samples should be collected using aseptic technique. The sample must be collected immediately with the collection loop provided in the test kit, and must be tested immediately.

Oral samples should be collected by following specific technique. The sample must be tested immediately after collection.

The test devices are **stable** until the expiration date on the box and pouch. They must be stored at a temperature between (2°-27° C; 35°-80°F. If refrigerated, the pouch **must** be brought to room temperature before opening as the temperature range for testing is (15°-37° C; 59°-99° F).

**QUALITY CONTROL:**

EXTERNAL QUALITY CONTROL:

**ORAQUICK® ADVANCE RAPID HIV - 1/2 ANTIBODY CONTROL TEST KIT CONTAINS:**

- HIV-1 Positive Control, 1 vial (Black cap, 0.2 mL)
- HIV-2 Positive Control, 1 vial (Red cap, 0.2 mL)
- Negative Control, 1 vial (White cap, 0.2 mL)

The controls are human, plasma-based reagents. The positive controls contain antibodies that will show REACTIVE results and the Negative Control will show a Non-Reactive result when run with the OraQuick® ADVANCE Rapid HIV-1/2 Antibody Test. The controls are liquid, ready to use and require no reconstitution or dilution. Both controls contain .2 mL of photo chemically inactivated human plasma which is either positive or negative for antibodies to HIV-1 and HIV-2 diluted by a defibrinated pool of normal human plasma. Both specimens are negative for Hepatitis B surface antigen and Hepatitis C antibody.

The controls must be stored at (2° - 8°C; 35°-46° F) and are stable until the expiration date stated on the box label. **HOWEVER, ONCE OPENED THE CONTROLS EXPIRE IN 8 WEEKS.** The date received, date opened and the expiration date must be clearly marked on the box containing the controls or on the individual vials.

**When to perform quality control?**

1. **Whenever a new shipment of reagents is put into use**, a set of controls shall be run on the first new box used from that shipment. Validation of each reagent lot will be performed prior to release through the RWJMS Rapid Testing Support Program. For this reason, **each lot does not need to be re-validated on receipt at the testing site—just each shipment.**
2. At the beginning of **each week**, one set of controls must be run, to make sure that the reagents have not deteriorated in storage.
3. **Whenever there has been a change in the test environment** including such items as:
  - The temperature in the test storage area falling outside of (2°– 27° C; 35°-80° F)
  - A new location has been selected to perform testing.

**Reminder: If refrigerator storage temperature is out of range (2-8° C; 35° - 46° F), record the temperature and note any corrective action taken. This temperature problem may mean that the control solutions may give wrong results in the future. You need to know this in case you have a problem in the future, but a problem with refrigerator temperature does not mean that you need to run controls.**

**How to Perform Quality Control?**

1. Check the expiration date of the external control solutions. Once opened, a control solution expires in 8 weeks not 2 months (You must count 8 weeks). **DO NOT USE EXPIRED CONTROL SOLUTIONS.**

2. If you open new controls, write the new expiration date on either the box or the vials.
3. Label the test vial and test device to indicate which control is being run on each device.
4. Insert the round end of an unused Specimen Collection Loop into the vial of the control reagent. Visually inspect the loop to make sure that it is completely filled with the control reagent. Use separate unused Specimen Collections Loops for each control reagent. NOTE: The Kit Control reagents are clear to straw-colored. Do not use if the reagent appears visually cloudy or discolored.
5. Immediately immerse the control-reagent-filled Specimen Collection Loop in the developer solution inside the Developer Solution Vial. Use the Specimen Collection Loop to stir the specimen in the developer solution. Remove the Specimen Collection Loop from the Developer Solution Vial and discard in a biohazardous waste container.
6. Reseal the Kit Control Reagent vials and store them in their original container at (2°-8° C or 35°-46° F).
7. Remove the Test Device from the Divided Pouch without touching the flat pad. Insert the Test Device, flat pad first, into the Developer solution Vial containing the specimen. Be sure that the result window faces forward and the flat pad touches the bottom of the Developer Solution Vial.
8. Leave the Test Device in the Developer solution and start a timer and record the start time. Do not remove the Test Device from the vial until you have read the results. Read the results after 20 minutes but not more than 40 minutes in a fully lighted area. Read the results as described in the Interpretation of "Test Results" section below.
9. Dispose of the used Developer Solution Vial and the Test Device in a biohazard waste. If controls do not give their expected results, (Preliminary positive for the Black and Red caps, Negative for the White cap), the test is invalid and you cannot do client testing. You must first figure out what went wrong. Check all temperature logs for out of range temperatures and the repeat the controls. If you do not get the expected results, discard the controls and if available, open a new box of controls. If you still do not get expected results discontinue testing inform the HIV support team. You can not test any patients until the controls perform correctly. Instead of testing the client, offer to draw two white top tube and call our discordant line at (732) 236-7013 for pick up.

## INTERNAL QUALITY CONTROL

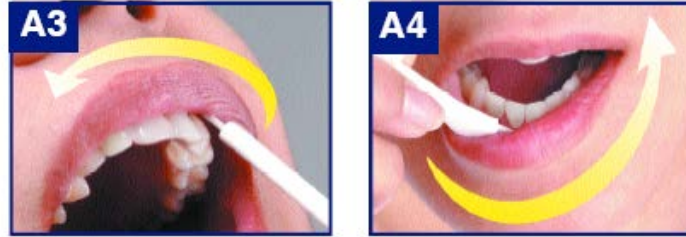
In addition, the OraQuick® *ADVANCE* HIV-1/2 Antibody test has a built in quality control feature that demonstrates assay validity. A reddish-purple line develops next to the letter "C" on the test device indicating that a specimen was added and the fluid moved through the test device. If the "C" line does not develop, the test result is invalid and cannot be interpreted. If a red background color appears and interferes with the ability to read the test, the result is invalid. Before looking at the Test line "T" check for the reddish-purple line next to the "C". The Control line appears on all valid tests whether nonreactive or reactive.

The procedure for interpreting the internal quality control is included in the Interpretation of Test Results section below.

## TEST PROCEDURE:

1. Check to see whether client testing can be done by first following the Quality Control checklist (Section 2.6).
2. Check room temperature and record it on the test log. DO NOT continue if the temperature is outside the following range (15° -37° C) (59° – 99° F).
3. Make sure you are wearing disposable gloves.
4. Open both portions of the test pouch. Make sure that an absorbent packet was packed with the test device. If not, discard the device and open a new pouch.
5. **Label both the Developer Solution Vial and the Test Device with the client's ID.** Be careful not to block or cover the two holes on the back of the test device.
6. Carefully remove the cap from the vial and place the vial in the stand gently, without splashing the solution out of the vial.
7. Now, Follow **Either**: A. Using Oral Specimen or B. Using Fingerstick Specimen below:
  - A. **Using Oral Specimen**
    - I. Before obtaining the specimen from the patient have the patient review "Oral Fluid Illustration" so that the patient understands the proper method of specimen collection. See illustration below.
    - II. Wearing gloves, remove the test device from the pouch. Give the test device to the patient. Be careful not to touch the flat surface of the test device.

- III. Once the device is given to the patient, make sure the patient collecting the specimen swabs the upper and lower gums; do not allow the patient to swab the roof of the mouth, the tongue or inside of the cheek. Both sides of the pad can be used. See illustration below.



- IV. Once swabbing is complete, collect the device from the patient and insert the device into the developer.
- V. Return to TEST PROCEDURE #8 Below:

## B. Using Fingertick

- I. Clean the finger of the person being testing with an antiseptic wipe, and allow area to dry.
  - II. Using a sterile lancet, puncture the skin off the center of the finger pad.
  - III. Hold the finger downward. Apply gentle pressure beside the point of the puncture. Avoid "squeezing" or "milking" the finger to obtain blood.
  - IV. Wipe away the first drop of blood with a sterile gauze pad. Allow a new drop to form.
  - V. Take a clean, unused Specimen Collection Loop, and fill the loop completely with blood.
  - VI. Immediately insert the blood-filled end of the loop into the solution in the vial and stir the blood sample into the solution (preferably in a back and forth motion).
  - VII. Make sure that the solution appears pink. If blood did not fully fill the loop, or if the solution is not pink, discard the test materials and start again with a new pouch, new lancet, and fresh fingertick.
8. Insert the flat pad of the test device (labeled with the client's ID) into the developer solution. Make sure that the pad touches the bottom of the vial and that you can see the result window.
  9. Start timing the test. Record the start time on the test log sheet.
  10. Read the results after at least 20 minutes, but not more than 40 minutes have passed. Record the read time on the test log. If the test is not read within 40 minutes, discard the test materials and start again. The test is invalid.

## TEST INTERPRETATION:

Preliminary Positive	A <b>complete reddish-purple</b> line in the zone next to the letter "T" (test) and a <b>complete reddish-purple</b> line next to the letter "C" (control) in the result window.
<i>Negative</i>	<b>No reddish-purple</b> line next to the letter "T", and a <b>complete reddish-purple</b> control line next to the letter "C" (control) in the result window.
<i>No Result(Invalid)</i>	If either: <b>No reddish-purple</b> line appears next to the letter "C" (control), or a partial line next to the letters 'T' or 'C', or a <b>reddish background</b> makes it impossible to see a line in the "T" zone, the subject must be re-tested using a new test device. The reddish-purple result lines must appear inside the "C" or "T" triangle areas. <b>IF THE LINES ARE NOT INSIDE THE TRIANGLES AREA, THE TEST IS INVALID, AND THE SUBJECT MUST BE RE-TESTED USING A NEW TEST DEVICE.</b>

**IF YOU WERE UNABLE TO GET A VALID RESULT AFTER TWO ATTEMPTS, RUN BOTH POSITIVE AND NEGATIVE CONTROLS, AND CALL THE NJ RAPID HIV TESTING SUPPORT OFFICE (732) 743-3624 FOR ASSISTANCE. OFFER TO DRAW TWO WHITE TOP TUBES AND CALL OUR DISCORDANT LINE AT (732) 236-7013 FOR PICK UP.**

11. Record test results:

- Record results on the testing log and report the result to the counselor for recording in the counseling records.

- Control and patient results should be recorded on the same log. Enter the control lot number in the Patient/Control ID column.
- Each site is responsible for maintaining inventory of the test kits. Every test kit is accounted for and recorded on the test log. Do not throw out expired test kits. They should be returned to RWJMS and noted on log with reason code 7. There is a reference sheet listing the reasons for non-patient test kit use with accompanying codes which should be noted on the test logs when a specific situation arises.
- Completed log pages (or copies of them) must be returned to the POCT office, and must be kept for at least two years. If there is a problem with the test materials or methods, we need to track back and see which test subjects were tested when, and with which lot of reagents.

**Expected Values:**

Negative if the person has not been exposed to the HIV virus.

This test is a screening test. If the result of this test is positive, please refer to the Preliminary Positive procedure for steps to follow.

**Procedural Notes:**

- Reading the result earlier than 20 minutes or later than 40 minutes may yield erroneous results. If the result is not read within 40 minutes, the test is invalid and must be repeated.
- This test is not approved for use in persons less than 12 years of age. It cannot be used to test newborns or infants for infections that may have been acquired from their mothers.
- For positive (reactive) results, the intensity of the line does not necessarily correlate with the amount of antibody in the specimen, or with the stage of disease.

**Limitations of the Procedure:**

A negative (non-reactive) result does not preclude the possibility of exposure to, or infection with, HIV. It can take several months for antibodies to appear after exposure to the HIV virus. **No test is 100% accurate:**

- In one study of 521 specimens that were repeatedly reactive using a licensed EIA, and positive by Western blot, 519 gave a reactive (positive) result with OraQuick.
- In another study of 625 high-risk subjects, 20 were repeatedly reactive by EIA. Of those 20, 17 were positive by OraQuick, and were also positive by Western Blot. Of the remaining three (which were negative by OraQuick), two were negative and one indeterminate by Western Blot.

To assess the sensitivity of the OraQuick® ADVANCE Rapid HIV-1/2 Antibody Test for HIV variants for various geographic regions, 215 confirmed antibody positive specimens were tested 214 were reactive.

Individuals infected with HIV-1 or HIV-2 who are receiving highly active antiretroviral therapy (HAART) may produce false negative results.

*Counseling should reflect these imperfections of testing.*

**References:**

1. NCCLS, *Clinical Laboratory Technical Procedure Manual-Third Edition; Approved Guideline*. NCCLS document GP2-A3 (ISBN 1-56238). NCCLS Wayne, PA. 1996.
2. Product Insert, *OraQuick Rapid HIV-1 Antibody Test*, OraSure Technologies, 4/03.
3. Product Insert, *OraQuick ADVANCE Rapid HIV-1/2 Antibody Test*, OraSure Technologies, revised 10/07.
4. Product Insert, *Oraquick ADVANCE Rapid HIV-1/2 Antibody Test*, Orasure Technologies, revised 4/09.
5. Product Insert, *Oraquick ADVANCE Rapid HIV-1/2 Antibody Test*, Orasure Technologies, revised 4/12
6. Tietz, N.W., *Fundamentals of Clinical Chemistry*, 2nd ed., W.B.
7. Saunders. Philadelphia, PA. 1976.

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Approved by: <u>Evan Cadoff, M.D.</u>	Date: <u>8/6/2013</u>

*ANTI-HIV 1 / 2 ANTIBODY SCREENING by Clearview® STAT-PAK*

## PRINCIPLE:

The Clearview® HIV 1/2 STAT-PAK™ assay is a single-use immunochromatographic test for the detection of antibodies to Human Immunodeficiency Virus Type 1 (HIV-1) and Type 2 (HIV-2) in fingerstick whole blood, venous whole blood, serum or plasma specimens. The Clearview® HIV 1/2 STAT-PAK™ assay is intended for use as a point-of-care test to aid in the diagnosis of infection with HIV-1 and HIV-2.

No special patient preparation is needed. However, all test subjects should have received the "Subject Information" pamphlet prior to specimen collection.

Fingerstick blood samples should be collected using antiseptic technique. The sample must be collected immediately with the collection loop provided in the test kit, and must be tested immediately.

The test devices are **stable** until the expiration date on the box and pouch. They must be stored at a temperature between 8°-30° C (46°-86°F). If refrigerated, the pouch **must** be brought to room temperature before opening as the temperature range for testing is 18°-30° C (64°-86° F).

### MATERIALS PROVIDED:

Each package contains the components to perform HIV tests:

- 20 STAT-PAK™ Individually Pouched Test Devices
- 20 Copies of Subject Information Notice
- 20 Disposable 5uL Sample Loops
- 1 HIV Running Buffer (3.5 mL)
- 1 Product Insert for the HIV 1 / 2 STAT-PAK Assay

## QUALITY CONTROL:

The controls must be stored at (2° - 8°C; 36° - 46° F) and are stable until the manufacturer's expiration date as stated on the box label. The date the controls are received, opened as well as the expiration date must be clearly marked on the box containing the controls. The Control Reagents are clear to straw-colored. Do not use if the Control Reagent appears visually cloudy or discolored.

### EXTERNAL QUALITY CONTROL:

Clearview® HIV 1/2 Reactive/Nonreactive Controls contain:

- HIV-1 Reactive Control, 1 vial ( 0.25 mL)
- HIV-2 Reactive Control, 1 vial ( 0.25 mL)
- Nonreactive Control, 1 vial ( 0.25 mL)

### When to Perform External Quality Control?

1. **Whenever a new shipment of reagents is put into use**, a set of controls shall be run on the first new box used from that shipment. Validation of each reagent lot will be performed prior to release through the RWJMS Rapid Testing Support Program. For this reason, **each lot does not need to be re-validated on receipt at the testing site—just each shipment.**
2. At the beginning of **each week**, one set of controls must be run, to make sure that the reagents have not deteriorated in storage.
3. **Whenever there has been a change in the test environment** including such items as:
  - The temperature in the test storage area falling outside of 8°-30° C (46°-86°F).
  - A new location has been selected to perform testing.
4. After Invalid client test results on two consecutive attempts. Cease client testing until controls are run with valid results.

**Reminder:** If refrigerator storage temperature is out of range (2-8° C; 36° - 46° F), record the temperature and note any corrective action taken. This temperature problem may mean that the control solutions may give wrong results in the future. You need to know this in case you have a problem in the future, but a problem with refrigerator temperature does not mean that you need to run controls.

## How to Perform Quality Control?

1. Check the expiration date of the external control solutions. DO NOT USE EXPIRED CONTROL SOLUTIONS.
2. If you open new controls, write the date the controls are opened, and the new expiration date on the box containing the controls.
3. Label the test device to indicate which control is being run on each device.
4. Insert the round end of an unused Specimen Collection Loop into the vial of the control reagent. Visually inspect the loop to make sure that it is completely filled with the control reagent. Use separate unused Specimen Collections Loops for each control reagent. Only open one vial at a time, so that you don't accidentally put cap back on the wrong vial. NOTE: The Kit Control reagents are clear to straw-colored. Do not use if the reagent appears visually cloudy or discolored.
5. Immediately, touch the filled Specimen Collection Loop to the sample pad in the center of the SAMPLE well of the Test Device to dispense the fluid from the loop onto the sample pad. Discard used loop directly into a biohazard waste container.
6. Put the Kit Control Reagent vials back in their box and in the refrigerator (2°-8° C; 36°-46° F).
7. Invert the Running Buffer bottle and hold it vertically (not at an angle) over the sample well. Add 3 drops (approximately 105 uL) of buffer slowly, dropwise, into the SAMPLE well. Do not touch tip of buffer bottle to well.
8. Start timing the test. Record the start time on the test log sheet.
9. Read the results between 15 and 20 minutes after the addition of the Running Buffer. Record the read time on the test log. If the test is not read within 20 minutes, discard the test materials and start again. The test may not be accurate and should be recorded as an operator error, (Code 3 on log sheet).
10. Dispose of the used Test Device in a biohazard waste.
11. If controls do not give their expected results, you cannot do client testing. You must first figure out what's wrong. Check all temperature logs for out of range temperatures and then repeat the controls. If you do not get the expected results, discard the opened controls and if available open a new box. If you still do not get the expected results call the HIV support staff for instructions. You cannot test any patients until the controls perform correctly. Offer to draw two white top tubes and call our discordant line at (732) 236-7013.

## INTERNAL QUALITY CONTROL:

In addition, the Clearview® HIV-1/2 STAT-PAK Test has a built in quality control feature. A pink-purple line develops next to the letter "C" on the test devices as a positive procedural control. If the line does not develop, the test result is invalid. The procedure for interpreting the internal quality control is included in the Interpretation of Test Results section below.

## TEST PROCEDURE:

1. Check to see whether client testing can be done by first following the Quality Control checklist (Section 2.6).
2. Check room temperature and record it on the test log. DO NOT continue if the temperature is outside the following range (18° -30° C) (64° – 86° F).
3. Make sure you are wearing disposable gloves
4. Open the test pouch. Make sure that an absorbent packet was packed with the test device. If not, discard the device and open a new pouch.
5. **Label the Test Device with the client's ID number.**
6. **Using Fingerstick Whole Blood**
  - Clean the finger of the person being testing with an antiseptic wipe, and allow to it dry.
  - Using a sterile lancet, puncture the skin on the side of the finger pad (toward the thumb).
  - Hold the finger downward. Apply gentle pressure beside the point of the puncture.
  - Wipe away the first drop of blood with a sterile gauze pad. Allow a new drop to form.
  - Take a clean, unused Specimen Collection Loop, and fill the loop completely with blood.
  - Holding the specimen loop straight over and touch it to the center of the SAMPLE well of the device to dispense the sample onto the sample pad.
  - Hold the Running Buffer bottle upside down (not at an angle) over the sample well. Avoid touching the tip of the bottle to Sample well. Add 3 drops of buffer slowly, drop wise, into the SAMPLE well.
7. Start timing the test. Record the start time on the test log sheet.

8. Read the results between 15 and 20 minutes. Record the read time on the test log. If the test is not read within 20 minutes, discard the test materials and start again. If the test is not read within 15 to 20 min it may not be accurate. Record it as an operator error, (Code 3).
9. After recording result immediately discard test device into a biohazard waste container.

## TEST INTERPRETATION:

Preliminary Positive	A <b>pink-purple</b> line in the zone next to the letter "T" (test) and a <b>pink-purple</b> line next to the letter "C" (control) in the result window. For positive (reactive) results, the intensity of the " T " line does not necessarily correlate with the amount of antibody in the specimen, or with the stage of disease
Negative	<b>No pink-purple line</b> next to the letter "T", and a <b>pink-purple</b> control line next to the letter "C" (control) in the result window.
No Result(Invalid)	If either: <b>No pink-purple line</b> appears next to the letter "C" (control). Any line that appears outside of the Control (C) Area or Test (T) Area cannot be interpreted. <b>ANY INVALID TEST, THE SUBJECT MUST BE RE-TESTED USING A NEW TEST KIT.</b>

**IF YOU WERE UNABLE TO GET A VALID RESULT AFTER TWO ATTEMPTS, RUN BOTH POSITIVE AND NEGATIVE CONTROLS, AND CALL THE NJ RAPID HIV TESTING SUPPORT OFFICE (732) 743-3624 FOR ASSISTANCE. OFFER TO DRAW TWO WHITE TOP TUBES AND CALL OUR DISCORDANT LINE AT (732) 236-7013.**

### Record Test Results:

- Record results on the testing log and if indicated report the result to the appropriate person for documentation.
- Control and patient results should be recorded on the same log. Enter the patient identification number in the Patient/Control ID column.
- Utilize NJHIV RAPID HIV TEST LOGS only. Every test kit utilized must be logged including controls run, wasted test kits and so on.
- As log pages are completed they must be faxed to the NJ Rapid HIV Testing office (utilizing the fax number on the test log), and they must be kept for at least two years. If there is a problem with the test materials or methods, we need to track back and see which test subjects were tested when, and with which lot of reagents.
- Each site is responsible for maintaining inventory of the test kits. Every test kit is accounted for and recorded on the test log. Do not throw out expired test kits. They should be returned to RWJMS and noted on log with reason code 7. There is a reference sheet listing the reasons for non-patient test kit use with accompanying codes which should be noted on the test logs when a specific situation arises.
- The log sheet is a communication tool between the test site and the NJ Rapid HIV Testing Support team.

### Expected Values:

- Negative if the person has not been exposed to the HIV virus.
- This test is a screening test. If the result of this test is preliminary positive, please refer to the Rapid-2-Rapid procedure for steps to follow.

### Procedural Notes:

- Reading the result earlier than 15 minutes or later than 20 minutes may yield erroneous results. If the result is not read within 20 minutes, the test is invalid and must be repeated.
- This assay has not been evaluated for newborn screening, cord blood specimens, or individuals less than 13 years and greater than 64 years of age.
- For positive (reactive) results, the intensity of the line does not necessarily correlate with the amount of antibody in the specimen, or with the stage of disease.

### Limitations of the Procedure:

A negative (non-reactive) result does not preclude the possibility of exposure to, or infection with, HIV. It can take several months for antibodies to appear after exposure to the HIV virus. **No test is 100% accurate:**

- In one study of 601 specimens that were repeatedly reactive using a licensed EIA and positive by Western blot, 599 gave a reactive (positive) result with the Clearview® HIV-1/2 STAT-PAK Test.

- In another study of 776 high-risk subjects, 41 were repeatedly reactive by EIA. Of those 41, 36 were positive by the Clearview® HIV-1/2 STAT-PAK Test, and 35 were also positive by Western Blot.

**Counseling should reflect these imperfections of testing.**

## References:

Product Insert, *Clearview® HIV-1/2 STAT-PAK Test*, Inverness Medical Professional Diagnostics, 2006.

Product Insert, *Clearview® HIV-1/2 Rapid Test Control Pack*, Inverness Medical Professional Diagnostics, 11/2006.

Product Insert, *Clearview® HIV-1/2 Rapid Test Control Pack*, Inverness Medical Professional Diagnostics, 1/2009.

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Approved by: Evan Cadoff, M.D. Date: 8/6/2013

*ANTI-HIV 1 ANTIBODY SCREENING by Uni-Gold™ Recombigen® HIV*

**PRINCIPLE:**

The Uni-Gold™ Recombigen® HIV was designed as a rapid immunoassay and is intended to detect antibodies to HIV-1 and/or HIV-2 in human serum, plasma and whole blood (venipuncture and fingerstick). The Uni-Gold™ Recombigen® HIV uses proteins representing regions of the HIV virus. If antibodies to HIV-1 and/or HIV-2 are present in the sample, they combine with these proteins and a color reagent and this complex binds to the proteins in the test forming a visible pink/red band in the test region of the device adjacent to the word "test". A control line should always appear as a visible pink/red band in the "control" region of the device to indicate that the device is functioning correctly.

No special patient preparation is needed. However, all test subjects should have received the "Subject Information" pamphlet prior to specimen collection.

Fingerstick blood samples should be collected using antiseptic technique. The sample must be collected immediately with the collection loop provided in the test kit, and must be tested immediately.

The test devices are **stable** until the expiration date on the box and pouch. They must be stored at a temperature between 2°-27° C (36°-81°F). If refrigerated, the pouch **must** be brought to room temperature before opening as the temperature range for testing is 15°-27° C (59°-81° F).

**MATERIALS PROVIDED:**

Each Kit contains the components to perform HIV tests:

- 20 Individually Pouched Test Devices
- 20 Copies of Subject Information Notice
- 20 Disposable Pipettes
- 20 Disposable Fingerstick Sample Collection and Transfer Pipettes
- 1 Bottle Wash Solution (5.0 mL)
- 1 Package Insert

**QUALITY CONTROL:**

The controls are human serum or plasma reactive for antibody for HIV-1 and HIV-2. They have been treated to inactivate any HIV virus that may be present. The positive controls contain antibodies that will show REACTIVE results and the Negative Control will show NONREACTIVE results when run with the Uni-Gold™ Recombigen®. The controls are liquid, ready to use and require no reconstitution or dilution. Uni-Gold™ Recombigen® HIV Controls and all human blood products should be handled as though capable of transmitting infectious disease and should be disposed into biohazardous waste containers or bags.

The controls must be stored at (2° - 8°C; 36° - 46° F) and are stable for one month after opening or the manufacturers expiration date as stated on the box label, whichever is sooner. The date the controls are received, opened and the one-month expiration date must be clearly marked on the box containing the controls. Do not use if the Control Reagent appears visually cloudy or discolored.

**EXTERNAL QUALITY CONTROL:**

Uni-Gold™ Recombigen® HIV Controls contain:

- HIV-1 Positive Control, 1 vial (0.5 mL) with red cap.
- HIV-2 Positive Control, 1 vial (0.5 mL) with green cap.
- Negative Control, 1 vial (0.5 mL) with black top.

**When to Perform External Quality Control?**

1. **Whenever a new shipment of reagents is put into use**, a set of controls shall be run on the first new box used from that shipment. Validation of each reagent lot will be performed prior to release through the

- RWJMS Rapid Testing Support Program. For this reason, **each lot does not need to be re-validated on receipt at the testing site—just each shipment.**
2. At the beginning of **each week**, one set of controls must be run, to make sure that the reagents have not deteriorated in storage.
  3. **Whenever there has been a change in the test environment** including such items as:
    - The temperature in the test storage area falling outside of 2°-27° C (36°-81° F).
    - A new location has been selected to perform testing.

**Reminder:** If refrigerator storage temperature is out of range (2° - 8°C; 36°-46° F), record the temperature and note any corrective action taken. This temperature problem may mean that the control solutions may give wrong results in the future. You need to know this in case you have a problem in the future, but a problem with refrigerator temperature does not mean that you need to run controls.

#### How to Perform External Quality Control?

1. Check the expiration date of the external control solutions. **DO NOT USE EXPIRED CONTROL SOLUTIONS.**
2. If you open new controls, write the date the controls are opened on the box containing the controls or on the individual vials. Write the new expiration date on the box (one month from the date opened, unless the printed expiration date is earlier than that).
3. Label the test device to indicate which control is being run on each device.
4. Mix contents of vials by gentle swirling or inversion.
5. Draw up adequate sample to the first gradation on the larger Disposable Pipette (included in the kit). Use separate unused Disposable Pipette for each control reagent. NOTE: The Kit Control reagents are clear to straw-colored. Do not use if the reagent appears visually cloudy or discolored.
6. Holding the Disposable Pipette vertically over the sample port, add one (1) free falling drop of sample carefully. Do not add the full volume contained within the Disposable Pipette.
7. Allow the sample to absorb into the paper in the sample port. Ensure there are no air bubbles in the sample port. Discard the Disposable Pipette in a biohazard waste container.
8. Reseal the Kit Control Reagent vials and store them in their original container at (2°-8° C; 36°-46° F).
9. Holding the dropper bottle of Wash Solution in a vertical position, add 4 drops of Wash Solution into the SAMPLE port.
10. Start timing the test. Record the start time on the test log sheet.
11. Read the results at 10 minutes, but no more than 12 minutes. Record the read time on the test log. If the test is not read within 12 minutes, discard the test materials and start again. The test is invalid.
12. Results should be determined in the same manner as that used for unknown specimens when testing with Uni-Gold™ Recombigen® HIV assay.
13. Dispose of the used Test Device in a biohazard waste.
14. If controls do not give their expected results, you cannot do client testing. You must first figure out what's wrong. Check all temperature logs for out of range temperatures and the repeat the controls. If you do not get the expected results, discard the controls and if available, open a new box of controls and label open and expiration dates. If you still do not get expected results call the HIV support team. **You can not test any patients until the controls perform correctly.** Draw two 7 ml serum separator tubes and one 5 ml white top tube (with at least 2 mls in the white top tube). Spin all the tubes down. Refrigerate the serum separator tubes and freeze the white top tube upside down.)and call our discordant line at (732) 236-7013 for pick up.
15. Control and patient results should be recorded on the same log. Enter the control lot number in the Patient/Control ID column.

#### **INTERNAL QUALITY CONTROL:**

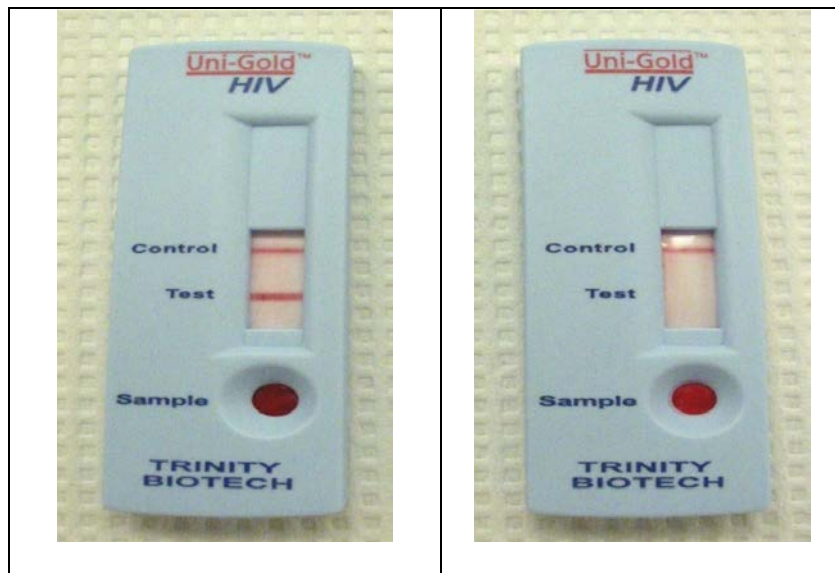
In addition, the Uni-Gold™ Recombigen® HIV assay has a built in quality control feature. A red/pink line develops next to the letter "C" on the test devices as a positive procedural control. If the line does not develop, the test result is invalid. The procedure for interpreting the internal quality control is included in the Interpretation of Test Results section below.

#### **TEST PROCEDURE:**

1. Check to see whether client testing can be done by first following the Quality Control checklist. (Section 2.6)

2. Check room temperature and record it on the test log. DO NOT continue if the temperature is outside the following range (15° -27° C) (59° – 81° F).
3. Allow the kit (unopened devices and wash solution) to reach room temperature (at least 20 minutes) if previously stored in the refrigerator.
4. Make sure you are wearing disposable gloves
5. Open the test pouch. Make sure that an absorbent packet was packed with the test device. If not, discard the device and open a new pouch. Document on test log as Code 6, manufacturer error.
6. **Label the Test Device with the client's ID number.**
7. Lay the device on a clean flat surface. .
8. **Using Fingerstick Whole Blood**
  - A. Clean the finger of the person being tested with an antiseptic wipe, and allow to dry.
  - B. Using a sterile lancet capable of producing a large drop of blood, puncture the skin on the side of the finger pad.
  - C. Hold the finger downward. Apply gentle pressure beside the point of the puncture.
  - D. Wipe away the first drop of blood with a sterile gauze pad. Allow a new drop to form.
  - E. Collect the blood into the pipette provided following the procedure below:
    - Hold the Pipette bulb gently in a sideways (horizontal) position to the blood sample to be collected (specimen may not be adequately drawn if held upright).
    - Place the tip of the pipette into the drop of blood on the finger; take care not to squeeze the bulb. Maintain this position until the flow of sample into the pipette has stopped. The sample should fill to the first mark on the pipette. If the sample is not collected to the mark, discard this sample and obtain another sample from a new fingerstick.
    - Fully discharge the sample by squeezing the pipette bulb into the sample port. Should the sample not fully discharge, cover the small opening at the mark on the pipette with a gloved finger. Then squeeze the bulb until the sample is fully discharged.
    - Allow the sample to absorb into the paper in the sample port. Make sure air bubbles are not introduced into the sample port.
    - Dispose of the Pipette in biohazard waste.
  - F. Hold the dropper bottle of Wash Solution in an upright (vertical) position; add four (4) drops of Wash Solution to the Sample Port.
  - G. Start timing the test. Record the start time on the test log sheet.
  - H. Read the results at **10 minutes, but no more than 12 minutes**. Record the read time on the test log. *If the test is not read within 12 minutes, discard the test materials and start again.* The test may not be accurate and should be recorded as an operator error, Code 3.

### TEST INTERPRETATION:



REACTIVE or POSITIVE	NON-REACTIVE or NEGATIVE RESULT
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Positive	A <b>red-pink</b> line in the zone next to the letter "T" (test), a <b>red-pink</b> line next to the letter "C" (control) in the result window, with a <b>red</b> sample port
Negative	<b>No red-pink line</b> next to the letter "T", a <b>red-pink</b> control line next to the letter "C" (control) in the result window, with a <b>red</b> sample port.
No Result (Invalid)	If either: <b>No red-pink line</b> appears next to the letter "C" (control). Any line that appears outside of the Control (C) Area or Test (T) Area or <b>no red</b> sample port, cannot be interpreted. <b>ANY INVALID TEST, THE SUBJECT MUST BE RE-TESTED USING A NEW TEST KIT.</b>

**IF YOU WERE UNABLE TO GET A VALID RESULT AFTER TWO ATTEMPTS, RUN BOTH POSITIVE AND NEGATIVE CONTROLS, AND CALL THE NJ RAPID HIV SUPPORT OFFICE (732) 743-3624 FOR ASSISTANCE. DRAW TWO WHITE TOP TUBES AND CALL THE DISCORDANT LINE AT (732) 236-7013 FOR PICK UP..**

**Record Test Results:**

- Record results on the testing log and if indicated report the result to the appropriate person for documentation.
- Control and patient results should be recorded on the same log. Enter the patient identification number in the Patient/Control ID column.
- Utilize NJHIV RAPID HIV TEST LOGS only. Every test kit utilized must be logged including controls run, wasted test kits and so on.
- As log pages are completed they must be faxed to the NJ Rapid HIV Testing office (utilizing the fax number on the test log), and they must be kept for at least two years. If there is a problem with the test materials or methods, we need to track back and see which test subjects were tested when, and with which lot of reagents.
- Each site is responsible for maintaining inventory of the test kits. Every test kit is accounted for and recorded on the test log. Do not throw out expired test kits. They should be returned to RWJMS and noted on log with reason code 7. There is a reference sheet listing the reasons for non-patient test kit use with accompanying codes which should be noted on the test logs when a specific situation arises.

**Expected Values:**

- Negative if the person has not been exposed to the HIV virus.
- This test is a confirmatory test. If the result of this test is positive, please refer to the Rapid-2-Rapid procedure for steps to follow.

**Procedural Notes:**

- Reading the result earlier than 10 minutes or later than 12 minutes may yield erroneous results. If the result is not read within 12 minutes, the test is invalid and must be repeated.
- For positive (reactive) results, the intensity of the line does not necessarily correlate with the amount of antibody in the specimen, or with the stage of disease.

**Limitations of the Procedure:**

A negative (non-reactive) result does not preclude the possibility of exposure to, or infection with, HIV. It can take several months for antibodies to appear after exposure to the HIV virus. **No test is 100% accurate:**

- In one study of 1000 specimens that were repeatedly reactive using a licensed EIA, and positive by Western blot, 1000 gave a reactive (positive) result with the Uni-Gold™ Recombigen® HIV assay.
- In another study of 1000 high-risk subjects, 32 were repeatedly reactive by EIA. Of those 34 were positive by the Uni-Gold™ Recombigen® HIV assay, and 32 were also positive by Western Blot.

**Counseling should reflect these imperfections of testing.**

**References:**

- Product Insert, *Uni-Gold™ Recombigen® HIV assay*, TRINITY BIOTECH, 07/2004.
- Product Insert, *Uni-Gold™ Recombigen® HIV assay*, TRINITY BIOTECH, 11/2008.
- Product Insert, *Uni-Gold™ Recombigen® HIV assay*, TRINITY BIOTECH, 9/2010.
- Product Insert, *Uni-Gold™ Recombigen® HIV assay*, TRINITY BIOTECH, 2/2013

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Reviewed by: Joanne Corbo, MBA, MT (ASCP) Date: 5/29/13  
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## DETERMINE™ HIV-1/2 Ag/Ab Combo TESTING PROCEDURE

### PRINCIPLE:

The Determine™ HIV-1/2 Ag/Ag Combo assay is a qualitative immunoassay for the simultaneous detection of Human Immunodeficiency Virus Type 1 (HIV-1) p24 antigen (Ag) and antibodies (Ab) HIV Type 1 and Type 2 (HIV-1 and HIV-2) in capillary (fingerstick) whole blood. Although not used in our program, the test unit can also be used on human serum, plasma or venipuncture (venous) whole blood. It is intended for use as a point of care test to aid in the diagnosis of infection with HIV-1 and HIV-2, including an acute HIV-1 infection, and may distinguish acute HIV-1 infection from established HIV-1 infection when the specimen is positive for HIV-1 p24 antigen and negative for anti-HIV-1 and anti-HIV-2 antibodies.

No special patient preparation is needed. However, all test subjects should have received the "Subject Information" pamphlet prior to specimen collection.

Fingerstick blood samples should be collected using antiseptic technique. The sample must be collected immediately with the specimen collection pipette provided in the test kit, and must be tested immediately.

The test units are stored until the expiration date on the box and pouch. They must be stored at a temperature between 2°-30° C (36°-86°F). If refrigerated, the pouch **must** be brought to room temperature before opening as the temperature range for testing is 15°-30° C (59°-86° F).

### MATERIALS PROVIDED:

Each package contains the components to perform HIV tests:

- Aluminum ziplock pouch containing Alere Determine HIV1/2 Ag/Ag Combo Cards. Each card consists of 5 to 10 test units that can be separated from each other by tearing along the perforated lines. Each Test Unit has a cover that is to be removed for sample application and reading of results.
- Desiccant Package
- Chase Buffer
- Quick reference guide
- Package insert
- Information Notices: 25 in the 25 Test Units kit, and 100 in the 100 Test Units kit.
- Customer Letter
- Disposable Capillary Tubes: For collection and transfer of fingerstick samples
- Disposable Pipettes (for External Controls and proficiency testing)
- Disposable Workstations: 25 in the 25 Test Units kit, and 100 in the 100 Test Units kit.

### MATERIALS REQUIRED, BUT NOT PROVIDED

- Clock, watch, or other timing device
- Disposable gloves
- Sterile gauze (for fingerstick whole blood specimens)
- Antiseptic wipes
- Biohazard disposal container

### SPECIMEN STORAGE

The sample must be collected with the specimen collection pipette provided in the test kit, and must be tested *immediately*.

### QUALITY CONTROL:

The controls must be stored at (2° - 8°C; 36° - 46° F) and are stable until the manufacturer's expiration date as stated on the box label. The date the controls are received, opened as well as the expiration date must be clearly marked on the box containing the controls. The Control Reagents are clear to straw-colored. Do not use if the Control Reagent appears visually cloudy or discolored.

## EXTERNAL QUALITY CONTROL:

Determine™ HIV1/2 Ag/Ag Combo Controls contain:

- HIV-1 Reactive Control, 1 red capped vial (1.5 mL)
- HIV-2 Reactive Control, 1 green capped vial (1.5 mL)
- HIV-1 p24 Antigen Control, 1 lavender capped vial (1.5 mL)
- Nonreactive Control, 1 white capped vial (1.5 mL)
- Disposable pipettes for use in testing external controls and proficiency samples

## When to Perform External Quality Control?

1. **Whenever a new shipment of reagents is put into use**, a set of controls shall be run on the first new box used from that shipment. Validation of each reagent lot will be performed prior to release through the RWJMS Rapid Testing Support Program. For this reason, **each lot does not need to be re-validated on receipt at the testing site—just each shipment.**
2. At the beginning of **each week**, one set of controls must be run, to make sure that the reagents have not deteriorated in storage.
3. **Whenever there has been a change in the test environment** including such items as:
  - The temperature in the test storage area falling outside of 15°-30° C (59°-86°F).
  - A new location has been selected to perform testing.
4. After Invalid client test results on two consecutive attempts. Cease client testing until controls are run with valid results.

**Reminder:** If refrigerator storage temperature is out of range (2-8° C; 36° - 46° F), record the temperature and note any corrective action taken. This temperature problem may mean that the control solutions may give wrong results in the future. You need to know this in case you have a problem in the future, but a problem with refrigerator temperature does not mean that you need to run controls.

## How to Perform Quality Control?

1. Check the expiration date of the external control solutions. **DO NOT USE EXPIRED CONTROL SOLUTIONS.**
2. If you open new controls, write the date the controls are opened, and the new expiration date on the box containing the controls.
3. Remove the desired number of test units from the 5 or 10 test card units by bending and tearing at the perforation. The test(s) should be initiated within 2 hours after removing the protective foil cover from each test.
4. Remove the protective foil cover from each test and place it on a flat surface or in the workstation.
5. Open a Control Vial containing the Control Reagent.
6. Using the disposable pipette that comes with the external controls apply one hanging drop of control reagent to the Sample Pad (marked by the arrow symbol). **Use a new disposable pipette or pipette tip with each Control Reagent. Follow steps 5 and 6 until all control reagents have been pipetted.**
7. **DO NOT USE CHASE BUFFER** with control reagents! **BUFFER IS USED ONLY WITH BLOOD SPECIMENS.**
8. Start timing the test. Timing starts at 20 minutes but not more than 30 minutes.
9. Read the results between 20 and 30 minutes. Record the read time on the test log. If the test is not read within 30 minutes, discard the test materials and start again. The test may not be accurate and should be recorded as an operator error, (Code 3 on log sheet).
10. Dispose of the used Test Unit in a biohazard waste.
11. Reseal the Control Reagent Vials and store them in their original container at 2 to 8°C (36 to 46°F).
12. If controls do not give their expected results, you cannot do client testing. You must first figure out what's wrong. Check all temperature logs for out of range temperatures and then repeat the controls. If you do not get the expected results, discard the opened controls and if available open a new box. If you still do not get the expected results call the HIV support staff for instructions. You cannot test any patients until the controls perform correctly. Call our discordant line at (732) 236-7013 for further instructions.

## INTERNAL QUALITY CONTROL:

In addition, the Determine™ HIV-1/2 Ag/Ab Combo Test has a built in quality control feature. A pink-purple line develops in the control window on the unit as a positive procedural control. If the line does not develop, the test result is invalid. Please refer to the Determine™ HIV-1/2 Ag/Ag Combo Package Insert for pictorial examples of Reactive, NonReactive and Invalid Test Results. The procedure for interpreting the internal quality control is included in the Interpretation of Test Results section below.

**PROFICIENCY TESTING:**

Proficiency Test (PT) specimens, as required by the Proficiency Testing Program policy, are tested in the same manner as External Quality Control samples. Reporting of PT results varies; follow specific instructions with each PT challenge.

**TEST PROCEDURE:**

1. Check to see whether client testing can be done by first following the Quality Control checklist (Section 2.6).
  2. Check room temperature and record it on the test log. DO NOT continue if the temperature is outside the following range (15° -30° C) (59° – 86° F).
  3. Before testing make sure the testing area has adequate lighting.
  4. Make sure you are wearing disposable gloves
  5. Open the test pouch. Make sure that an Absorbent packet was packed with the test device. If not, discard the device and open a new pouch. Note on the test log that the absorbent packet was not enclosed. This makes the packet invalid.
  6. **Remove the test unit from the perforation. Label the Test Unit with the client’s ID number (not much space on unit; may use last 3 digits of client ID).**
  7. **Using Fingerstick Whole Blood**
    - Clean the finger of the person being tested with an antiseptic wipe, and allow to it dry.
    - Using a sterile lancet, puncture the skin on the side of the finger pad (toward the thumb).
    - Hold the finger downward. Apply gentle pressure beside the point of the puncture.
    - Wipe away the first drop of blood with a sterile gauze pad. Allow a new drop to form.
    - Avoid squeezing the fingertip to accelerate the bleeding. Collect the second drop of blood by holding the capillary tube horizontally, and touch the tip of the capillary tube to the blood sample.  
Note: Filling of the capillary tube is automatic-do not squeeze the bulb while sampling. Maintain this position until the flow of the sample has reached the fill line and stopped.
    - Touch the tip of the Capillary Tube containing the blood sample to the Sample Pad (marked by the arrow symbol) and gently squeeze the bulb. Avoid air bubbles. Wait until all the blood is transferred from the Capillary Tube to the Sample Pad.
- Caution: Do not lift the Capillary Tube from the Sample Pad before all the blood has been transferred – a bubble may form which will prevent the complete transfer of sample. If a sample won't expel, cover the small opening at the mark on the capillary with a gloved finger. Then squeeze the bulb until the sample is fully dispensed onto the Sample Pad.*
8. Wait one minute, then apply one drop of Chase Buffer to the Sample Pad.
  9. Start timing the test. Record the start time on the test log sheet.
  10. Read the results between 20 and 30 minutes. Record the read time on the test log. If the test is not read within 30 minutes, discard the test materials and start again. If the test is not read within 20 to 30 minutes it may not be accurate. Record it as an operator error, (Code 3).
  11. After recording the result immediately discard the test unit into a biohazard waste container.

**TEST INTERPRETATION:**

Antibody Reactive	A <b>pink-red line</b> in the Control Area and a pink/red Ab line appears in the Lower Test Area of the Test Unit. The intensity of the Ab and Control lines may vary. Any visible pink/red color in both the Control and Lower Test Areas, regardless of intensity, is considered Reactive. A Reactive test result means that HIV-1 and/or HIV-2 antibodies have been detected in the specimen. The test result is interpreted as <b>Preliminary Positive</b> for HIV-1 and/or HIV-2 antibodies.
Antigen (HIV-1 p24) Reactive (Two Lines – Control and Ag Line)	A <b>pink-red line</b> in the Control Area and a pink/red Ag line appears in the Upper Test Area of the Test Unit. The intensity of the Ag and Control lines may vary. Any visible pink/red color in both the Control and Upper Test Areas, regardless of intensity, is considered Reactive. A Reactive test result means that HIV-1 p24 antigen has been detected in the specimen. The test result is interpreted as <b>Preliminary Positive</b> for HIV-1 p24 antigen.
Antibody Reactive and Antigen (HIV-1 p24) Reactive (Three Lines – Control, Ab and Ag)	A <b>pink-red line</b> in the Control Area and a pink/red Ab line appears in the Lower Test Area AND a pink/red Ag line appears in the Upper Test Area of the Test Unit. The intensity of the Ab, Ag and Control lines may vary. Any visible pink/red color in

Lines)	the Control Area, the Lower and Upper Test Areas, regardless of intensity, is considered Reactive. The test result is interpreted as <b>Preliminary Positive</b> for HIV-1 and/or HIV-2 antibodies and HIV-1 p24 antigen.
Non-Reactive (One Control Line)	A <b>pink-red</b> Control line appears in the Control Area of the Test Unit, and no pink/red Ab or Ag line appears in the Lower Test Area and the Upper Test Area of the Test Unit, respectively. A Non-Reactive test result means that HIV-1 or HIV-2 antibodies and HIV-1 p24 antigen were not detected in the specimen.
Invalid (No Control Line)	If there is no pink-red Control line in the Control Area of the Test Unit, even if a pink/red line appears in the Lower or Upper Test Area of the Test Unit, the result is <b>INVALID</b> and the test should be repeated. If the problem persists, contact the Rapid HIV Support Program for assistance at 732-743-3624 or call our Discordant Hotline of 732-236-7013.

**IF YOU WERE UNABLE TO GET A VALID RESULT AFTER TWO ATTEMPTS, RUN CONTROLS, AND CALL THE NJ RAPID HIV TESTING SUPPORT OFFICE (732) 743-3624 FOR ASSISTANCE OR CALL OUR DISCORDANT LINE AT (732) 236-7013.**

### Record Test Results:

- Record results on the testing log and if indicated report the result to the appropriate person for documentation.
- Control and patient results should be recorded on the same log. Enter the patient identification number in the Patient/Control ID column.
- Utilize NJHIV RAPID HIV TEST LOGS only. Every test kit utilized must be logged including controls run, wasted test units and so on.
- As log pages are completed they must be faxed to the NJ Rapid HIV Testing office (utilizing the fax number on the test log), and they must be kept for at least two years. If there is a problem with the test materials or methods, we need to track back and see which test subjects were tested when, and with which lot of reagents.
- Each site is responsible for maintaining inventory of the test kits. Every test kit is accounted for and recorded on the test log. Do not throw out expired test kits. They should be returned to RWJMS and noted on log with reason code 7. There is a reference sheet listing the reasons for non-patient test kit use with accompanying codes which should be noted on the test logs when a specific situation arises.
- The log sheet is a communication tool between the test site and the NJ Rapid HIV Testing Support team.

### Expected Values:

- Negative if the person has not been exposed to the HIV virus.
- This test is a screening test. If the result of this test is preliminary positive, please refer to the Rapid-2-Rapid procedure for steps to follow.

### Procedural Notes:

- Reading the result earlier than 20 minutes or later than 30 minutes may yield erroneous results. If the result is not read within 20 minutes, the test is invalid and must be repeated.
- This assay has not been evaluated for newborn screening, cord blood specimens, or individuals less than 12 years of age.
- For positive (reactive) results, the intensity of the line does not necessarily correlate with the amount of antibody in the specimen, or with the stage of disease.

### Limitations of the Procedure:

A negative (non-reactive) result does not preclude the possibility of exposure to, or infection with, HIV. It can take several months for antibodies to appear after exposure to the HIV virus. **No test is 100% accurate:**

This assay has not been evaluated for newborn screening, cord blood specimens, or individuals less than 12 years of age.

Use only materials that are supplied and/or required in accordance with the Alere Determine HIV-1/2 Ag/Ab Combo test kit.

For more information regarding Limitations of the Procedure please refer to your package insert.

**Counseling should reflect these imperfections of testing.**

### References: SEE INSIDE PACKAGE INSERT

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Date: 11/13/2013

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Revised by: Claudia E. Carron, MSN, RN Date: 2/5/2015

Revised by: Joanne Corbo, MBA, MT (ASCP) Date: 3/21/2015

Approved by: Gratian Salaru, M.D Date: 3/22/2015

## RESULT REPORTING

### Purpose:

The purpose of this procedure is to ensure the quality of technical services provided by the staff at sites performing rapid HIV testing staff by establishing a standard for result reporting and reviewing.

### Responsibility:

It is the responsibility of certified staff at all sites performing rapid HIV testing under RWJMS to:

- Properly identify patients and maintain the identity of the source patient throughout the testing process.
- Sign off on all testing performed by them.
- Report and document any aberrations to the Rapid HIV Testing Support Program.

It is the responsibility of the on-site coordinator or designee to:

- Review all patient and quality control testing results weekly and document their review.
- Forward all testing logs to the Rapid HIV Testing Support on a monthly basis.
- Investigate and report back to the Rapid HIV Testing Support Program coordinator all problems and questions as they occur.
- Implement corrective action plans as required.

It is the responsibility of the Rapid HIV Testing Support Program staff to:

- Review quality control, proficiency test results and patient logs.
- Assist the laboratory directors in identifying significant reporting, QC or PT issues.
- Train, recertify and monitor competency of staff.

### Procedure:

#### Patient Identification

1. Confirm the identity of the patient verbally with the patient and/or someone accompanying the patient.
2. Label any specimen collection containers while still at the patient's side. The single use test devices must be labeled so as to uniquely identify the patient.
3. Identifying numbers are used, not the patient's name.

#### Reporting

1. All testing results must be documented on the appropriate Test Log and reported to the HIV Testing Support Program, appropriate State and/or CDC departments.
2. Quality Control and Proficiency testing
  - A. The results of all quality control and proficiency testing performed will be documented on the Test Log.
  - B. All reagent lot numbers and expiration dates will be documented on the Test Log.
  - C. All temperature monitoring or any other information regarding quality control shall be documented on the Test Log.
  - D. All testing personnel will initial the Test Log for any testing performed. A legible signature or printed name is required at least once per Test Log sheet.
3. Patient/Client test results
  - A. All patient testing results must be documented in both the Test Log and the patient chart maintained at the site.

- B. Once properly recorded on the paper Test Log and on paper or electronic State or CDC reporting systems, the result, along with the required additional information, should be entered onto the Rapid HIV Test Result Form and then may be transferred by the testing staff to the clinical record.
- C. All negative results will be shared verbally with the patient and recorded in the Medical record/chart. As per current NJDHSS/DHAS policy, negative results are not directly provided to the client in writing at the time of testing.
- D. All preliminary positive results will be shared with the patient. The staff will refer to the Rapid-2-Rapid HIV Testing Policy for follow-up procedures.
- E. Once the result has been properly recorded on the paper Test Log and on paper or electronic State or CDC reporting systems, the result may be transmitted to the site's clinical record using the Rapid HIV Test Result Form. If the Rapid HIV Test Result Form is used, a copy must be maintained in the client's record, or if the HIV test was requested individually, rather than through the testing site's standing order, the result shall be transmitted to the requester using the Rapid HIV Test Result Form. If the Rapid HIV Test Result Form is used, a copy must be maintained in the client's record.

Written by: POCT Committee  
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Revised by: Patricia A Ribeiro, MT (ASCP)  
Reviewed by: Joanne Corbo, MBA, MT(ASCP)  
Approved by: Evan Cadoff, M.D.

Date: 01/15/02  
Date: 01/15/02  
Date: May 2013  
Date: May 2013  
Date: 8/6/2013

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# POLICY & PROCEDURE – Rapid-2-Rapid HIV Testing

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## **Protocol for Rapid to Rapid (R2R) HIV testing:**

This Protocol/Procedure outlines the process for the Test to Treat Program being implemented by the Division of HIV, STD & TB Services (DHSTS) in order to link HIV screen positive clients into treatment as quickly as possible. Under this program, an individual who has tested positive by 2 different HIV testing methods can be immediately linked to care.

This process may differ slightly as to data handling and client linkage to treatment depending on which of three categories your site falls into:

### **Category 1: Rapid-Rapid Testing Site and Treatment Site:**

Your testing site is a Rapid Rapid Testing site and is also a clinical treatment site. You use Clearview StatPak or Determine™ as the first Rapid HIV test and confirm the positive antibody result by using a second Rapid test (e.g., Trinity Unigold or OraQuick). The client is then referred to treatment within the organization on the same or next business day.

### **Category 2: Rapid Rapid Testing Site & Non Treatment Site-Client Will Be Transported to Treatment:**

Your testing site is a Rapid Rapid Testing site, but is **not** a clinical treatment site. You use Clearview StatPak or Determine™ as the first Rapid HIV test and confirm a positive antibody result by using a second Rapid test (e.g., Trinity Unigold or OraQuick). Under this category, the client is referred for treatment to a clinical treatment site with which your organization has established a Memorandum of Agreement (MOA) permitting linkage to care within one business day. The initial testing site will be responsible for seeing that the screen positive client is transported to the treatment site on the same or next business day.

### **Category 3: Rapid Testing Site- Client Will Be Transported to Rapid Rapid Site For Second Test & Treatment:**

Your testing site is **not a** Rapid Rapid Testing site. You use Clearview StatPak or Determine™ as the first Rapid HIV test and confirm the positive antibody result by sending the client to a Rapid Rapid Testing/Treatment site (Category 1) that performs a second Rapid test (Trinity Unigold or OraQuick) and links any positive client to treatment on the same or next business day.

The Category 1 site may elect to have certified staff travel and perform the second Rapid test at the Category 3 site's physical location, following the appropriate Mobile Travel Pack Policy. Testing records must be maintained according to the Travel Pack Policy. All record keeping and reporting requirements of this policy apply based on each counselor's primary location.

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## PROCEDURES: RAPID TO RAPID (R2R) TESTING

### **Category 1- Rapid Rapid Testing Site and Treatment Site:**

Your testing site is a Rapid Rapid Testing site and is also clinical treatment site. You use Clearview StatPak or Determine™ as the first Rapid HIV test and confirm a positive antibody result using a second Rapid test (e.g., Trinity Unigold or OraQuick). The client is referred to treatment within your organization, or a site of the client's choosing, within the same or next business day.

1. Client is tested using first Rapid HIV Test, Clearview StatPak, OraQuick or Determine™. If a positive antibody result is obtained using the Clearview StatPak, OraQuick or Determine™ Rapid test, follow the counseling message and perform a second Rapid HIV test to confirm the first positive result.
  - a. **Data:** Enter all the required information on the **NJ HIV Positive Tracking Form** for the First Rapid HIV test result. This information will also be entered into Evaluation Web and on the RAPID HIV Test Report.
2. Second Rapid HIV Test: A secondary Trinity Unigold Rapid HIV test or OraQuick Rapid HIV test is performed. If a positive result is obtained using the Trinity Unigold Rapid HIV test or OraQuick Rapid HIV test, the second test will verify the first positive antibody result. Follow the counseling message and navigate the client to a medical provider within your organization for treatment and any referrals for other services that may be needed.

If the first positive **result is only a positive** Antigen (Ag) line using Determine, follow the appropriate counseling message and navigate the client to a medical provider. Currently there are no Rapid tests available to an Antigen positive result, and the patient may be in the window phase of HIV infection. The medical provider will need to evaluate the patient. Call the NJ Rapid HIV Support Clinician at 732-236-7013 to report this result and report the case to the HIV Surveillance Program.

- a. **Data:** Enter all the required information on the **NJ HIV Positive Tracking Form** for the Second Rapid HIV test result. *It is not necessary to enter the site and counselor information unless it is different from the first result.* Check the box indicating both tests were positive. Be sure to fax the form to 732-235-9012. This information will also be entered into Evaluation Web and on to the HIV Test Report.
  - b. **Data:** Enter all the required information on the **NJ HIV Positive Tracking Form** for the Client Referral to Treatment. **Be sure to fax the form to 732-235-9012**
  - c. **The NJ HIV Positive Tracking form and the Rapid HIV Test Report must go with the client to the treatment site** (per your sites agreement with the treatment location you may be able to fax the form and report to ensure it is there for the client's appointment).
3. If the Second Rapid HIV Test is a negative result using the Trinity Unigold Rapid HIV test or OraQuick Rapid HIV test, you now have a **discordant result**. Call the NJ Rapid

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HIV Support Clinician at 732-236-7013 for guidance. Site staff should notify their medical director that a discordant has been identified and that additional testing will be done.

- a. Draw two 7 ml serum separator tubes and two 5 ml white top tubes (with at least 2 mls in the white top tube). Spin all the tubes down. Refrigerate the serum separator tubes and freeze the white top tube upside down.) Call NJ Rapid HIV Support Testing at 732-743-3624 to arrange for someone to pick up all the tubes.  
  
**Caution:** *After collection, BD Vacutainer® SST™ Serum Separation Tubes should be inverted five times, allowed to rest for 30 minutes to clot, and centrifuged for 10 minutes. After collection BD Vacutainer® PPT™ Plasma Preparation Tubes (white top) should be inverted 8 times and centrifuged for 10 minutes. This can be done immediately or within 2 hours. The PPT tubes do not require any rest time as they do not clot.*
  - b. Follow the counseling message regarding a **discordant result**. One of the program doctors will work with the site regarding this discordant. NJ Rapid HIV Testing support will send you tubes for the blood draw if you do not have them. PLEASE make sure your site always has a couple of tubes available with valid expiration dates.
  - c. Upon arrangement, the NJ HIV Testing Support Program doctor will be available in person or by phone at the post-test counseling session to help answer any questions the counselor or the client may have about the indeterminate or inconclusive result.
  - d. **Data:** Enter all the required information on the **NJ HIV Positive Tracking Form** for the Second Rapid HIV test result. It is not necessary to enter the site and counselor information unless it is different from the first result. Check the box indicating the test result is discordant. Be sure to fax the form to 732-235-9012.
4. If the client refuses a second Rapid HIV test or refuses blood work if the result is discordant refer the client to Partner Services.
    - a. Upon arrangement the NJ Rapid HIV Testing Support Program doctor will be available in person or by phone to help answer any questions the counselor or the client may have about the false positive result.
  5. **Make sure the NJ HIV Positive Tracking Form is completed and faxed to NJ HIV Rapid Support Services at 732-235-9012.** This should be faxed once the first and second results are completed and again when the client has an appointment for treatment and the appointment is kept.
  6. All sites conducting Rapid-Rapid Testing are required to report all positive cases to the HIV Surveillance Program. The case may be reported to the state by submission of a printed copy of the completed Evaluation Web form. Identifying client information is to be provided on the back of the hard copy document. The needed information includes: Client Name; Client Address and Client Telephone Number, when available. The form can be sent to the Surveillance Program using a state supplied confidential envelope which is self addressed and postage paid. Envelopes or further

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guidance may be obtained by calling (609) 984-5940.

### **Category 2: Rapid Rapid Testing Site & Non Treatment Site- Client Will Be Transported to Treatment:**

Your testing site is a Rapid Rapid Testing site and is **not** clinical treatment site. You use Clearview StatPak , Determine™ or OraQuick as the first Rapid HIV test and confirm the positive result by using a second Rapid test (Trinity Unigold or OraQuick). The client is referred to treatment to a clinical treatment site with whom you have an MOA, or a site of the client's choosing, within the same or next business day.

1. Client is tested using first Rapid HIV Test, Clearview StatPak, OraQuick or Determine™. If a positive antibody result is obtained using the Clearview StatPak, OraQuick or Determine™ Rapid test, follow the counseling message and perform a second Rapid HIV test to confirm the first positive result.
  - a. **Data:** Enter all the required information on the **NJ HIV Positive Tracking Form** for the First Rapid HIV test result. This information will also be entered into Evaluation Web and on the RAPID HIV Test Report.
2. Second Rapid HIV Test: A secondary Trinity Unigold Rapid HIV test or OraQuick Rapid HIV test is performed. If a positive result is obtained using the Trinity Unigold Rapid HIV test or OraQuick Rapid HIV test, the second test will verify the first positive result. Follow the counseling message and navigate the client to a medical provider within your organization for treatment and any referrals for other services that may be needed.

If the first positive **result is only a positive** Antigen (Ag) line using Determine, follow the appropriate counseling message and navigate the client to a medical provider. Currently there are no Rapid tests available to confirm an Antigen positive result, and the patient may be in the window phase of HIV infection. The medical provider will need to evaluate the patient. Call the NJ Rapid HIV Support Clinician at 732-236-7013 to report this result and report the case to the HIV Surveillance Program.

- a. **Data:** Enter all the required information on the **NJ HIV Positive Tracking Form** for the Second Rapid HIV test result. *It is not necessary to enter the site and counselor information unless it is different from the first result.* Check the box indicating both tests were positive. **Be sure to fax the form to 732-235-9012.** This information will also be entered into Evaluation Web.
  - b. **Data:** Enter all the required information on the Rapid HIV Positive Form for the Client Referral to Treatment. **Be sure to fax the form to 732-235-9012.**
  - c. **The NJ HIV Positive Tracking form and the Rapid HIV Test Report must go with the client to the treatment site** (per your sites agreement with the treatment location you may be able to fax the form and report to ensure it is there for the client's appointment).
2. If the Second Rapid HIV Test is a negative result is obtained using the Trinity Unigold Rapid HIV test or OraQuick Rapid test, you now have a **discordant result**. Call the NJ Rapid HIV Support Physician at 732-236-7013 for guidance, if needed. Site staff should

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notify their medical director that a discordant has been identified and that additional testing will be done.

- a. Draw two 7 ml serum separator tubes and two 5 ml white top tubes (with at least 2 mls in the white top tube). Spin all the tubes down. Refrigerate the serum separator tubes and freeze the white top tube upside down.) Call NJ Rapid HIV Support Testing at 732-743-3624 to arrange for someone to pick up all the tubes.

**Caution:** After collection, BD Vacutainer® SST™ Serum Separation Tubes should be inverted five times, allowed to rest for 30 minutes to clot, and centrifuged for 10 minutes. After collection BD Vacutainer® PPT™ Plasma Preparation Tubes (white top) should be inverted 8 times and centrifuged for 10 minutes. This can be done immediately or within 2 hours. The PPT tubes do not require any rest time as they do not clot.

- a. Follow the counseling message regarding a **discordant result**. One of the program doctors will work with the site regarding this discordant. NJ Rapid HIV Testing support will send you tubes for the blood draw if you do not have them (but PLEASE make sure your site always has a couple of tubes available with valid expiration dates).
  - b. Upon arrangement the NJ Rapid HIV Testing Support Program doctor will be available in person or by phone at the post-test counseling session to help answer any questions the counselor or the client may have about the indeterminate or inconclusive result.
  - c. **Data:** Enter all the required information on the **NJ HIV Positive Tracking Form** for the Second Rapid HIV test result. It is not necessary to enter the site and counselor information unless it is different from the first result. Check the box indicating the test result is discordant. Be sure to fax the form to 732-235-9012.
3. If the client refuses a second Rapid HIV test or refuses blood work if the result is discordant refer the client to Partner Services..
    - a. Upon arrangement the NJ Rapid HIV Testing Support Program doctor will be available in person or by phone at the post-test counseling session to help answer any questions the counselor or the client may have about the false positive result.
  4. **Make sure the NJ HIV Positive Tracking Form is completed and faxed to NJ HIV Rapid Support Services at 732-235-9012.** This should be faxed once the first and second results are completed and again when the client has an appointment for treatment and the appointment is kept.

All sites conducting Rapid-Rapid Testing are required to report all positive cases to the HIV Surveillance Program. The case may be reported to the state by submission of a printed copy of the completed Evaluation Web form. Identifying client information is to be provided on the back of the hard copy document. The needed information includes: Client Name; Client Address and Client Telephone Number, when available. The form can be sent to the Surveillance Program using a state supplied confidential envelope which is self addressed and postage paid. Envelopes or further guidance may be obtained by calling (609) 984-5940.

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### **Category 3: Rapid Testing Site- Client Will Be Transported to Rapid Rapid Site For Second Test & Treatment:**

Your testing site is **not a** Rapid Rapid Testing site. You use Clearview StatPak, Determine™ or Oraquick as the first Rapid HIV test and confirm the positive result by sending the client to a Rapid Rapid Testing site in Category 1 who will use a second Rapid test (Trinity Unigold or OraQuick). The client is referred to treatment within the Category1 testing site organization within the same or next business day.

1. Client is tested using first Rapid HIV Test, Clearview StatPak, OraQuick or Determine™. If a positive antibody result is obtained using the Clearview StatPak, OraQuick or Determine™ Rapid test, follow the counseling message and perform a second Rapid HIV test to confirm the first positive result.
  - a. **Data:** Enter all the required information on the **NJ HIV Positive Tracking Form** for the First Rapid HIV test result. This information will also be entered into Evaluation Web and on the RAPID HIV Test Report.
2. Second Rapid HIV Test: A secondary Trinity Unigold Rapid HIV test or OraQuick Rapid HIV test is performed. If a positive result is obtained using the Trinity Unigold Rapid HIV test or OraQuick Rapid HIV test, the second test will verify the first positive result. Follow the counseling message and navigate the client to a medical provider within your organization for treatment and any referrals for other services that may be needed.

If the first positive **result is only a positive** Antigen (Ag) line using Determine, follow the appropriate counseling message and navigate the client to a medical provider. Currently there are no Rapid tests available to confirm an Antigen positive result, and the patient may be in the window phase of HIV infection. The medical provider will need to evaluate the patient. Call the NJ Rapid HIV Support Clinician at 732-236-7013 to report this result and report the case to the HIV Surveillance Program.

- a. **Data:** Enter all the required information on the Rapid HIV Positive Form for the Second Rapid HIV test result. **It is necessary to enter the second site's site and counselor information since it is different from the first result.** A copy of this form will be kept at the SECOND site and a copy can be forwarded to the treatment center if required for appointment. **The staff at the SECOND site will NOT enter data in Evaluation Web. The original form, now completed, should go back to the FIRST site. The first site will enter all the information into Evaluation Web.**
  - i. In order to document that the second result was done at a site other than testing site one, in Evaluation Web the second testing site number should be entered into local field 1 and the second counselor number should be entered into local field 2.
  - ii. Check the box indicating both tests were positive. Be sure to **fax the form to 732-235-9012**. This information will also be entered into Evaluation Web as usual.
- b. **Data:** Enter all the required information on the **Rapid HIV Positive Tracking Form** for the Client Referral to Treatment. Be sure to fax the form to 732-235-9012

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- c. **Data:** The staff at the SECOND site needs to enter the site number for the FIRST site on their test log so it can be referenced back to the first positive result. The FIRST site's number should be entered in the Testing type box and an S for second test should be in the control code box on the test log
2. If a negative result is obtained using the Trinity Unigold Rapid HIV test or OraQuick Rapid test, you now have a **discordant result**. Call the NJ Rapid HIV Support Physician at 732-236-7013 for further guidance, if needed.

- a. **SITE 2. Discordant protocol**

- i. Site staff should notify their medical director that a discordant result with previous rapid testing has been identified.
- ii. Draw two 7 ml serum separator tubes and two 5 ml white top tubes (with at least 2 mls in the white top tube). Spin all the tubes down. Refrigerate the serum separator tubes and freeze the white top tube upside down.) Call NJ Rapid HIV Support Testing at 732-743-3624 to arrange for someone to pick up all the tubes. Please let NJHIV staff know that the samples at your site are a discordant from **SITE 1**, so that NJHIV can link the case appropriately.

**Caution:** After collection, BD Vacutainer® SST™ Serum Separation Tubes should be inverted five times, allowed to rest for 30 minutes to clot, and centrifuged for 10 minutes. After collection BD Vacutainer® PPT™ Plasma Preparation Tubes (white top) should be inverted 8 times and centrifuged for 10 minutes. This can be done immediately or within 2 hours. The PPT tubes do not require any rest time as they do not clot.

- iii. Follow the counseling message regarding a discordant result. One of the program doctors will work with both sites regarding this discordant, as needed. NJHIV Testing support will replace used collection tubes.
- iv. Communicate discordant result to **SITE 1. The client will follow-up with SITE 1 for resolution of the discordant result.**
- v. **Data:** Enter all the required information on the **Rapid HIV Positive Tracking Form** for the Second Rapid HIV test result. It is necessary to enter the site and counselor information since it is different from the first result entry. Check the box indicating the test result is discordant. Keep a copy of the form. The original form, now completed will return to the first site. Do not enter data into Evaluation Web.

- a. **SITE 1. Discordant protocol.**

- i. Record discordant result and file the completed form in the client chart. Follow discordant protocol (as for a Rapid-Western Blot discordant) and arrange for client to return to your site for final resolution.

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- ii. If final resolution is POSITIVE, contact **SITE 2** and arrange client appointment to the treatment center of **SITE 2**.
  - iii. If final resolution is NEGATIVE (false positive first rapid tests), follow counseling messages, notify client of status.
  - iv. **Data:** Enter all required information in Evaluation Web.
3. If the client refuses a second Rapid HIV test or refuses blood work if the result is discordant refer the client to Partner Services.
  - a. Upon arrangement the NJ Rapid HIV Testing Support Program doctor will be available in person or by phone at the post-test counseling session to help answer any questions the counselor or the client may have about the false positive result.
4. Make sure the Rapid HIV Positive Tracking Form is completed and faxed to NJ HIV Rapid Support Services at 732-235-9012. This should be faxed once the first and second results are completed and again when the client has an appointment for treatment and the appointment is kept.
5. All sites conducting Rapid-Rapid Testing are required to report all positive cases to the HIV Surveillance Program. The case may be reported to the state by submission of a printed copy of the completed Evaluation Web form. Identifying client information is to be provided on the back of the hard copy document. The needed information includes: Client Name; Client Address and Client Telephone Number, when available. The form can be sent to the Surveillance Program using a state supplied confidential envelope which is self addressed and postage paid. Envelopes or further guidance may be obtained by calling (609) 984-5940.

Written by: Joanne Corbo, MBA, MT(ASCP) Date: 2/26/2013

Approved by: Evan Cadoff, M.D. Date: 9/25/2013

Revised by: Claudia E. Carron, MSN,RN,NE-BC Date: 11/8/2013

Approved by: Evan Cadoff, M.D. Date: 12/12/13

Revised by: Joanne Corbo, MBA, MT(ASCP) Date: 3/21/2015

Approved by: Gratian Salaru, M.D. Date: 3/22/2015

## **Confirming a Preliminary Positive Rapid Test with a Second Rapid Test Counseling Messages and Reporting Procedures**

### **Counseling Messages**

Review testing methodology with patient prior to obtaining a signed consent form.

Inform the patient that a rapid HIV test(s) will be performed.

Provide the following information as needed.

#### **Non-Reactive Rapid Test**

If the test is non-reactive it means you have tested negative for HIV. However, since it takes about 1-3 months for the virus to be detected by a test, we will need to talk about the last time you put yourself at risk. If it was in the last 3 months, the test may not be accurate and we will discuss retesting. NOT putting yourself at risk again and retesting, will allow us to give you an accurate finding of whether or not you are infected.

#### **1st Rapid Test – Reactive**

If the test is reactive it means you have a Preliminary Positive test result and it is very likely you are infected with HIV. We will perform a second rapid test or make arrangements for a second test using a different kind of test to see if we get the same result.

#### **2nd Rapid Test – Reactive**

If both tests are reactive it means you should assume that you are infected with HIV. You are not required to have any further testing at this moment.

**Medical Care/Support Services:** We will discuss appropriate services and I will make an appointment for you with a medical care provider and provide you with referrals for other services you may need. The medical care provider will determine if further testing is indicated.

**Partner Notification:** It is important to take all necessary precautions to protect your current and future partners. We need to discuss notifying your past and present partners to let them know they have been exposed to HIV. We will offer them testing services so they can learn their own HIV status. (Elicit partner contact information and refer to NAP).

#### **2nd Rapid Test – Non-Reactive**

- If the first test is Antibody reactive and if the second test is antibody non-reactive it means we cannot provide you with a conclusive result. We will draw blood today and send it to our lab for confirmatory testing. You will need to return to the clinic in about 3 days to get the result of this test. (Counselors should follow current discordant procedures and must contact the discordant Hotline asap.)

- If the first test is both Antigen and Antibody reactive, we will draw blood for additional confirmatory testing, and make an appointment for you with a medical provider.

## **2nd Rapid Test – Non-Reactive**

If the first positive **result is only an** Antigen (Ag) reactive **it means we cannot provide you with a conclusive result immediately.** Currently there are no Rapid tests available to confirm an Antigen positive result. , and the patient may be in the window phase of HIV infection. The medical provider will need to evaluate the patient. Call the NJ Rapid HIV Support Clinician at 732-236-7013 to report this result and report the case to the HIV Surveillance Program. **A reactive antigen test could mean that you are in the window phase of an HIV infection, before your body has made detectable antibodies. We will make an appointment for you with a medical care provider and provide you with referrals for other services you may need. The medical care provider will determine if further testing is indicated. We will also draw blood today and send it to our lab for confirmatory testing. (Counselors should follow current discordant procedures and must contact the discordant Hotline asap.)**

## Reporting Procedures

### Whether you are Category 1, 2 or 3:

- The FIRST testing site completes the EvalWeb for all testing performed on that client.
- The FIRST testing site initiates the NJHIV Positive Tracking Form for all positive tests.

- The first testing site performs a second (on-site) rapid test with a different kind of Rapid HIV test if they are a Category 2 or 3.

### Category 3 As First Testing Site For Preliminary Positive Client

- Category 3 sites will make arrangements for a second test.
  - Connect with Navigator services
  - Completes for 1<sup>st</sup> test and Faxes to NJ Rapid HIV Support Program the NJHIV Tracking Form
  - Provide second site (preferably a Category 1 site) with NJHIV Tracking Form
  - Provide second site (Category 1) with Confidential Rapid HIV Result Report
  - Completes EvalWeb for all testing completed on that client.

### Category 2 As First Testing Site For Preliminary Positive Client

- Category 2 sites will complete a second test using a different Rapid Test device.
  - Make appointment with Treatment Site
  - Completes the NJHIV Tracking Form for 1<sup>st</sup> & 2<sup>nd</sup> test and appointment information and Faxes to NJ Rapid HIV Support Program
  - Connect with Navigator services
  - Provide second site (Category 1 or other treatment site) with Confidential Rapid HIV Result Report (if medical release form signed)
  - Follows up on whether appointment was kept
  - Completes EvalWeb for all testing completed on that client.

### Category 1 As First Testing Site For Preliminary Positive Client

- Category 1 sites will complete a second test using a different Rapid Test device.
  - Make appointment with onsite Treatment provider
  - Completes the NJHIV Tracking Form for 1<sup>st</sup> & 2<sup>nd</sup> test and appointment information and Faxes to NJ Rapid HIV Support Program
  - Provide treatment Provider with Confidential Rapid HIV Result Report
  - Follows up on whether appointment was kept
  - Completes EvalWeb for all testing completed on that client.

### Category 1 As Second Testing Site For Preliminary Positive Client

- Category 1 sites receive client with a documented preliminary positive result from a Category 3 or 2 site (documented on a Confidential Rapid HIV Result Report)
- Category 1 sites will complete a second test using a different Rapid Test device.
  - Make appointment with onsite Treatment provider
  - Completes the NJHIV Tracking Form for 2<sup>nd</sup> test and appointment information and Faxes to NJ Rapid HIV Support Program Plus Faxes form back to original testing site for EvalWeb completion
  - Provide treatment Provider with Confidential Rapid HIV Result Report
  - Follows up on whether appointment was kept

## *PROFICIENCY TESTING PROGRAM*

### **Purpose:**

The purpose of Proficiency Testing is to monitor the quality of technical services provided by physicians, nursing staff; medical assistants and any other individual trained and competent for rapid HIV testing and to ensure that problems related to these are identified and addressed. The monitoring system is designed to be compatible with the standards of the NJ Department of Health and Senior Services, and CLIA 88. Federal regulations, state regulations and deeming authorities such as the College of American Pathologists mandate that all testing facilities must successfully participate in an approved proficiency program for all regulated testing being performed in each specialty.

Proficiency testing is an ongoing part of a process intended to ensure that the analytic system of the testing site is functioning correctly. The basic premise of proficiency testing is that proficiency test specimens are tested simultaneously with patient unknowns and the results compared with results generated in many other institutions. Failure to obtain the expected values results in a series of corrective actions designed to protect UMDNJ-RWJMS and its clients from the generation of aberrant and incorrect data.

### **Responsibility:**

The responsibility of the Rapid HIV Testing Support Program is to:

- Oversee and evaluate the quality of testing provided by sites licensed to perform rapid HIV testing under the auspices of RWJMS.
- Ensure laboratory compliance with existing federal and state regulations.
- Assist the staff at these sites in meeting the clinical laboratory testing needs of their patients.

Rapid HIV Testing Support sites staff must participate in the proficiency testing periodically as a requirement for inclusion in the Rapid HIV Testing Support Program, in accordance with state and federal regulations.

### **Procedure:**

In order to provide central coordination of these activities and to alert the license holder of significant failures in proficiency performance, all proficiency testing is processed through the Department of Pathology. Annually, the Department elects to participate in a number of Proficiency Test programs from organizations including the College of American Pathologists (CAP), the American Association of Bioanalysts (AAB), the NJ Department of Health and Senior Services and the Center for Disease Control.

In order to insure compliance with state and federal regulations, all proficiency test (PT) specimens are shipped directly to each primary site licensed under RWJMS. As closely as possible, these specimens must be analyzed in the same manner, using the same testing methods as patient samples, by the same personnel who routinely test patient samples. Results are then forwarded to the Rapid HIV Testing Support Program on appropriate result sheets including reagent and control lot numbers and expiration dates and indicating the testing individual. These results will be submitted to the appropriate proficiency testing organization by the Rapid HIV Testing Support Program.

Proficiency testing will be rotated among all staff at the site certified to perform rapid HIV testing to ensure that all personnel performing patient testing are evaluated periodically. It is the responsibility of the Point of Care Testing staff to perform proficiency testing as specimens are received. There will be no interlaboratory communication about PT samples until after the submission of data deadline. PT samples may not be transferred to or discussed with another testing site or lab during testing period.

**Action to Improve Services and Resolve Problems**

Any failure of proficiency testing must be investigated by the Rapid HIV Testing Support Program staff in conjunction with the site staff that performed the proficiency testing and the on-site coordinator. These individuals will analyze the PT failure in an effort to identify the source of the failure and to develop a plan of corrective action. The results of the investigation and any corrective action taken must be documented appropriately, and be submitted to the Bioanalytical Laboratory Director. Additional technical assistance will be provided to the site by the HIV Rapid Testing Support Program to insure successful test performance by site staff and adequate analysis of proficiency test failures.

Written by: <u>POCT Committee</u>	Date: <u>01/15/02</u>
Approved by: <u>Evan Cadoff, M.D.</u>	Date: <u>01/15/02</u>
Reviewed by: <u>Patricia Ribeiro, MT(ASCP)</u>	Date: <u>4/12/13</u>
Reviewed by: <u>Joanne Corbo, MBA, MT</u>	Date: <u>4/12/13</u>
Approved by: <u>Gratian Salaru, M.D.</u>	Date: <u>4/12/13</u>
Approved by: <u>Parisa Javidian, M.D.</u>	Date: <u>4/12/13</u>

*MOBILE TRAVEL PACK FOR ORAQUICK*

**OBJECTIVE:** To provide a mechanism for testing at sites where counselors travel on an adhoc basis.

The OraQuick test kits are to be maintained at temperatures of 2-27°C or 35-80°F. Specially manufactured refrigerator packs have been designed to maintain temperatures of test kits for longer periods of time. If and when the temperature in the main compartment goes out of range, you will use your back-up compartment for testing. If the back-up compartment goes out of temperature range, **testing is no longer permitted**.

**MATERIALS NEEDED:**

- Test Kits, loops, blue stands, and thermal carrying case
- Procedure manual & copy of lab license
- Travel test log
- Paper work (PEMS form, client information, and consent form)
- 3 thermometers: 2 for travel compartments (make sure cable probe is with correct thermometer) and 1 for room temperature.
- 4 (22°C) frig. Packs from the refrigerator – **MUST BE KEPT IN REFRIGERATOR OVERNIGHT BEFORE USE.**
- Sharps container(s)
- Timer
- Lancets, band aids, gauze, alcohol pads
- Phlebotomy supplies
- Preliminary Positive test tubes
- Pen and marker for test labeling

*Note: If controls have not been done for the week, or if the storage temperature goes out of range, you must run controls before you start your travel. Log the controls onto the main site log sheet, not the travel log.*

**PROCEDURE:**

**1. Packing Travel Carrier:** **NEVER mix kits from different lots**

**Main Compartment:**

You should always take kits from the Return Box first. If there are no kits in the return box, you may take kits from the main site box. Place the kits in the main compartment with a frig pack on either side. Place the thermometer probe under the frig packs and place the test kits inside the compartment. Attach the probe to the thermometer and press the reset button.

**Back-up Compartment:**

Place the frig packs on either side and insert thermometer probe under the frig packs. Place the test kits inside. For this compartment you should test kits from the main site box, never the return box.

**Travel Test Log:**

The top portion of the travel test log must be completed before you leave. Do NOT take the main site test log from its primary location.

**2. Testing:**

For EACH patient, record on the travel log: the room temperature, client identification, **whether oral or blood**, start and end time, and the temperature of the compartment that you took the kit(s) from. Testing is performed in the same manner as if you were testing at the primary site.

**3. Returning to Main Site:**

**Test Kits:**

All kits from both compartments are placed in the return box EXCEPT if the kits went out of temperature range. If the temperature of the compartment goes out of range, the kits inside go in a separate box: **"OUT OF RANGE"** AND SHOULD BE RETURNED TO THE NJ RAPID HIV TESTING SUPPORT PROGRAM.

**Travel Log:**

Complete the travel log. Fill in the number of kits used and the number of kits returned. Make sure the min/max temperatures are entered on the bottom of the travel log. On the main log, document the testing information from your travel log (i.e. document the date, CTS number, result and your initials on the main log). Attach the travel log to the main log.

Written by: Dolores Van Pelt RN Date: 2-28-06

Approved by: Evan Cadoff, M.D. Date: 3-14-06

Reviewed by: Patricia Ribeiro,MT(ASCP) Date: 4/12/13

Reviewed by: Joanne Corbo,MBA,MT(ASCP) Date: 4/12/13

Approved by: Gratian Salaru, M.D. Date: 4/12/13

Approved by: Parisa Javidian, M.D. Date: 4/12/13

*MOBILE TRAVEL PACK FOR CLEARVIEW STAT-PAK*

**OBJECTIVE:** To provide a mechanism for testing at sites where counselors travel on an adhoc basis.

The Clearview STAT-PAK test kits are to be maintained at temperatures of 8-30°C or 46-86°F. Specially designed frig packs have been designed to maintain temperatures of test kits for longer periods of time. If and when the temperature in the main compartment goes out of range, you will use your back-up compartment for testing. If the back-up compartment goes out of temperature range, **testing is no longer permitted.**

**MATERIALS NEEDED:**

- Test Kits, loops, and thermal carrying case
- Procedure manual & copy of lab license
- Travel test log
- Paper work (PEMS form, client information, and consent form)
- 3 thermometers: 2 for travel compartments (make sure cable probe is with correct thermometer) and 1 for room temperature.
- 4 (22°C) frig. Packs from the refrigerator – **MUST BE KEPT IN REFRIGERATOR OVERNIGHT BEFORE USE.**
- Sharps container(s)
- Timer
- Lancets, band aids, gauze, alcohol pads
- Phlebotomy supplies
- Preliminary Positive test tubes
- Pen and marker for test labeling

*Note: If controls have not been done for the week, or if the storage temperature goes out of range, you must run controls before you start your travel. Log the controls onto the main site log sheet, not the travel log.*

**PROCEDURE:**

**1. Packing Travel Carrier:** **NEVER mix kits from different lots**

**Main Compartment:**

You should always take kits from the Return Box first. If there are no kits in the return box, you may take kits from the main site box. Place the kits in the main compartment with a frig pack on either side. Place the thermometer probe under the frig packs and place the test kits inside the compartment. Attach the probe to the thermometer and press the reset button.

**Back-up Compartment:**

Place the frig packs on either side and insert thermometer probe under the frig packs. Place the test kits inside. For this compartment you should test kits from the main site box, never the return box.

**Travel Test Log:**

The top portion of the travel test log must be completed before you leave. Do NOT take the main site test log from its primary location.

**2. Testing:**

For EACH patient, record on the travel log: the room temperature, client identification, start and end time, and the temperature of the compartment that you took the kit(s) from. Testing is performed in the same manner as if you were testing at the primary site.

**3. Returning to Main Site:**

**Test Kits:**

All kits from both compartments are placed in the return box EXCEPT if the kits went out of temperature range. If the temperature of the compartment goes out of range, the kits inside go in a separate box: **"OUT OF RANGE"** AND SHOULD BE RETURNED TO THE NJ RAPID HIV TESTING SUPPORT PROGRAM.

**Travel Log:**

Complete the travel log. Fill in the number of kits used and the number of kits returned. Make sure the min/max temperatures are entered on the bottom of the travel log. On the main log, document the testing information from your travel log (i.e. document the date, CTS number, result and your initials on the main log). Attach the travel log to the main log.

Written by: Dolores Van Pelt RN Date: 2-28-06

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Approved by: Gratian Salaru, M.D. Date: 4/12/13

Approved by: Parisa Javidian, M.D. Date: 4/12/13

*MOBILE TRAVEL PACK FOR UNI-GOLD*

**OBJECTIVE:** To provide a mechanism for testing at sites where counselors travel on an adhoc basis.

The Uni-Gold™ Recombigen® HIV test kits are to be maintained at temperatures of 2°-27° C (36° - 81°F). Specially designed frig packs have been designed to maintain temperatures of test kits for longer periods of time. If and when the temperature in the main compartment goes out of range, you will use your back-up compartment for testing. If the back-up compartment goes out of temperature range, **testing is no longer permitted.**

**MATERIALS NEEDED:**

- Test Kits, Disposable Fingertick Sample Collection and Transfer Pipettes, Bottle Wash Solution
- Thermal carrying case
- Procedure manual & copy of lab license
- Travel test log
- Paper work (PEMS form, client information, and consent form)
- 3 thermometers: 2 for travel compartments (make sure cable probe is with correct thermometer) and 1 for room temperature.
- 4 (22°C) frig. Packs from the refrigerator – **MUST BE KEPT IN REFRIGERATOR OVERNIGHT BEFORE USE.**
- Sharps container(s)
- Timer
- Lancets, band aids, gauze, alcohol pads
- Phlebotomy supplies
- Preliminary Positive test tubes
- Pen and marker for test labeling

*Note: If controls have not been done for the week, or if the storage temperature goes out of range, you must run controls before you start your travel. Log the controls onto the main site log sheet, not the travel log.*

**PROCEDURE:**

**1. Packing Travel Carrier:** **NEVER mix kits from different lots**

**Main Compartment:**

You should always take kits from the Return Box first. If there are no kits in the return box, you may take kits from the main site box. Place the kits in the main compartment with a frig pack on either side. Place the thermometer probe under the frig packs and place the test kits inside the compartment. Attach the probe to the thermometer and press the reset button.

**Back-up Compartment:**

Place the frig packs on either side and insert thermometer probe under the frig packs. Place the test kits inside. For this compartment you should test kits from the main site box, never the return box.

**Travel Test Log:**

The top portion of the travel test log must be completed before you leave. Do NOT take the main site test log from its primary location.

**2. Testing:**

For EACH patient, record on the travel log: the room temperature, client identification, start and end time, and the temperature of the compartment that you took the kit(s) from. Testing is performed in the same manner as if you were testing at the primary site.

**3. Returning to Main Site:**

**Test Kits:**

All kits from both compartments are placed in the return box EXCEPT if the kits went out of temperature range. If the temperature of the compartment goes out of range, the kits inside go in a separate box: **"OUT OF RANGE"** AND SHOULD BE RETURNED TO THE NJ RAPID HIV TESTING SUPPORT PROGRAM.

**Travel Log:**

Complete the travel log. Fill in the number of kits used and the number of kits returned. Make sure the min/max temperatures are entered on the bottom of the travel log. On the main log, document the testing information from your travel log (i.e. document the date, CTS number, result and your initials on the main log). Attach the travel log to the main log.

Written by: Dolores Van Pelt RN Date: 2-28-06

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Approved by: Gratian Salaru, M.D. Date: 4/12/13

Approved by: Parisa Javidian, M.D. Date: 4/12/13

# RAPID HIV TEST REPORT

**CONFIDENTIAL**

Last Name	First Name	MI	CTS (Barcode #or unique ID code)
Date of Birth:			

## 1<sup>st</sup> RAPID TEST OraQuick StatPak Determine Unigold Other \_\_\_\_\_

Result: <input type="radio"/> <b>NEGATIVE</b>	Reference Range: <b>Negative</b>	Test Date: Test Site:
<input type="radio"/> <b>PRELIMINARY POSITIVE</b> <input type="radio"/> <b>Antibody</b> <input type="radio"/> <b>Antigen/Antibody (Determine)</b> <input type="radio"/> <b>Antigen only(Determine)</b>		Laboratory Director: Site telephone#:
<input type="radio"/> 2 <sup>nd</sup> RAPID TEST performed, see below		<input type="radio"/> CONFIRMATORY testing performed, see separate report

## 2<sup>nd</sup> RAPID TEST OraQuick StatPak Determine Unigold Other \_\_\_\_\_

Result: <input type="radio"/> <b>NEGATIVE</b> <input type="radio"/> <b>POSITIVE</b>	Reference Range: <b>Negative</b>	Test Date: Test Site:
		Laboratory Director: Site telephone#:

### Rapid HIV testing considerations:

- If the 1<sup>st</sup> rapid test is **NEGATIVE**, the screen is considered Negative for HIV antibodies
- If the 1<sup>st</sup> rapid test is **POSITIVE**, further testing is needed: either confirmatory testing (Western blot or molecular tests) from an outside laboratory, or a second rapid test:
  - If two orthogonal (different) rapid tests have been performed and are **both POSITIVE**: Based on current guidelines, the patient is considered positive for HIV and has been referred for care. Additional testing may be performed at the treatment center, to confirm and further evaluate the condition.
  - Two orthogonal (different) rapid tests have been performed with the **second test NEGATIVE**: The results are **DISCORDANT** and require further investigation. Refer to **DISCORDANT** procedures and call NJHIV support for assistance with interpretation at **732-236-7013**.
- If the 1<sup>st</sup> rapid test is Determine, and the result is **ANTIGEN ONLY POSITIVE**, collect samples as for a discordant work-up and call NJHIV support, but **REFER patient to care**. This may represent an acute HIV case; the confirmation of the preliminary result may take 7-10 days.

<b>A Medical Records Release Form was signed.</b>	<b>Date:</b>
<b>Signature of Patient</b>	

This form goes to the ordering physician with a copy kept in the patient chart. The rapid tests used have been evaluated and approved for use by the FDA. The rapid test(s) have been interpreted by a trained operator, competent in the performance of these tests and reflect the HIV status of the patient identified above at the time of the testing. A copy of the form can be released to referral/treatment centers, provided the results of the rapid tests were used for referral AND the patient signed the medical records release, above.

# Rapid HIV *Partner Services* Referral

Client CTS number \_\_\_\_\_ Site ID: \_\_\_\_\_ Today's date: \_\_\_\_\_

- **Always call *Partner Services* first** at 973-648-7474 with details of the client you are referring.
- Check the corresponding box appropriate to the client's needs.
- Follow instructions in that box.
- **Fax** this and all forms within 24 hours to ***Partner Services*** at 973-648-7384.
- Also **fax** a NJ HIV Positive Tracking form to HIV Rapid Testing Support at 732-235-9012.
- **Always** keep copies for your files and/or records of everything you submit to *Partner Services*.

## Counselor at site

## *Partner Services*

<input type="checkbox"/>	1	<p><b>Client refused second confirmatory test.</b></p> <p><b><u>Fax</u></b> to <i>Partner Services</i>:</p> <ul style="list-style-type: none"> <li>• Evaluation Web form, part 1</li> <li>• NJ HIV Positive Tracking Form</li> <li>• <i>Partner Services</i> Referral. <i>Do not include client identifiers other than CTS number.</i></li> </ul> <p>Is client aware of positive Rapid HIV test result?</p> <p><input type="checkbox"/> YES    <input type="checkbox"/> NO</p>	<ul style="list-style-type: none"> <li>• Do a UniGold <b>to confirm result.</b></li> <li>• Call Navigator</li> </ul>
<input type="checkbox"/>	2	<p><b>Client received first and second rapid test but did not receive result of second test.</b></p> <p><b><u>Fax</u></b> to <i>Partner Services</i>:</p> <ul style="list-style-type: none"> <li>• Evaluation Web form, part 1</li> <li>• NJ HIV Positive Tracking Form</li> <li>• <i>Partner Services</i> Referral. <i>Do not include client identifiers other than CTS number.</i></li> </ul>	<ul style="list-style-type: none"> <li>• <i>Post test counseling</i></li> <li>• <i>Call Navigator</i></li> </ul>
<input type="checkbox"/>	3	<p><b>Client tested positive on StatPak and negative on the second rapid test, but the client refused the discordant work up.</b></p> <p><b><u>Fax</u></b> to <i>Partner Services</i>:</p> <ul style="list-style-type: none"> <li>• Evaluation Web form, part 1</li> <li>• NJ HIV Positive Tracking Form</li> <li>• <i>Partner Services</i> Referral. <i>Do not include client identifiers other than CTS number.</i></li> </ul>	<ul style="list-style-type: none"> <li>• Do a UniGold to confirm result.</li> <li>• Refer client back to site for additional testing.</li> </ul>
<input type="checkbox"/>	4	<p><b>Client did not return for the discordant results.</b></p> <p><b><u>Fax</u></b> to <i>Partner Services</i>:</p> <ul style="list-style-type: none"> <li>• Evaluation Web form, part 1</li> <li>• NJ HIV Positive Tracking Form</li> <li>• <i>Partner Services</i> Referral. <i>Do not include client identifiers other than CTS number.</i></li> </ul>	<ul style="list-style-type: none"> <li>• Do a UniGold to confirm the result.</li> <li>• Refer the client back to the site.</li> </ul>

**For *Partner Services* use only:**

Did you reach the client?            \_\_\_ No    \_\_\_ Yes (If Yes, Date \_\_\_\_\_)

Did you do an OraSure?                \_\_\_ No    \_\_\_ Yes (If Yes, Date \_\_\_\_\_)

Did you do a Rapid HIV test?         \_\_\_ No    \_\_\_ Yes (If Yes, Date \_\_\_\_\_)

Did you link client to Medical Services   \_\_\_ No    \_\_\_ Yes (If Yes, Date \_\_\_\_\_)

When the case is closed, **fax** this form back to HIV Rapid Testing Support at 732-235-9012.

**For Technical Assistance, call RWJ at 732-743-3624**

Test Kit	Daily Responsibilities	Client (or QC) Testing	Preliminary Positive	Confirmed Positive/ Discordant	Client Referral to Treatment	Proficiency Testing
<b>Test Kits</b>	<ul style="list-style-type: none"> <li>Record min/max for refrigerator and reagent storage (Reset thermometer); record room temperatures before set up.</li> <li>Check QC rotation schedule</li> <li>Control Storage Temperature: 36 - 46° F</li> <li>Check expiration date of controls</li> <li>Perform QC if needed:               <ul style="list-style-type: none"> <li>Every Monday or 1<sup>st</sup> day of testing each week</li> <li>New Shipments</li> <li>Storage area out of temperature range.</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>Check expiration dates</li> <li>Make sure QC is current (✓ storage temperature)</li> <li>Don't test if <b>testing temperature</b> is out of range – see below</li> <li>Use personal protective equipment</li> <li>Check for desiccant pack</li> <li>Label the vial &amp; test device</li> <li>Fill loop completely; if buffer is required make sure proper amount is dispensed into the well of the test device, if using a pipette bulb make sure to hold the bulb correctly for ease of specimen collection into the port. <b>If unsure of procedure please check your procedure manual.</b></li> <li>Record in testing log.</li> </ul>	<ul style="list-style-type: none"> <li>Follow R2R Procedure</li> <li>Fax NJ HIV Tracking Form to 732 235-9012</li> </ul>	<p><b>Confirmed Positive:</b></p> <ul style="list-style-type: none"> <li>Fax NJ HIV Positive Tracking Form to NJ Rapid HIV Testing Support Program. Fax: 732-235-9012.</li> </ul> <p><b>Discordant:</b></p> <ul style="list-style-type: none"> <li>Draw two 7 ml serum separator tubes and one 5 ml white top tube (with at least 2 mls in the white top tube). Spin all the serum separator tubes and freeze the white top tube upside down.)</li> <li>Call NJ Rapid HIV Testing Support to pick up specimens. Call <b>732-743-3624</b></li> </ul>	<p><b>Confirmed Positive:</b></p> <ul style="list-style-type: none"> <li>Fax Positive Tracking Form with the referral to treatment information to 732-235-9012</li> </ul> <p><b>Discordant:</b></p> <ul style="list-style-type: none"> <li>Call discordant phone for advice: 732-236-7013</li> </ul>	<ul style="list-style-type: none"> <li>Perform test when requested.</li> <li>Test as a client fingerstick sample, but solution will not turn pink.</li> <li>If available, MPEP results entered by site.</li> <li>AAB or CAP results entered by HIV Support Team</li> <li>All results to NJ HIV Support Program. Call site liaison for fax number.</li> </ul>
<b>Alere Determine</b>	<ul style="list-style-type: none"> <li>Control expiration: Until printed date on box</li> <li>Test kit storage range: 36 - 86° F</li> <li>Test Units must be maintained in re-sealable pouch</li> <li>Do not use Buffer when running Controls or PT</li> </ul>	<ul style="list-style-type: none"> <li>Testing Temp: 59 - 86°F</li> <li><b>Wait one minute after applying specimen prior to</b> adding one (1) drop of Buffer</li> <li>Read between 20, but no more than 30 minutes</li> <li>Detects HIV-1 p24 antigen &amp; HIV 1/2 antibodies</li> </ul>				
<b>Clearview STAT-PAK</b>	<ul style="list-style-type: none"> <li>Control expiration: Until printed date on box</li> <li>Test kit storage range: 46 -86° F</li> </ul>	<ul style="list-style-type: none"> <li>Testing Temp: 64 - 86°F</li> <li>Add three (3) drops of buffer</li> <li>Read after 15, but less than 20 minutes</li> </ul>				
<b>Trinity Uni-Gold</b>	<ul style="list-style-type: none"> <li>Control expiration: 4 weeks after opening</li> <li>Test kit storage range: 36 -81° F</li> </ul>	<ul style="list-style-type: none"> <li>Testing Temp: 59 - 81°F</li> <li>Add four (4) drops of buffer</li> <li>Read after 10, but no more than 12 minutes</li> <li>Sample port must be RED when testing clients</li> </ul>				



Robert Wood Johnson  
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**OPERATOR CHECKLIST**  
NJ RAPID HIV TESTING SUPPORT PROGRAM  
<http://www.njhiv1.org/>

<b>OraQuick</b>	<ul style="list-style-type: none"><li>• Control expiration: 8 weeks after opening</li><li>• Test kit storage range: 35 - 80° F</li></ul>	<ul style="list-style-type: none"><li>• Testing Temp: 59 - 99°F</li><li>• Developer solution in vial</li><li>• Read after 20, but less than 40 minutes</li><li>• Oral testing: do not over-swab</li></ul>				
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# NJ HIV Positive Tracking Form

## First Rapid HIV Test Result

Client ID # \_\_\_\_\_

Date: \_\_\_\_\_

First Test Site ID Number \_\_\_\_\_ First Test Site Name \_\_\_\_\_

First Test Site Counselor Name \_\_\_\_\_ First Test Site Counselor Number \_\_\_\_\_

**First Rapid HIV Test Type:** OraQuick Clearview STAT-PAK Determine Other  
Result: Positive HIV 1/2 Antibody \_\_\_\_\_ Positive HIV Antigen (Determine) \_\_\_\_\_

Positive ANTIGEN ONLY (Determine)\_\_\_\_\_. No rapid tests can validate this result. Collect discordant work-up samples for confirmation, call NJHIV support for assistance and REFER client to care. This may represent an acute HIV case; confirmation may take 7-10 days.

Specimen (circle one): Oral Fingerstick Venipuncture Test Kit Lot Number: \_\_\_\_\_

**For Single Rapid Test Sites and Non Clinical Rapid Rapid Test sites, this form must accompany the patient to test site where second test will be performed and must go to the treatment site. The form must be returned to the first test site to capture the positive result and referral to care.**

## Second Rapid HIV Test Result

Date: \_\_\_\_\_

Enter site information if Second Test Site Is different from First Test Site:

Second Test Site ID Number \_\_\_\_\_ **Also enter in Local Field 1 in Evaluation Web**

Second Test Site Name \_\_\_\_\_

Second Test Site Counselor Name \_\_\_\_\_

Second Test Site Counselor Number \_\_\_\_\_ **Also enter in Local Field 2 in Evaluation Web**

**Second HIV Test Type:** Rapid: Unigold OraQuick Result: Positive\_\_\_\_ Negative\_\_\_\_  
Sent to Laboratory: Blood drawn for antigen confirmation\_\_\_\_ (see attached report)

Specimen (circle one): Oral Fingerstick Venipuncture Test Kit Lot Number: \_\_\_\_\_

## Test Result:

- Check One:  Both Tests Positive  
 Evaluation Web Result Form with client information mailed to Surveillance  
Date Mailed: \_\_\_\_\_ Mailed By: \_\_\_\_\_  
 Discordant Result (First test is positive and second test is negative. Also for **Antigen ONLY** positives). Draw 2 serum separator tubes and 2 white top tubes & Call NJ HIV Program at 732-743-3624 or 732-743-3620 for pickup. Process collected tubes according to instructions.  
 Second Test Not Done: Client refused - Contact Partner Services and complete Partner Services Referral Form.

**Fax to (732) 235-9012 when Rapid HIV Test Result part is completed**

## Client Referral To Treatment

Date client referred to treatment \_\_\_\_\_

Date of Appointment \_\_\_\_\_ Appointment Kept: Yes\_\_\_\_ No\_\_\_\_

If No, Why \_\_\_\_\_

Patient Navigated By: \_\_\_\_\_

**Fax to (732) 235-9012 when Appointment information is completed**



Robert Wood Johnson  
Medical School

NJ Rapid HIV Testing Support Program  
Phone: (732) 743-3624 Fax: (732) 235- 9012

### Rapid HIV Supply Order

Monthly Order \_\_\_\_\_ Special Request \_\_\_\_\_ Check if Rapid Rapid Site \_\_\_\_\_

DATE REQUESTED \_\_\_\_\_ DATE FILLED: \_\_\_\_\_

FACILITY/SITE NAME: \_\_\_\_\_

LOCATION: \_\_\_\_\_

PHONE: \_\_\_\_\_

DEPARTMENT/DIVISION (circle) **DHAS** or DAS REQUESTOR: \_\_\_\_\_

ITEM	REQUESTED	QUANTITY ON HAND	SUPPLIED
<b>HIV POCT Tests &amp; Controls:</b>			
STAT-PAK Test Kits (20 Tests/kit)			
STAT-PAK External Controls (pos, pos, & neg)			
Uni-Gold Test Kits (20 Tests/kit)			
Uni-Gold External Controls (pos & neg)			
OraQuick Kits (100 Test kits/box)	Available with Approval		
OraQuick External Controls (pos, pos, & neg)	Available with Approval		
Determine Test Kits (25 Tests/kit)			
Determine Controls (1 pos, 2 pos, Ag pos, neg)			
<b>General Supplies Required for Testing:</b>			
Lancets (High) – 150/box			
Lancets (Normal) – 150/box			
Sterile Alcohol Prep Pads – 200/box			
Gauze (2"x2") – 200/pack			
Band-Aids – 100/box			
Bench covers/Chux pads-Each			
Biohazard Containers (Small Tabletop)			
Biohazard Containers (Large Tabletop)			
Gloves (Small) – 100/box			
Gloves (Medium) – 100/box			
Gloves (Large) – 100/box			
Gloves (X-Large) – 100/box			
Lab Coats (Small)			
Lab Coats (Medium)			
Lab Coats (Large)			
Lab Coats (X-Large)			
TEST TUBE – Gold Top Tubes			
TEST TUBE – White Top Tubes			
<b>Special Request:</b>			
TRAVEL – Travel Box			
TRAVEL – Travel Box Refrigerator Packs			
Thermometer (Digital) for Room, Fridge, or Freezer			
Timers			
Laboratory Shields			
Refrigerator			
Waterless Hand Sanitizers- For Mobile Units & One Day Events Only			
Biohazardous Specimen Bags (6"x9)			

Additional Items:

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Validation of reagent lots is required by most regulatory agencies. Rutgers, RWJMS performs validation centrally on all new reagents received through the rapid HIV testing program. On occasion, you may notice that some of your reagents are consumed by this process.

REAGENT	UNOPENED	OPENED	NOTES
<b>OraSure Oraquick Controls</b> (HIV 1–pos, HIV 2–pos, neg)	Listed expiration date when stored at: (2-8 °C) (35°-46 °F)	Expires in 8 weeks when stored at: (2-8°C) (35°-46°F) When you open a new set, write the new expiration date on the back of the box.	DO NOT STORE AT ROOM TEMPERATURE  DO NOT FREEZE
<b>OraSure Oraquick Advance</b> HIV 1 and 2 antibody	Listed expiration date when stored at: (2-27°C )(35°-80°F)	If individual kit package is opened and not used, discard immediately.	DO NOT STORE <35° or >80° F RUN QC IF STORAGE WAS OUT OF RANGE
REAGENT	UNOPENED	OPENED	NOTES
<b>Uni-Gold Recombigen Controls</b> (HIV 1–pos, HIV 2–pos, neg)	Listed expiration date when stored at: (2°-8°C) (36o-46°F)	Expires in 4 weeks when stored at: (2°-8°C) (36°-46°F)  When you open a new set, write the expiration date on the back of the box.	DO NOT STORE AT ROOM TEMPERATURE  DO NOT FREEZE
<b>Uni-Gold Recombigen</b> HIV 1 antibody	Listed expiration date when stored at: (2°-27°C )(36-81°F)	If individual kit package is opened and not used, discard immediately.	DO NOT STORE <36° or >80° F RUN QC IF STORAGE WAS OUT OF RANGE
REAGENT	UNOPENED	OPENED	NOTES
<b>Clearview Stat-Pak Controls</b> (HIV 1–pos, HIV 2–pos, neg)	Listed expiration date when stored at: (2°-8°C) (36°-46°F)	Manufacturer expiration date when stored at: (2°-8°C) (36°-46°F)  When you open a new set, write the expiration date on the back of the box.	DO NOT STORE AT ROOM TEMPERATURE  DO NOT FREEZE
<b>Clearview Stat-Pak</b> HIV 1 and 2 antibody	Listed expiration date when stored at: (8°-30°C )(46°-86°F)	If individual kit package is opened and not used, discard immediately.	DO NOT STORE <47 ° or >86° F  RUN QC IF STORAGE WAS OUT OF RANGE

<b>REAGENT</b>	<b>UNOPENED</b>	<b>OPENED</b>	<b>NOTES</b>
<b>Determine Controls</b>	Listed expiration date when stored at: (2°-8°C) (36°-46°F)	Manufacturer expiration date when stored at: (2°-8°C) (36°-46°F)  When you open a new set, write the expiration date on the back of the box.	<b>DO NOT STORE AT ROOM TEMPERATURE</b>  <b>DO NOT FREEZE</b>
<b>Determine HIV 1 and 2 Antigen/Antibody Combo</b>	Listed expiration date when stored at: (2°-30°C )(36°-86°F)	If stored refrigerated test units must be brought to operating temperatures (15°-30°C )(59°-86°F) Must be used within 2 hours after removing protective foil	<b>DO NOT STORE &lt;36 ° or &gt;86° F</b>  <b>RUN QC IF STORAGE WAS OUT OF RANGE</b>

As you prepare to test each client with a Rapid HIV test, run through this entire checklist:

1. **Look at the temperature log.** If it is not filled out for today:
  - Record the reagent storage temperature and reset the thermometer. If the temperature was out of range, run quality control tests (use reason code 2)
  - Record the refrigerator temperature and reset the thermometer. If the refrigerator temperature is out of range, indicate on the back of the log what you (or your coordinator) did to fix the problem.
2. **Look at the testing log.**
  - Was the last test result in the log invalid? (*please refer to step 7*)
    - i) If so, find out who's working on the invalid test, or proceed to step 5 and run quality control tests (use reason code 6)
  - **Were control samples run on (or after) Monday?** If not, proceed to step 5 and run quality control tests (use reason code 1)
3. **Is this the first box of a shipment** of reagents?
  - If yes, proceed to step 5 and run quality control tests (use reason code 4)
4. **Check reagent storage thermometer,** then get a test kit from the box.
  - If min or max temperature is out of range, run quality control tests (use reason code 2).
  - Check the thermometer every time to get a test kit from the box...not just the first time.
5. **Running quality control:**
  - On the testing log, record that you are running control tests, and what the reason is.
  - Put the control lot number in the Client ID column on the log sheet.
    - i) Don't open a new box unless the old box is expired or one of the control samples is depleted.
  - Run the control tests and record the results. The positive control should have a positive result (C and T lines). The negative control should have a negative result (C line, but no T line).
  - **If the control results are not what they should be, or if they are invalid, repeat the quality control tests.** (use reason code 6).
  - **If controls fail a second time, repeat controls a third time using a new box, if available, of controls.** (use reason code 6)
    - i) Use a new box of controls and throw out the old ones.
    - ii) Put the open and expiration dates on the new box of controls.
    - iii) If the control results do not work a third time, call us for help. You cannot test your client using the Rapid Test. You should have them come back another time or draw two white top tubes. Call our discordant phone number (732) 236-7013 for pick up from RWJMS. Further information and instructions will be given then.
6. **You need to run quality control samples at least once quarterly.**
  - If you notice that it's near the end of the quarter, or your coordinator asks you, run your quarterly quality control samples using reason code 5.
7. **Invalid client results**
  - If you get an invalid result on a client, enter the invalid in the log. In the comments box, write why the test was invalid, (for example, "No C line" or "Lines not inside the triangle" or "No lines").

- If the client agrees, repeat the test (and put it in the test log). Use same Client ID number.
- If it's invalid again, do not run the sample a third time. Run quality control (reason code 6) before you resume testing on another client sample.
- If the client doesn't want to be tested again, run control samples (reason code 6).
- Don't leave the test log with an invalid result as the last entry.
- Do not repeat an invalid client a third time. You need to draw two white top tubes and call our discordant phone number (732) 236-7013 for pick up from UMDNJ. Further information and instructions will be given then.

Revised by: Patricia A Ribeiro, MT (ASCP)

Date: 5/28/13

Approved by: Evan Cadoff, M.D.

Date: 8/6/2013



Robert Wood Johnson  
Medical School

## OraQuick Temperature Log

New Jersey Rapid HIV Testing Support Program

Location

Somerset, NJ 08873

Fax: 732-235-9012

SITE NAME:

SITE:#

MONTH/YEAR:

DIVISION:

DATE	TEST KITS	KIT CONTROL	Operator
	2°-27° C (35°-80° F) ROOM (Storage) (Min/Max)	2-8°C (35°-46° F) REFRIGERATOR (Min/Max)	
1.	/	/	
2.	/	/	
3.	/	/	
4.	/	/	
5.	/	/	
6.	/	/	
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31.	/	/	

Please use a new sheet each month.

Please record the minimum → maximum temperatures recorded each day

SECTION 2.7.1



Robert Wood Johnson  
Medical School

## Stat-Pak Temperature Log

New Jersey Rapid HIV Testing Support Program

Location

Somerset, NJ 08873

Fax: (732) 235-9012

SITE NAME: SITE:#

MONTH/YEAR:

DIVISION:

DATE	TEST KITS	KIT CONTROL	Operator
	8°-30° C (46°-86° F) ROOM (Storage) (Min/Max)	2-8°C (35°-46° F) REFRIGERATOR (Min/Max)	
1.	/	/	
2.	/	/	
3.	/	/	
4.	/	/	
5.	/	/	
6.	/	/	
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**Please use a new sheet each month.**

**Please record the minimum → maximum temperatures recorded each day**

SECTION 2.7.2



Robert Wood Johnson  
Medical School

## Uni-Gold Temperature Log

New Jersey Rapid HIV Testing Support Program  
Location  
Somerset, NJ 08873  
Fax: (732) 235-9012

SITE NAME:                   SITE:#  
MONTH/YEAR:  
DIVISION:

DATE	TEST KITS	KIT CONTROL	Operator
	2°-27° C (36°-81° F) ROOM (Storage) (Min/Max)	2-8°C (35°-46° F) REFRIGERATOR (Min/Max)	
1.	/	/	
2.	/	/	
3.	/	/	
4.	/	/	
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**Please use a new sheet each month.**

**Please record the minimum → maximum temperatures recorded each day**

SECTION 2.7.3



Robert Wood Johnson  
Medical School

**Stat Pak & Uni-Gold  
TEMPERATURE LOG**

New Jersey Rapid HIV Testing Support Program

Location

Somerset, NJ 08873

Fax: 732 235-9012

SITE NAME:

SITE:#

MONTH/YEAR:

DATE	TEST KITS				KIT CONTROLS				Operator
	StatPak		Unigold		StatPak		Unigold		
	8°-30° C (46°-86° F) TEST KITS (Min/Max)		2°-27° C (36°-81° F) TEST KITS (Min/Max)		2°-8° C (36°-46° F) CONTROLS (Min/Max)		2°-8° C (36°-46° F) CONTROLS (Min/Max)		
	Min	Max	Min	Max	Min	Max	Min	Max	
1.	/		/		/		/		
2.	/		/		/		/		
3.	/		/		/		/		
4.	/		/		/		/		
5.	/		/		/		/		
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Please use a new sheet each month.

Please record the minimum → maximum temperatures recorded each day

**SECTION 2.7.4**



Robert Wood Johnson  
Medical School

## Determine Temperature Log

New Jersey Rapid HIV Testing Support Program

Location

Somerset, NJ 08873

Fax: (732) 235-9012

Room Thermometer Expiration: \_\_\_\_\_

SITE NAME:

SITE:#

MONTH/YEAR:

DIVISION:

Refrigerator Thermometer Expiration: \_\_\_\_\_

DATE	TEST KITS	KIT CONTROL	Operator
	2°-30° C (36°-86° F) ROOM (Storage) (Min/Max)	2-8°C (36°-46° F) REFRIGERATOR (Min/Max)	
1.	/	/	
2.	/	/	
3.	/	/	
4.	/	/	
5.	/	/	
6.	/	/	
7.	/	/	
8.	/	/	
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**Please use a new sheet each month.**

**Please record the minimum → maximum temperatures recorded each day**

SECTION 2.7.5



Robert Wood Johnson  
Medical School

**Determine & Uni-Gold  
TEMPERATURE LOG**

New Jersey Rapid HIV Testing Support Program

Location

Somerset, NJ 08873

Fax: 732 235-9012

Room Thermometer Expiration: \_\_\_\_\_

SITE NAME:

SITE:#

MONTH/YEAR:

Refrigerator Thermometer Expiration: \_\_\_\_\_

DATE	TEST KITS		KIT CONTROLS		Operator				
	Determine	Unigold	Determine	Unigold					
	2°-30° C (36°-86° F) TEST KITS (Min/Max)	2°-27° C (36°-81° F) TEST KITS (Min/Max)	2°-8° C (36°-46° F) CONTROLS (Min/Max)	2°-8° C (36°-46° F) CONTROLS (Min/Max)					
	Min	Max	Min	Max	Min	Max	Min	Max	
1.	/	/	/	/	/	/			
2.	/	/	/	/	/	/			
3.	/	/	/	/	/	/			
4.	/	/	/	/	/	/			
5.	/	/	/	/	/	/			
6.	/	/	/	/	/	/			
7.	/	/	/	/	/	/			
8.	/	/	/	/	/	/			
9.	/	/	/	/	/	/			
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26.	/	/	/	/	/	/			
27.	/	/	/	/	/	/			
28.	/	/	/	/	/	/			
29.	/	/	/	/	/	/			
30.	/	/	/	/	/	/			
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Please use a new sheet each month.  
Please record the minimum → maximum temperatures recorded each day  
SECTION 2.7.6



# RAPID HIV TEST LOG

v 7/25/2012

## TESTING TYPE CODES

{DMHAS: OUT-outpatient,INT-intensive outpatient, PC-partial care,HH-halfway house, LTR-long term residential, STR- short term residential, MMID-medically monitored inpatient detox}

Facility Name: \_\_\_\_\_ BOX LOT #: \_\_\_\_\_ EXPIRATION DATE: \_\_\_\_\_  
 Shipment NUMBER: \_\_\_\_\_ Kits # \_\_\_\_\_ REAGENT LOT #: \_\_\_\_\_

Site ID (PEMS or EvalWeb) # : \_\_\_\_\_  
 Contact Name: \_\_\_\_\_  
 Phone#: \_\_\_\_\_

#	Testing type:	DATE: MM/DD/YY	ID NUMBER	ROOM TEMP	Oral/Blood Control Proficiency	CONTROL PRESENT?	CONTROL CODES	RESULTS: POS NEG INV	START/ END TIMES:	OPERATOR
---	---------------	----------------	-----------	-----------	--------------------------------	------------------	---------------	----------------------	-------------------	----------

1										
2										
3										
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11										
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16										
17										
18										
19										
20										

Clients positive:	Total Proficiency:		Supervisor review	NJHIV MT review	
Clients negatives:	Total Controls:	Total Invalids:			



# RAPID HIV TEST LOG

v 7/25/2012

**TESTING TYPE CODES DHSTS:**

**STD- STD Services, FQHC- Federally Qualified Health Centers, TB- TB Services, PP/FP- Planned Parenthood/ Family Planning, OTE- One Time Event**

Facility Name: \_\_\_\_\_ BOX LOT #: \_\_\_\_\_ EXPIRATION DATE: \_\_\_\_\_

Shipment NUMBER: \_\_\_\_\_ Kits # \_\_\_\_\_ REAGENT LOT #: \_\_\_\_\_

Site ID (PEMS or EvalWeb) #:				ROOM TEMP	Oral/Blood Control Proficiency	CONTROL PRESENT?	CONTROL CODES	RESULTS: POS NEG INV	START/ END TIMES:	OPERATOR
Contact Name:										
Phone#:										
#	Testing type:	DATE: MM/DD/YY	ID NUMBER							

1										
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Clients positive:	Total Proficiency:		Supervisor review	NJHIV MT review	
Clients negatives:	Total Controls:	Total Invalids:			

# RAPID HIV TEST LOG

VAD March2014

**Facility Name:**

**Box Lot #:**

**Expiration Date:**

**Shipment #:**

**Reagent Lot #:**

Testing Type Codes DHSTS: STD-STD Svcs.,  
 FQHC-Federally Qualified Health Center, TB-TB  
 Svcs.,PP/FP-Planned Parenthood/FamilyPlanning  
 OTE- One Time Event

**# Tests:**

**Site ID (PEMS or Eval Web#):**

**Phone #:**

**Contact Name:**

#	Testing Type	DATE	ID NUMBER	ROOM TEMP	ORAL/BLOOD CONTROL PROFICIENCY	CONTROL PRESENT	CONTROL CODES	P24 Ag Pos or Neg	HIV Ab Pos or Neg	Interp: Pos/Neg/Inv	START END TIMES	OPERATOR
1												
2												
3												
4												
5												
6												
7												
8												
9												
10												
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22												
23												
24												
25												

**Clients Positive:**

**Total Proficiency:**

**Supervisor Review**

**NJHIVMT Review:**

**Clients Negatives:**

**Total Controls:**

**Total Invalids:**



Robert Wood Johnson  
Medical School

## OraQuick TRAVEL TEMPERATURE LOG

SITE NAME:

New Jersey Rapid HIV Testing Support Program  
Location

SITE:#

Somerset, NJ 08873

MONTH/YEAR:

Fax: (732) 235-9012

DATE	ARRIVAL AT SATELLITE		ARRIVAL BACK TO PRIMARY		Operator
	MAIN 2°-27° C (35°-80° F) TEST KITS (Min/Max)	BACKUP 2°-27° C (35°-80° F) TEST KITS (Min/Max)	MAIN 2°-27° C (35°-80° F) TEST KITS (Min/Max)	BACKUP 2°-27° C (35°-80° F) TEST KITS (Min/Max)	
1.	/	/	/	/	
2.	/	/	/	/	
3.	/	/	/	/	
4.	/	/	/	/	
5.	/	/	/	/	
6.	/	/	/	/	
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22.	/	/	/	/	
23.	/	/	/	/	
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25.	/	/	/	/	
26.	/	/	/	/	
27.	/	/	/	/	
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Please use a new sheet each month.

Please record the minimum → maximum temperatures recorded each day

**SECTION 2.9.1**



Robert Wood Johnson  
Medical School

## StatPak TRAVEL TEMPERATURE LOG

SITE NAME:

New Jersey Rapid HIV Testing Support Program

Location

Somerset, NJ 08873

Fax: (732) 235-9012

SITE:#

MONTH/YEAR:

DATE	ARRIVAL AT SATELLITE		ARRIVAL BACK TO PRIMARY		Operator
	MAIN 8°-30° C (46°-86° F) TEST KITS (Min/Max)	BACKUP 8°-30° C (46°-86° F) TEST KITS (Min/Max)	MAIN 8°-30° C (46°-86° F) TEST KITS (Min/Max)	BACKUP 8°-30° C (46°-86° F) TEST KITS (Min/Max)	
1.	/	/	/	/	
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Please use a new sheet each month.

Please record the minimum → maximum temperatures recorded each day

### SECTION 2.9.2



Robert Wood Johnson  
Medical School

## UniGold TRAVEL TEMPERATURE LOG

SITE NAME:

New Jersey Rapid HIV Testing Support Program

SITE:#

Location

Somerset, NJ 08873

MONTH/YEAR:

Fax: (732) 235-9012

DATE	ARRIVAL AT SATELLITE		ARRIVAL BACK TO PRIMARY		Operator
	MAIN 2°-27° C (36°-81° F) TEST KITS (Min/Max)	BACKUP 2°-27° C (36°-81° F) TEST KITS (Min/Max)	MAIN 2°-27° C (36°-81° F) TEST KITS (Min/Max)	BACKUP 2°-27° C (36°-81° F) TEST KITS (Min/Max)	
1.	/	/	/	/	
2.	/	/	/	/	
3.	/	/	/	/	
4.	/	/	/	/	
5.	/	/	/	/	
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Please use a new sheet each month.

Please record the minimum → maximum temperatures recorded each day

SECTION 2.9.3



Robert Wood Johnson  
Medical School

**StatPak & Unigold  
TRAVEL TEMPERATURE LOG**

New Jersey Rapid HIV Testing Support Program

FACILITY:

Location

SITE:#

Somerset,, NJ 08873

Fax: 732 235-9012

MONTH/YEAR:

DATE	ARRIVAL AT SATELLITE		ARRIVAL BACK TO PRIMARY		Operator				
	StatPak	Unigold	StatPak	Unigold					
	8°-30° C (46°-86° F) TEST KITS (Min/Max)	2°-27° C (36°-81° F) TEST KITS (Min/Max)	8°-30° C (46°-86° F) TEST KITS (Min/Max)	2°-27° C (36°-81° F) TEST KITS (Min/Max)					
	Min	Max	Min	Max	Min	Max	Min	Max	
1.	/		/		/		/		
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3.	/		/		/		/		
4.	/		/		/		/		
5.	/		/		/		/		
6.	/		/		/		/		
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26.	/		/		/		/		
27.	/		/		/		/		
28.	/		/		/		/		
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Please use a new sheet each month.

Please record the minimum → maximum temperatures recorded each day

**SECTION 2.9.4**



Robert Wood Johnson  
Medical School

# Determine TRAVEL TEMPERATURE LOG

FACILITY:

New Jersey Rapid HIV Testing Support Program  
Location  
Somerset, NJ 08873

SITE:#

MONTH/YEAR:

DATE	ARRIVAL AT SATELLITE		ARRIVAL BACK TO PRIMARY		Operator
	MAIN 2°-30° C (35°-86° F) TEST KITS (Min/Max)	BACKUP 2°-30° C (35°-86° F) TEST KITS (Min/Max)	MAIN 2°-30° C (35°-86° F) TEST KITS (Min/Max)	BACKUP 2°-30° C (35°-86° F) TEST KITS (Min/Max)	
1.	/	/	/	/	
2.	/	/	/	/	
3.	/	/	/	/	
4.	/	/	/	/	
5.	/	/	/	/	
6.	/	/	/	/	
7.	/	/	/	/	
8.	/	/	/	/	
9.	/	/	/	/	
10.	/	/	/	/	
11.	/	/	/	/	
12.	/	/	/	/	
13.	/	/	/	/	
14.	/	/	/	/	
15.	/	/	/	/	
16.	/	/	/	/	
17.	/	/	/	/	
18.	/	/	/	/	
19.	/	/	/	/	
20.	/	/	/	/	
21.	/	/	/	/	
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25.	/	/	/	/	
26.	/	/	/	/	
27.	/	/	/	/	
28.	/	/	/	/	
29.	/	/	/	/	
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31.	/	/	/	/	

Please use a new sheet each month.  
Please record the minimum → maximum temperatures recorded each day  
SECTION 2.9.5

New Jersey Rapid HIV Testing Support Program

Location

Somerset, NJ 08873

Fax: 732 235-9012

Room Thermometer Expiration: \_\_\_\_\_

Refrigerator Thermometer Expiration: \_\_\_\_\_

FACILITY:

SITE:#

MONTH/YEAR:

DATE	ARRIVAL AT SATELLITE		ARRIVAL BACK TO PRIMARY		Operator				
	Determine	Unigold	Determine	Unigold					
	2°-30° C (36°-86° F) TEST KITS (Min/Max)	2°-27° C (36°-81° F) TEST KITS (Min/Max)	2°-30° C (36°-86° F) TEST KITS (Min/Max)	2°-27° C (36°-81° F) TEST KITS (Min/Max)					
	Min	Max	Min	Max	Min	Max	Min	Max	
1.	/		/		/		/		
2.	/		/		/		/		
3.	/		/		/		/		
4.	/		/		/		/		
5.	/		/		/		/		
6.	/		/		/		/		
7.	/		/		/		/		
8.	/		/		/		/		
9.	/		/		/		/		
10.	/		/		/		/		
11.	/		/		/		/		
12.	/		/		/		/		
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28.	/		/		/		/		
29.	/		/		/		/		
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Please use a new sheet each month.

Please record the minimum → maximum temperatures recorded each day

SECTION 2.9.6

## SECTION 3 – HCV SITE POLICIES And FORMS

As of January 2105 Section Three policies are only funded and authorized for the five ARCH Nurse sites listed below:

Camden AHEC, Camden, NJ  
Hyacinth Foundation, Jersey City, NJ  
NJCRI, Newark, NJ  
Oasis Drop In Center, Atlantic City, NJ  
Well of Hope, Paterson, NJ

*ANTI-HCV SCREENING by ORAQUICK® HCV RAPID ANTIBODY TEST*

No special patient preparation is needed. However, all test subjects should have received the "Subject Information" pamphlet prior to specimen collection.

**All new operators MUST be able to correctly interpret the OraQuick® HCV Visual Reference Panel before use.**

Fingerstick/venipuncture blood samples should be collected using antiseptic technique. The sample must be collected immediately with the collection loop provided in the test kit, and must be tested immediately.

This test is to not be performed for those under 15 years of age or for pregnant women.

The test devices are **stable** until the expiration date on the box and pouch. They must be stored at a temperature between 2°-30°C; (36°-86°F). If refrigerated, the pouch **must** be brought to room temperature before opening as the temperature range for testing is 15°-37° C; (59°-99° F).

**QUALITY CONTROL:**

EXTERNAL QUALITY CONTROL:

ORAQUICK® HCV RAPID ANTIBODY CONTROL TEST KIT  
CONTAINS:

- HCV Positive Control, 1 vial (purple cap, 0.2 mL)
- HIV Negative Control, 1 vial (white cap, 0.2 mL)

ORAQUICK® HCV VISUAL REFERENCE PANEL  
CONTAINS:

- HCV Limit of Detection (1 Device)
- HCV Low Reactive (1 Device)
- HCV Non-Reactive (1 Device)

The controls are photo chemically inactivated human, plasma-based reagents. The positive controls contain antibodies that will show REACTIVE results and the Negative Control will show a Non-Reactive result when run with the OraQuick® ADVANCE Rapid HIV-1/2 Antibody Test. The controls are liquid, ready to use and require no reconstitution or dilution. Both controls contain .2 mL of photo chemically inactivated human plasma which is either positive or negative for antibodies HCV diluted by a defibrinated pool of normal human plasma.

The controls must be stored at 2° - 8°C; (35°-46° F) and are stable until the expiration date stated on the box label. **HOWEVER, ONCE OPENED THE CONTROLS EXPIRE IN 8 WEEKS.** The date received, date opened and the expiration date must be clearly marked on the box containing the controls or on the individual vials. **When to perform quality control?**

1. **Whenever a new shipment of reagents is put into use**, a set of controls shall be run on the first new box used from that shipment. Validation of each reagent lot will be performed prior to release through the RWJMS Rapid Testing Support Program. For this reason, **each lot does not need to be re-validated on receipt at the testing site—just each shipment.**
2. At the beginning of **each week**, one set of controls must be run, to make sure that the reagents have not deteriorated in storage.
3. **Whenever there has been a change is the test environment** including such items as:
  - The temperature in the test storage area falling outside of (2°– 30° C; 36°-86° F)
  - The temperature of the testing area falls outside of 15°-37° C (59°-99°F)
4. **Each new operator prior to performing tests of patient specimens.**

**Reminder: If refrigerator storage temperature is out of range (2-8° C; 35° - 46° F), record the temperature and note any corrective action taken. This temperature problem may mean that the control solutions may give**

*wrong results in the future. You need to know this in case you have a problem in the future, but a problem with refrigerator temperature does not mean that you need to run controls.*

### How to Perform Quality Control?

1. Check the expiration date of the external control solutions. Once opened, a control solution expires in 8 weeks not 2 months (You must count 8 weeks). **DO NOT USE EXPIRED CONTROL SOLUTIONS.**
2. If you open new controls, write the new expiration date on either the box or the vials.
3. Label the test vial and test device to indicate which control is being run on each device.
4. Insert the round end of an unused Specimen Collection Loop into the vial of the control reagent. Visually inspect the loop to make sure that it is completely filled with the control reagent. Use separate unused Specimen Collections Loops for each control reagent. NOTE: The Kit Control reagents are clear to straw-colored. Do not use if the reagent appears visually cloudy or discolored.
5. Immediately immerse the control-reagent-filled Specimen Collection Loop in the developer solution inside the Developer Solution Vial. Use the Specimen Collection Loop to stir the specimen in the developer solution. Remove the Specimen Collection Loop from the Developer Solution Vial and discard in a biohazardous waste container.
6. Reseal the Kit Control Reagent vials and store them in their original container at (2°-8° C or 35°-46° F).
7. Remove the Test Device from the Divided Pouch without touching the flat pad. Insert the Test Device, flat pad first, into the Developer solution Vial containing the specimen. **Be sure that the result window faces forward and the flat pad touches the bottom of the Developer Solution Vial.**
8. Leave the Test Device in the Developer solution and start a timer and record the start time. Do not remove the Test Device from the vial until you have read the results. Read the results after 20 minutes but not more than 40 minutes in a fully lighted area. Read the results as described in the Interpretation of "Test Results" section below.

Dispose of the used Developer Solution Vial and the Test Device in a biohazard waste. If controls do not give their expected results, (Reactive for the Purple cap, Non- Reactive for the White cap), the test is invalid and you cannot do client testing. You must first figure out what went wrong. Check all temperature logs for out of range temperatures and the repeat the controls. If you do not get the expected results, discard the controls and if available, open a new box of controls. If you still do not get expected results discontinue testing inform the HIV support team. You can not test any patients until the controls perform correctly.

### INTERNAL QUALITY CONTROL

In addition, the OraQuick® HCV Rapid Antibody test has a built in quality control feature that demonstrates assay validity. A reddish-purple line develops next to the letter "C" on the test device indicating that a specimen was added and the fluid moved through the test device. If the "C" line does not develop, the test result is invalid and cannot be interpreted. If a red background color appears and interferes with the ability to read the test, the result is invalid. Before looking at the Test line "T" check for the reddish-purple line next to the "C". The Control line appears on all valid tests whether nonreactive or reactive.

The procedure for interpreting the internal quality control is included in the Interpretation of Test Results section below.

### TEST PROCEDURE:

1. Check to see whether client testing can be done by first following the Quality Control checklist.
2. Check room temperature and record it on the test log. DO NOT continue if the temperature is outside the following range (15° -37° C) (59° – 99° F).
3. Make sure you are wearing disposable gloves.
4. Open both portions of the test pouch. Make sure that an absorbent packet was packed with the test device. If not, discard the device and open a new pouch.
5. **Label both the Developer Solution Vial and the Test Device with the client's ID.** Be careful not to block or cover the two holes on the back of the test device.
6. Carefully remove the cap from the vial and place the vial in the stand gently, without splashing the solution out of the vial.
7. Continue using the following Fingerstick procedure.

#### A. Using Fingerstick

- I. Clean the finger of the person being testing with an antiseptic wipe, and allow area to dry.

- II. Using a sterile lancet, puncture the skin off the center of the finger pad.
  - III. Hold the finger downward. Apply gentle pressure beside the point of the puncture. Avoid "squeezing" or "milking" the finger to obtain blood.
  - IV. Wipe away the first drop of blood with a sterile gauze pad. Allow a new drop to form.
  - V. Take a clean, unused Specimen Collection Loop, and fill the loop completely with blood.
  - VI. Immediately insert the blood-filled end of the loop into the solution in the vial and stir the blood sample into the solution (preferably in a back and forth motion).
  - VII. Make sure that the solution appears pink. If blood did not fully fill the loop, or if the solution is not pink, discard the test materials and start again with a new pouch, new lancet, and fresh fingerstick.
8. Insert the flat pad of the test device (labeled with the client's ID) into the developer solution. Make sure that the pad touches the bottom of the vial and that you can see the result window.
  9. Start timing the test. Record the start time on the test log sheet.
  10. Read the results after at least 20 minutes, but not more than 40 minutes have passed. Record the read time on the test log. If the test is not read within 40 minutes, discard the test materials and start again. The test is invalid.

### TEST INTERPRETATION:

Reactive	A <b>complete reddish-purple</b> line in the zone next to the letter "T" (test) and a <b>complete reddish-purple</b> line next to the letter "C" (control) in the result window.
<i>Negative</i>	<b>No reddish-purple line</b> next to the letter "T", and a <b>complete reddish-purple</b> control line next to the letter "C" (control) in the result window.
<i>No Result(Invalid)</i>	If either: <b>No reddish-purple line</b> appears next to the letter "C" (control), or a partial line next to the letters 'T' or "C", or a <b>reddish background</b> makes it impossible to see a line in the "T" zone, the subject must be re-tested using a new test device. The reddish-purple result lines must appear inside the "C" or "T" triangle areas. <b>IF THE LINES ARE NOT INSIDE THE TRIANGLES AREA, THE TEST IS INVALID, AND THE SUBJECT MUST BE RE-TESTED USING A NEW TEST DEVICE.</b>

**IF YOU WERE UNABLE TO GET A VALID RESULT AFTER TWO ATTEMPTS, RUN BOTH POSITIVE AND NEGATIVE CONTROLS, AND CALL THE NJ RAPID HIV TESTING SUPPORT OFFICE (732) 743-3624 FOR ASSISTANCE.**

### 11. Record test results:

- Record results on the testing log and report the result to the counselor for recording in the counseling records.
- Control and patient results should be recorded on the same log. Enter the control lot number in the Patient/Control ID column.
- Each site is responsible for maintaining inventory of the test kits. Every test kit is accounted for and recorded on the test log. Do not throw out expired test kits. They should be returned to RWJMS and noted on log with reason code 7. There is a reference sheet listing the reasons for non-patient test kit use with accompanying codes which should be noted on the test logs when a specific situation arises.
- Completed log pages (or copies of them) must be returned to the POCT office, and must be kept for at least two years. If there is a problem with the test materials or methods, we need to track back and see which test subjects were tested when, and with which lot of reagents.

### Expected Values:

**Non-Reactive:** This means that the HCV antibodies were not detected in the specimen. The patient is presumed to not be infected with HCV.

**Reactive:** This means that HCV antibodies have been detected in the specimen. A patient is presumed to be infected with HCV and additional HCV RNA testing will need to be completed during clinical follow-up. NJ HIV provides HCV screening ONLY. In the case that screening indicates HCV exposure, additional HCV RNA testing will need to be conducted, using an FDA-approved Nucleic Acid Testing Assay. This assay will detect HCV RNA in serum or plasma from the at risk patient. Positive results from both rapid HCV antibody and HCV RNA testing

are indicative of acute, past or present HCV infection. Persons who screen anti-HCV positive but have an HCV RNA-negative test result will be informed by their physician that they DO NOT have HCV infection and do not need follow-up testing. Persons who test positive for both HCV antibody and HCV RNA will be informed that they have HCV infection and will need further medical evaluation for liver disease, ongoing medical monitoring, and possible treatment.

**Procedural Notes:**

- Reading the result earlier than 20 minutes or later than 40 minutes may yield erroneous results. If the result is not read within 40 minutes, the test is invalid and must be repeated.
- For reactive results, the intensity of the line does not necessarily correlate with the amount of antibody in the specimen, or with the stage of disease.

**Limitations of the Procedure:**

A negative (non-reactive) result does not exclude the possibility of exposure to, or infection with, HCV. It can take several months for antibodies to appear after exposure to the HIV virus. **No test is 100% accurate:**

- Use of other specimens besides finger stick or whole blood venipuncture could yield inaccurate results. This includes specimens collected using a tube containing anticoagulants other than EDTA, lithium heparin, sodium heparin, or sodium citrate.
- This test is not approved for use in persons less than 15 years of age. It cannot be used to test pediatrics or pregnant women.
- A non-reactive result does not ban the hazard of exposure to HCV or infection with HCV. An antibody reaction to recent exposure may take several months to reach detectable limits.

**References:**

1. Product Insert, *OraQuick HCV Rapid Antibody Test*, OraSure Technologies, Kit Controls, 06/12.
2. Product Insert, *OraQuick HCV Rapid Antibody Test*, OraSure Technologies, revised 06/12.
3. Product Insert, *Oraquick HCV Rapid Antibody Test*, OraSure Technologies, Visual Reference Panel revised 06/12.
4. Testing for HCV Infection: An Update of Guidance for Clinicians and Laboratorians. (2013, May 10). Retrieved December 19, 2014.

Written by:	Date:
Approved by:	Date:
Revised by	Date:
Reviewed by: Joanne Corbo MBA, MT (ASCP)	Date:
Approved by:	Date:



Robert Wood Johnson  
Medical School

### OraQuick Temperature Log

New Jersey Rapid HCV Testing Support Program

Location

Somerset, NJ 08873

Fax: 732-235-9012

Room Thermometer Expiration: \_\_\_\_\_

SITE NAME:

SITE:#

MONTH/YEAR:

DIVISION:

Refrigerator Thermometer Expiration: \_\_\_\_\_

DATE	TEST KITS	KIT CONTROL	Operator
	2°-27° C (35°-80° F) ROOM (Storage) (Min/Max)	2-8°C (35°-46° F) REFRIGERATOR (Min/Max)	
1.	/	/	
2.	/	/	
3.	/	/	
4.	/	/	
5.	/	/	
6.	/	/	
7.	/	/	
8.	/	/	
9.	/	/	
10.	/	/	
11.	/	/	
12.	/	/	
13.	/	/	
14.	/	/	
15.	/	/	
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25.	/	/	
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30.	/	/	
31.	/	/	

Please use a new sheet each month.

Please record the minimum → maximum temperatures recorded each day

SECTION 3.2

PERFORM QC AT A MINIMUM - EVERY MONDAY, WHENEVER NEW SHIPMENTS ARRIVE, OR NEW TESTING PERSONNEL.  
CHECK QC ROTATION TO INSURE THAT ALL PARTICIPATE!!  
OraQuick HVC testing MUST be performed between 15-37 °C (59-99°F)

FACILITY NAME:  
SHIPMENT #:

BOX LOT #:  
REAGENT LOT #:

EXPIRATION DATE:

SITE ID (PEMS or EvalWeb) #:

Contact Name:

Phone#:

	DATE	IDENTIFICATION	ROOM TEMP	ORAL / BLOOD / CONTROL	CONTROL LINE?	REASON FOR CONTROL	TEST RESULT:	START - END TIME	OPERATOR
1				-					
2				-					
3									
4									
5									
6									
7									
8									
9									
10									
11									
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25									

# NJ HCV Positive Tracking Form

## Rapid HCV Screening Test Result

Client ID # \_\_\_\_\_

Date: \_\_\_\_\_

Test Site ID Number: \_\_\_\_\_

Site Counselor Name: \_\_\_\_\_

Test Site Name: \_\_\_\_\_

Site Counselor Number: \_\_\_\_\_

**Test Result:** OraQuick Rapid HCV

Result: Reactive \_\_\_\_ Non-Reactive \_\_\_\_

Specimen: Fingertick ■

Test Kit Lot Number: \_\_\_\_\_

**This form should accompany the patient to the site where follow-up testing will occur. The form must be returned to the initial test site to capture final results and any referral for additional care.**

## Client Referral

Date client referred to Primary Care Physician and Confirmatory Testing: \_\_\_\_\_

Date of Appointment: \_\_\_\_\_ with \_\_\_\_\_

Appointment: Kept: Yes \_\_\_\_ No \_\_\_\_ If No - Why not? \_\_\_\_\_

Date client referred to Infectious Disease Specialist (treatment): \_\_\_\_\_

Date of Appointment: \_\_\_\_\_ with \_\_\_\_\_

Appointment Kept: Yes \_\_\_\_ No \_\_\_\_ If No- Why not? \_\_\_\_\_

If no referral was made, is the client a current drug user? Yes \_\_\_\_ No \_\_\_\_

Did the client receive a drug treatment referral? Yes \_\_\_\_ No \_\_\_\_

Patient Referred By: \_\_\_\_\_

*Fax to (732) 235-9012*

**when Appointment information has been made**

## Follow Up Testing Results

NOT PERFORMED: Client refused Additional Testing

*Fax to (732) 235-9012*

**If client refuses additional testing**

**Repeat HCV EIA Test: :**

Result: Positive  Negative  Not Performed

**HCV RNA Test :**

Result: Positive  Negative  Not Performed

*Fax to (732) 235-9012*

**When Follow-up Testing is completed**

**Notes:**

## Section 3.4

# RAPID HCV TEST REPORT

**CONFIDENTIAL**

<b>Last Name</b>	<b>First Name</b>	<b>MI</b>	<b>CTS or SAP # (or unique ID code)</b>
<b>Date of Birth:</b>			

## 1<sup>st</sup> RAPID TEST OraQuick

<b>Result:</b> <input type="radio"/> <b>NON REACTIVE</b> <input type="radio"/> <b>REACTIVE</b>	<b>Reference Range:</b> <b>NON REACTIVE</b>	<b>Test Date:</b> <b>Test Site:</b>  <b>Laboratory Director:</b> <b>Site telephone#:</b>
--	--	--

**Rapid HCV testing considerations:**

Non-Reactive: This means that the HCV antibodies were not detected in the specimen. The patient is presumed to not be infected with HCV.

Reactive: This means that HCV antibodies have been detected in the specimen. A patient is presumed to be infected with HCV and additional HCV RNA testing will need to be completed during clinical follow-up. This report provides only HCV screening results. In the case that screening indicates HCV exposure, additional HCV RNA testing will need to be conducted, using an FDA-approved Nucleic Acid Testing Assay. This assay will detect HCV RNA in serum or plasma from the at risk patient. Positive results from both rapid HCV antibody and HCV RNA testing are indicative of acute, past or present HCV infection. Persons who screen anti-HCV positive but have an HCV RNA-negative test result will be informed by their physician that they DO NOT have HCV infection and do not need follow-up testing. Persons who test positive for both HCV antibody and HCV RNA will be informed that they have HCV infection and will need further medical evaluation for liver disease, ongoing medical monitoring, and possible treatment.

<b>A Medical Records Release Form was signed.</b>	<b>Date:</b>
<b>Signature of Patient</b>	

This form goes to the ordering physician with a copy kept in the patient chart. The rapid tests used have been evaluated and approved for use by the FDA. The rapid test(s) have been interpreted by a trained operator, competent in the performance of these tests and reflect the HCV status of the patient identified above at the time of the testing. A copy of the form can be released to referral/treatment centers, provided the results of the rapid tests were used for referral AND the patient signed the medical records release, above.



Robert Wood Johnson  
Medical School

NJ Rapid HIV Testing Support Program  
Phone: (732) 743-3624 Fax: (732) 235- 9012

### Rapid HCV Supply Order

Monthly Order \_\_\_\_\_ Special Request \_\_\_\_\_

DATE REQUESTED \_\_\_\_\_ DATE FILLED: \_\_\_\_\_

FACILITY/SITE NAME: \_\_\_\_\_

LOCATION: \_\_\_\_\_

PHONE/Contact: \_\_\_\_\_

DEPARTMENT/DIVISION (circle) **DHAS** or **DAS** REQUESTOR: \_\_\_\_\_

ITEM	REQUESTED	QUANTITY ON HAND	SUPPLIED
<b>HCV POCT Tests &amp; Controls:</b>			
OraQuick HCV Kits ( 25 Tests/kit)			
OraQuick HCV External Controls (pos, & neg)			
OraQuick HCV Visual Reference Panels			
<b>General Supplies Required for Testing:</b>			
Lancets (High) – 150/box			
Lancets (Normal) – 150/box			
Sterile Alcohol Prep Pads – 200/box			
Gauze (2"x2") – 200/pack			
Band-Aids – 100/box			
Bench covers/Chux pads-Each			
Biohazard Containers (Small Tabletop)			
Biohazard Containers (Large Tabletop)			
Gloves (Small) – 100/box			
Gloves (Medium) – 100/box			
Gloves (Large) – 100/box			
Gloves (X-Large) – 100/box			
Lab Coats (Small)			
Lab Coats (Medium)			
Lab Coats (Large)			
Lab Coats (X-Large)			
TEST TUBE – Gold Top Tubes			
TEST TUBE – White Top Tubes			
<b>Special Request:</b>			
TRAVEL – Travel Box			
TRAVEL – Travel Box Refrigerator Packs			
Thermometer (Digital) for Room, Fridge, or Freezer			
Timers			
Laboratory Shields			
Refrigerator			
Waterless Hand Sanitizers- For Mobile Units & One Day Events Only			
Biohazardous Specimen Bags (6"x9)			

Additional Items:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Validation of reagent lots is required by most regulatory agencies. Rutgers, RWJMS performs validation centrally on all new reagents received through the rapid HIV testing program. On occasion, you may notice that some of your reagents are consumed by this process.