

**Protocol for  
Rapid HIV Antibody Testing  
In  
Wisconsin Division of Public Health  
Designated  
CTR and PCRS Programs**

**March 2008**

**Wisconsin AIDS/HIV Program  
Division of Public Health  
Wisconsin Department of Health and Family Services**

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## **Introduction**

All rapid HIV antibody tests are screening tests. A reactive result on a rapid test must be confirmed by a Western blot test. A non-reactive result is interpreted as negative and means that the client is either not infected with HIV or it is too early to find out if infection has occurred. If the client has had a risk exposure within the last three months, the rapid HIV antibody test should be repeated three months after exposure.

The Wisconsin AIDS/HIV Program is currently using two different rapid tests: OraQuick Advance, which is used with either blood or oral specimens; and Clearview Stat-Pak which is used only with blood specimens. The following protocol has sections that address how to use either the OraQuick Advance or Stat-Pak test. Agency staff only need to read the section pertaining to the test that their agency uses.

This protocol has been developed to assure that rapid HIV antibody testing is reliable and that services provided throughout the testing process are of high quality. These protocols are meant to assure quality testing while allowing flexibility for use in a variety of settings. Significant adjustments related to the implementation of these protocols should be discussed with Kathleen Krchnavek, HIV Testing Technology Specialist, at 608-267-3583 or [krchnka@dhfs.state.wi.us](mailto:krchnka@dhfs.state.wi.us).

## Program Requirements

In order to provide rapid HIV testing, sites must meet the following requirements (a listing of core requirements is at the end of this section):

1. ***Compliance with all government and regulatory requirements including the Clinical Amendments Improvement Act of 1988 (CLIA) and Occupational Safety and Health Administration (OSHA) Bloodborne Pathogen Standards.***

The rapid tests used by the Wisconsin AIDS/HIV Program are classified as “waived” by the FDA when used with whole blood or oral fluid specimens. CLIA requires that all sites offering these tests have laboratory certification allowing them to conduct waived testing.

Sites must hold a CLIA Certificate of Waiver or Provider Performed Microscopy Procedure (PPMP) certificate. For more information on CLIA, view [www.cms.gov/clia/](http://www.cms.gov/clia/). For a CLIA application go to [www.cms.gov/forms/](http://www.cms.gov/forms/). Click on CMS 116. Staff in the Clinical Lab Unit of the Wisconsin Bureau of Quality Assurance (see below) are also available to answer questions.

The CLIA application should be mailed to:

Clinical Lab Unit  
Wisconsin Bureau of Quality Assurance  
2917 International Avenue, Suite 300  
Madison, WI 53704  
Ph: 608-243-2023  
E-mail: [abrahsa@dhfs.state.wi.us](mailto:abrahsa@dhfs.state.wi.us)

All sites must also adhere to the Occupational Safety and Health Administration (OSHA) *Occupational Exposure to Bloodborne Pathogen* standard.

(See: [www.osha.gov/SLTC/bloodbornepathogens/index.html](http://www.osha.gov/SLTC/bloodbornepathogens/index.html).) OSHA published this standard in 1991 to prescribe safeguards to protect workers against the health hazards related to bloodborne pathogens. Under the OSHA standard and in order to reduce or eliminate the hazards of occupational exposure, an employer must develop and implement a worksite exposure control plan with details on employee protection measures.

Since the external controls used with rapid tests are derived from plasma, all sites – regardless of whether they solely will be collecting oral specimens - must develop an exposure control plan and implement the bloodborne pathogen controls standard. Oral fluid (i.e. oral mucousal transudate) used with the OraQuick Advance test is not considered a biohazard but the plasma in the external controls is considered biohazardous.

In exposure control plans, employers must describe how they will use a combination of engineering and work practice controls, including but not limited to:

- Ensuring the use of personal protective clothing and equipment.
- Providing training.
- Maintaining medical surveillance.
- Providing hepatitis B vaccinations.
- Utilizing biohazard signs, labels, and waste disposal methods.

Engineering controls are the primary means of eliminating or minimizing employee exposure and include the use of safer medical devices such as needleless devices, shielded needle devices, and plastic capillary tubes. In January 2001, Congress passed the Needlestick Safety and Prevention Act directing OSHA to revise the bloodborne pathogens standard to establish, in greater detail, requirements that employers identify and make use of effective and safer medical devices. The revision to OSHA's bloodborne pathogens standard added new requirements for employers, including additions to the exposure control plan and keeping a sharps injury log.

Exposure control plans are required to cover the following areas:

- Determination of employee exposure.
- Methods of compliance addressing exposure control (including universal precautions, engineering and work practice controls, personal protective equipment, and housekeeping.)
- Vaccination and antibody testing for hepatitis B.
- Post-exposure evaluation and follow-up.
- Communication of hazards to employees.
- Keeping of records.
- Annual training.

Resources for developing and implementing a bloodborne pathogen control plan are available upon request by contacting Kathleen Krchnavek – HIV Testing Technology Specialist – at 608-267-3583 or krchnka@dhsf.state.wi.us. These resources include:

- A model and sample exposure control plan consistent with OSHA Bloodborne Pathogens standard.
- Policies and procedures related to bloodborne pathogen exposure control.
- A sample sharps injury log.

Also available is a copy of a multiple-ply form entitled *Determination of Exposure to Blood/Body Fluids*. As a condition for testing an individual without consent, Wisconsin statute 252.15(2)7ak specifies that a physician must determine and certify in writing that a significant exposure has occurred. For purposes of Worker's Compensation, this certification must be documented on a form developed by the Department of Commerce (DOC) or on one determined by the DOC to be substantially equivalent. (Form WKC-8165 is currently under the purview of the Department of Workforce Development.) Form WKC-8165 is to be completed whenever a person has been significantly exposed to the blood or body fluids of a patient. This form is to be used for Worker's Compensation and is not a record of medical treatment nor is it to be used for billing purposes. Form WKC-8165 is available for purchase from the Bureau of Document

Services at: 608-266-3358 (telephone), [docsales@doa.state.wi.us](mailto:docsales@doa.state.wi.us) (E-mail), <http://www.doa.state.wi.us/dsas/docserv/docsales> (Internet web site).

**2. Establishment of policies and procedures describing all steps in the performance of the test, including description of site flow and activities in the various settings where the test is performed.**

This protocol and accompanying bloodborne pathogen exposure control policies may serve as an agency's basic policies and procedures related to rapid HIV antibody testing. However each agency should have site specific policies and procedures that include a description of how the test is conducted in both clinic and outreach settings where agency staff conduct testing.

The following policies and procedures must be in place:

- Pre-test counseling pertaining to providing information regarding rapid testing to clients
- Use of gloves and other personal protective equipment (optional when testing with OraQuick Advance oral fluid specimens)
- Safe disposal of biohazardous waste (e.g. used lancets, external controls)
- Maintaining sufficient inventory and checking new lots and shipments
- Maintaining and documenting environmental temperature control
- Collecting a specimen
- Performing steps in the test procedure and reading results
- Performing quality control testing and identifying what to do when controls fail
- Participating in external quality assessment (proficiency testing) as required
- Reporting results
- Specimen collection and submission for confirmatory testing
- Documenting client and control test results
- Post-test counseling and provision of referrals
- Record review, storage, and disposal
- Troubleshooting activities – what to do when things go wrong
- Staff training, competency assessment, and documentation of training

**3. Utilization of personnel who are trained and competent in all components of rapid testing. Staff must participate in all training required by the Division of Public Health and have thorough knowledge of the package insert instructions for the rapid test prior to testing.**

Personnel providing rapid testing should possess the following qualities.

- Commitment to following procedures and precision in work habits.
- Literacy – the ability to read instructions and document testing activities, including reading results.
- The ability to resolve problems and discern when further help is needed.
- Organizational skills.

All site staff intending to offer rapid HIV antibody testing must first attend the following foundation courses conducted by the Wisconsin AIDS/HIV Program.

- Foundations for HIV Prevention in Wisconsin
- Basic Counseling Skills for HIV Prevention;
- HIV Counseling, Testing, and Referral Services – New Provider Training

Staff must then attend AIDS/HIV Program rapid testing training specific to either OraQuick Advance or Clearview Stat-Pak.

The only exception to the above requirement is for laboratory staff working in a moderate complexity laboratory. If these staff will not be conducting counseling, they may conduct the test by following the instructions in the package insert and program protocols without attending the foundation courses or rapid testing training. Typically, the HIV Testing Technology Specialist, Kathleen Krchnavek, will meet with the lead staff person in a moderate complexity laboratory to review rapid testing procedures and forms for the program and to assure that the testing process is consistent in all CTR sites.

Prior to testing client specimens all staff must read and understand the test package insert, in addition to this protocol. Also, staff should review the revision date of the package insert included with each test shipment to find out whether the instructions have been updated, and to review them if they have been changed.

**4. *Compliance with all quality assurance (QA) activities detailed in the package insert and additional activities delineated by the Wisconsin AIDS/HIV Program.***

All sites must assure quality testing by:

- 1) Assigning a lead staff person responsible for overseeing rapid testing and all quality assurance (QA) activities on-site.
- 2) Assuring that staff participate in state-sponsored trainings and successfully complete a competency assessment.
- 3) Following all testing requirements detailed in the most current package insert.
- 4) Using external controls as required.
- 5) Documenting testing processes and results.
- 6) Recording the storage temperature of test devices and external controls.
- 7) Participating in a state-sponsored proficiency testing program as outlined in this protocol.
- 8) Communicating testing problems to the on-site lead staff person (#1 above), the Wisconsin State Laboratory of Hygiene, or the Wisconsin AIDS/HIV Program, as appropriate, and taking action to assure that the test is providing valid and reliable results.

Quality assurance requirements are detailed in this protocol under the section “Assuring Quality” on p. 55.

**5. Adherence to all program record-keeping and data collection requirements.**

Agency staff must document all testing processes, including details about client and external control testing, receipt of test devices and controls, and storage temperature of both tests and controls.

Staff members must use the informed consent form that is appropriate for rapid HIV testing and provide results to clients based on the state format. (Samples of these forms are at the back of the OraQuick and Stat-Pak sections of this protocol). The Wisconsin AIDS/HIV Program provides hard-copy or electronic forms for these activities for sites to copy.

Data related to rapid testing must be completed on EvaluationWeb Form B: Testing Information, (see *EvaluationWeb Data Guidelines and Protocol for HIV CTR and PCRS Sites.*). Additional data may be required by the Wisconsin AIDS/HIV Program to assess the impact of rapid testing on clients and programs.

## **Core Requirements for Rapid HIV Antibody Testing**

The requirements for rapid HIV antibody testing described in the previous section (#1-5 under Program Requirements) are listed with more detail below under the following categories.

### Laboratory and Bloodborne Pathogen Requirements

- Valid CLIA certification for conducting waived tests
- Refrigeration to store controls, and provision for monitoring refrigerator temperatures (Per bloodborne pathogen standards – the refrigerator must not store food or beverages)
- Compliance with blood borne pathogen standard requirements listed below:
  - √ Exposure control plan including documentation of review and use by staff of safer devices
  - √ Exposure determination record
  - √ Initial and Annual staff training in standard/universal precautions
  - √ Availability of Hepatitis B vaccine to all employees conducting testing (at no cost to the employee)
  - √ Availability of post-exposure evaluation and follow-up, including prophylaxis (at no cost to the employee)
  - √ Individual employee records documenting training, vaccination, post-exposure evaluation & follow-up (to be kept for duration of employment + 30 years)
  - √ Training records (to be kept for 3 years from the date of training)
  - √ Sharps Injury Log
  - √ Warning labels affixed to all containers containing blood or other infectious materials (including refrigerators) or red containers
  - √ Biohazardous waste containers, gloves, decontamination materials
  - √ Access to hand washing facilities or appropriate antiseptic hand cleanser as indicated
  - √ Arrangements for biohazardous waste disposal

### Administrative Requirements

- Procedures describing activities and flow in various settings where testing is performed
- Supervisor or lead worker assuring that procedures are being followed to ensure high quality testing
- Supervisor or lead worker assuring that bloodborne pathogen control standards are being implemented
- Conventional testing (serum or oral fluid) to confirm reactive rapid tests.
- Participation in the State's Quality Assurance (QA) program and compliance with its QA plan
- Referral systems for reactive rapid results

### Staff Training and Quality Assurance Requirements

- Prior attendance at Wisconsin AIDS/HIV Program core courses, including the HIV Counseling, Testing and Referral training
- Attendance at Wisconsin AIDS/HIV Program training regarding rapid HIV testing and counseling
- Competence in conducting fingerstick blood draws
- Thorough knowledge of and adherence to package insert instructions for the rapid test
- Successful completion of a competency assessment by testing samples and accurately reading the results prior to testing clients
- Successful test administration and interpretation of test results for both positive and negative controls prior to testing clients
- Agency participation in the state proficiency program to assure staff competency in testing.

### Record-Keeping Requirements

- Maintenance of testing logs (per state requirements) for all rapid tests conducted for a minimum of two years
- Maintenance of other logs – such as storage temperature logs – as recommended in the State’s Quality Assurance plan
- Reporting of data on the EvaluationWeb form as directed by the state
- Individual employee records documenting training, vaccination, post-exposure evaluation and follow-up (to be kept for duration of employment, plus 30 years)
- Training records (to be kept for 3 years from the date of training)
- Sharps Injury Log

## Agency Flow of Services

Rapid HIV testing may not feel “rapid” to the client being tested. Since the pre-test counseling, specimen collection, testing, and post-test counseling all occur in one visit, a client can expect to be at an agency at least 30 – 60 minutes before receiving their test result. Some clients may feel this is too long and opt for conventional HIV antibody testing requiring them to return two weeks later for their results. Some agencies may decide to perform a rapid test and arrange for the client to return later in the day or the next day. However, under these circumstances the risk of the client not returning for their test result remains. The Wisconsin AIDS/HIV Program does not encourage adopting this practice, except in special circumstances.

Rapid testing typically requires more personnel for conducting the same quantity of tests since agency staff must now do the testing in addition to the counseling. Agencies should consider how to use their staff most effectively in order to provide efficient client services. Some agencies may use two or three staff to conduct rapid testing services – one or two to provide the counseling and referral and the other to process the test. Other agencies may decide to “overlap” clients: while one client is waiting for their test to develop, the staff person may begin counseling and testing another. Each site will need to review how site flow is established based on their personnel resources and other logistics of their setting. Regardless, agencies must assure that staff members are available to assist and support the client receiving a reactive rapid test. Persons with reactive rapid results may require much more time for post-test counseling and referrals than those with non-reactive (negative) results. This must be considered and expected when determining site flow.

Since staff members are responsible for every aspect of HIV counseling, testing, and referral services, some agencies have indicated that staff members are mentally or emotionally drained after a limited number of tests. Agency administration should assess how staff are managing rapid testing services and provide any additional support they may need. This is important since staff “burn-out” could decrease the quality of testing and counseling services. Rapid testing also may increase the demand for HIV testing services, so it is important that agencies are prepared to manage these site flow issues.

## Rapid Testing in Non-Traditional or Outreach Settings

The Wisconsin AIDS/HIV Program approves of conducting rapid HIV testing in non-traditional or outreach settings as long as specific conditions are met. It is the responsibility of the agency and all testing staff to assure that these conditions are in place prior to testing in these locations:

The following conditions must be present for rapid HIV antibody testing in non-traditional settings:

- Lighting: Sufficient lighting to safely and accurately conduct the test and read the result. If the natural or room lighting is not bright enough to read the result, staff should use a flashlight to illuminate the result window.
- Temperature: The temperature of the testing environment should be within the operating temperature for the test specified in the package insert and this protocol. Staff must use a thermometer in the field to assure that the temperature is within the proper range. The temperature during each test should be documented on the *Testing Site Log* (a sample of this form is at the back of the OraQuick and Stat-Pak sections of this protocol). Test kits should be stored during transport and prior to testing within the storage temperature range listed in the package insert and this protocol.
- Surface area: The test must be performed on a level, clean surface. Consistent with bloodborne pathogen control procedures, no food or drink should be consumed in the area where testing is performed. Staff should set up their workspace as recommended under “Testing Steps” in the OraQuick and Stat-Pak sections of this protocol. Testing staff may wish to use a portable supply box to make it easier to test in outreach settings.

The psychosocial conditions associated with rapid testing in non-traditional settings are as important as the above technical conditions. Agency staff should be certain that the following conditions are present to assure that clients who are being tested are able to receive their result in a confidential and emotionally supportive setting.

- A confidential, private space for testing, counseling, and providing results: Since the test is actually conducted in the outreach setting, staff must be certain that tests develop in a private place where only the testing staff can view results. A confidential space must also be used to provide pre-test, prevention, and post-test counseling to clients. Testing staff must be particularly conscious of the confidentiality issues of clients with a reactive result. For instance, if a client meets with staff for a longer period of time than those clients with a non-reactive result, this may inadvertently break their confidentiality, since others may assume the client had a reactive result. Staff must consider all the ways that confidentiality may be broken and develop strategies to protect the client’s privacy.

- Testing staff prepared to provide a reactive result: For many staff, providing a reactive result may be much more difficult than providing a confirmed HIV positive result. A reactive rapid test result is provided in a short time frame that does not allow staff to prepare for providing this difficult news. A reactive result also is not definitive, limiting the type of referrals the staff person can provide and leaving the client in a state of uncertainty. In outreach, these difficulties are compounded by the inability of staff to access on-site agency resources and support that are usually available in the clinic setting.

For these reasons, staff providing rapid testing in an outreach setting must be adept at interpreting a reactive result, prepared to support a client through the confirmatory process, and ready to respond to a client in crisis. Staff must know what referrals can be immediately accessed for the client and be ready to link the client to these services. If outreach testing is being done late in the evening or on the weekend, staff must have a plan of how to emotionally support clients who receive a reactive result.

- Linkage to referrals available: Although a reactive result is not definitive, clients may need resources to help them understand and cope with the news of possible HIV infection. Staff must have their referral lists available, and immediately link clients to service if possible. If staff are offering rapid testing outside of business hours, they must have a plan of how to refer clients to needed services – including mental health or crisis intervention services – during those hours.
- A supportive setting for clients to respond to their test result: Certain settings may make it harder for a client to emotionally respond and accept their test results. Bars, street fairs, and public sex environments – where the setting is primarily social; alcohol or drug use is typical; and privacy is difficult to maintain – may be settings where rapid testing may be difficult to implement. Testing staff must review the above conditions as well as the social atmosphere to determine whether rapid testing is appropriate in such a venue.

In addition:

- Agency staff should educate personnel at the venue where they will be testing regarding the details of rapid HIV testing, including issues related to bloodborne pathogen control (and how proper procedures will be maintained), as well confidentiality issues and how clients with a reactive test result will be supported.
- Agency staff should determine the number of staff needed to conduct the expected volume of tests in the setting. In high volume settings, several staff may be needed to handle testing demand.

# OraQuick Advance Testing

## Introduction

The OraQuick Advance rapid HIV antibody test can be used with oral or whole blood specimens:

- When used with an oral specimen, the test device (which resembles a paddle) is swabbed against the gums once, and then is placed in a vial that contains a developing solution.
- When used with a whole blood specimen, the test device is placed in a vial that contains both the developing solution and a blood specimen;

The result is read 20-40 minutes after the paddle is placed in the developing solution.

OraQuick Advance<sup>1</sup> is FDA approved to identify HIV-1 and HIV-2 infection. In clinical studies by the manufacturer, OraQuick had a sensitivity of 99.6% and a specificity of 100% when used with whole blood. This means that the test correctly identified 99.6% of people in the trial who were HIV infected and 100% of those who were not infected with HIV-1. When used with oral fluid specimens, the sensitivity of the test is 99.3% and the specificity is 99.8%

Some individuals who are not infected with HIV will have reactive results with OraQuick (false positives). Reactive results should not be considered definitive until confirmatory testing is completed.

Also, a small number of people who are infected with HIV will have a negative test result (false negatives). Individuals with HIV infection who are taking highly active antiretroviral therapy (HAART) may have false negative results with the OraQuick test.

There will be more false positives and false negatives when using OraQuick with oral fluid specimens than with blood specimens.

## Materials Required for Testing

The following materials are provided to the site:

- The OraQuick Advance Rapid HIV-1/2 Antibody Test packaged in a divided pouch that contains the device in one side and the developing solution in the other. Tests are packaged in boxes of 25 or 100.
- Reusable test stands.
- Specimen collection loops.
- Subject information pamphlets.
- Package insert.
- External controls (set of HIV-1 positive, HIV-2 positive and negative).

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<sup>1</sup> For the rest of this document, when the name “OraQuick” is used, it refers to “OraQuick Advance.”

The following materials are not provided to the site but are required for blood or oral testing:

- Latex, vinyl or nitrile disposable gloves (gloves are optional when testing with oral fluid, but must be worn when running external quality controls)
- Timer or watch capable of timing 20-40 minutes
- Clean, disposable, absorbent workspace cover (“chux” pad)
- Trash bags
- Surface disinfectant to clean up accidental spills(EPA-registered, hospital grade, intermediate activity disinfectant such as Dispatch, Virex TB, or Cavicide)
- Alcohol-based waterless hand cleanser
- Laboratory grade thermometers- ideally minimum/maximum thermometers which record the high and low temperature since the last reading - to measure storage temperature of test devices and controls and temperature of testing location.
- Refrigerator dedicated to storage of biohazardous materials
- Required forms (see appendices A-E)

In addition, for blood testing:

- Sterile retractable lancets or phlebotomy supplies and blood tubes. Lancets should have a depth that ranges from 1.8 mm to 2.4 mm. Blood tubes must contain any of the following anticoagulants: EDTA (lavender top), sodium heparin (green top), sodium citrate (light blue top), or ACD Solution A (yellow top).
- Antiseptic wipes
- Sterile gauze pads (2”x2”)
- Small adhesive bandages
- Biohazard sharps container

Also, a flashlight may be helpful to illuminate the result window in case the result is difficult to read.

### **Conditions for Testing**

The following conditions must be present to use OraQuick:

- Sufficient lighting to safely and accurately perform the test and read the result.
- A level, clean surface where testing can be performed.
- Storage temperature of the test kit between 35° and 80° Fahrenheit.
- Operating temperature (temperature during testing) between 59° and 99° Fahrenheit.
- Space that assures confidentiality for both testing and counseling. Ideally the test is set up in an area apart from the client and where no other individuals can read the result.

### **Use of External Quality Controls**

The Wisconsin AIDS/HIV Program supplies each site with external quality controls that verify whether the tests are working properly or staff are properly performing the test. Each set consists of three vials:

- an HIV-1 positive control (black capped vial),
- an HIV-2 positive control (red capped vial)\* and
- a negative control (white capped vial).

The positive controls contain a serum-based solution containing antibodies that will show a reactive result when used with the OraQuick test.

The negative control contains a solution of normal human serum negative for antibodies to HIV-1 and 2 that will create a non-reactive result when tested.

To run controls, run the test using the solution in a control vial rather than a client specimen. If the device does not show the expected result when each control is used, either the test was performed improperly or the device is defective. Staff should thoroughly review all of their testing procedures prior to assuming that the device is defective (See “Troubleshooting” p.58).

**\*Please note:** only the HIV-1 positive control (black capped vial) and the negative control (white capped vial) should be used to run controls. It is not necessary – and the Program does not recommend – using the HIV-2 positive control.

External quality controls should be run under the following conditions:

- When a staff person has been trained to conduct OraQuick testing, prior to testing client specimens.
- When a new box of test kits is opened at the testing site or tests have been shipped from another site.
- If the temperature of the test kit storage area falls outside 35°-80° Fahrenheit.
- If the temperature of the testing area falls outside 59°-99° Fahrenheit.
- Including any of the above reasons, external controls should be conducted at least once every 25 tests or once a month – whichever occurs first.

When controls are run, these tests should be documented on the *OraQuick Testing Log*.

External controls do not need to be run in distinct venues provided the testing conditions outlined above have been met. The external controls must be refrigerated (temperature must be between 35-46° Fahrenheit). Controls do not need to be warmed prior to use.

Although the controls have an expiration date that is one year post-production, once controls are opened they must be used within 8 weeks. **Controls should be dated when they are opened and discarded 8 weeks after this date.** The *OraQuick Testing Log* has a space on top of the page to write the date when the controls should be discarded. Controls must be disposed of in a biohazardous waste container.

If the results of the controls are not as expected, assess all possible reasons for the failure of the controls (see Troubleshooting guidelines on p. 58).

- If you have not determined the reason for the failure, run the controls again using a new box of tests.

- If the controls fail again, open a new set of controls and run them.
- If the controls fail again, discontinue testing and contact Kathleen Krchnavek, HIV Testing Technology Specialist at 608-267-3583 or [krchnka@dhfs.state.wi.us](mailto:krchnka@dhfs.state.wi.us) for further guidance

When controls fail, all results prior to the last control run are suspect.

### **Shelf-Life and Storage of Test and Control Kits**

OraQuick tests expire six months after production. The expiration date is marked with the month and year on both the box and test device. The tests expire on the last day of the identified month.

Tests must be *stored* between 35°-80° Fahrenheit. The tests can only be *run* between 59°-99° Fahrenheit. Therefore, any tests that have been stored in the refrigerator should be warmed to room temperature prior to using.

External quality controls expire one year after production, and must be stored between 35°-46° Fahrenheit. Once controls are opened, they are good for only eight weeks. The date the controls are opened should be written on the box, and controls should be disposed of eight weeks after this date.

To assure that the proper storage temperature is maintained for test and control kits, a thermometer should be placed in the storage areas (e.g. a refrigerator for the controls, a closet for the tests). Agency staff should log test and control storage temperatures each day that testing is performed. The best thermometer to use is one that records the high and low temperature since the last reading, known as a “min/max” thermometer.

If storage temperature falls outside of the listed range for either the tests or controls:

- a set of external controls should be run on the tests in question, or
- the external controls in question should be run on tests that have been kept at the appropriate temperature range.

If the proper result is received, the item in question may be used. However, the agency should report this to Kathleen Krchnavek at 608-267-3583 or [krchnka@dhfs.state.wi.us](mailto:krchnka@dhfs.state.wi.us) to discuss if further assessment should be done.

If the expected results are not obtained the tests or controls in questions should be disposed.

### **Assuring Proper Testing Temperature**

The temperature in the area where the test will be performed must be within the range of 59°-99° Fahrenheit. Staff must use a thermometer to determine whether the temperature is within the specified range. If the temperature is out of this range, staff should not conduct testing.

## **Testing Steps**

The following section summarizes steps required to complete an OraQuick test with a blood or oral specimen. Detailed instructions are described in the OraQuick package insert and in the “*Step-by-Step Instructions for OraQuick Advance Rapid HIV-1/2 Antibody Test*” included with this protocol. Staff must read and understand both of these documents prior to testing clients.

### *Preparation:*

1. Cover the area with a workspace cover and set up the materials you need for blood and/or oral fluid specimen collection.
2. Tests used during *this testing session* should be kept at 59° - 80° Fahrenheit.
3. When a test is performed the room temperature must be between 59° - 99° Fahrenheit
4. Check expiration date of packet. If expired, discard and obtain a new pouch that is not expired.
5. Check to make sure there is an absorbent packet in the paddle side of the pouch. If none is present discard the entire pouch and obtain a new one.
6. Open the two chambers of the divided pouch and label the test device AND the developer solution vial with a Test ID sticker and write the client code or client initials on the sticker. Keep the flat pad of the device inside the package to avoid contamination. **DO NOT COVER THE HOLES ON THE BACK OF THE DEVICE.**
7. Remove the cap from the vial and slide the vial into the stand from the top. Make sure that the vial is pushed all the way to the bottom of the slot in the stand. Place the cap on the workspace cover near the stand.
8. Put on disposable gloves if collecting blood specimens. The use of gloves is optional when using oral fluid specimens.

### ***Whole Blood Specimens – Fingertick or Venipuncture***

#### *Collection:*

##### *Fingertick whole blood specimens:*

1. Clean the patient’s finger with an alcohol wipe and allow it to dry thoroughly.
2. Using a sterile retractable lancet (depth range: 1.8 mm – 2.4 mm), puncture the skin just off the center of the finger pad.
3. Discard lancet in a sharps container.
4. Hold hand palm-side up, but pointing downward toward the floor to facilitate blood flow. Apply gentle pressure beside point of puncture. Avoid squeezing the finger to make it bleed.
5. Wipe away the first drop of blood with a sterile gauze pad. Allow a new drop of blood to form.
6. Place the “rounded” end of the loop on this drop. Make sure the blood completely fills the inside of the loop.

### *Venipuncture whole blood specimens*

1. Using standard phlebotomy procedures, collect a whole blood sample using a tube containing any of the following anticoagulants: EDTA (lavender top), sodium heparin (green top), sodium citrate (light blue top), or ACD Solution A (yellow top). **Other anticoagulants have not been tested and may give an incorrect result.** If the specimens are not tested at the time of collection, the whole blood may be stored at 35 -64° Fahrenheit for up to 30 hours.
2. Prior to testing, mix the blood tube by inversion several times to ensure a homogenous sample.
3. Carefully open the tube of blood. Use personal protective equipment such as a face shield or goggles to protect face from a blood splash.
4. Put the “rounded” end of the loop into the tube of blood. Make sure the blood completely fills the inside of the loop.

### *Mixing:*

1. Insert the loop into the developing solution, being careful not to touch the loop to the sides of the vial.
2. Stir the solution with the loop to properly mix.
3. Discard the loop in a waste container.
4. Make sure the solution appears pink.

### *Testing:*

1. Remove the paddle from the pouch. **DO NOT** touch the pad.
2. Insert the flat pad of the device into the developing solution with the result window facing forward.
3. Write the starting time on the testing log. It also may be helpful to set a timer for 20 minutes.
4. Read the result of the test after 20 minutes but not more than 40 minutes from the time the paddle was placed in the solution.

### ***Oral Fluid Specimens***

#### *Collection:*

1. Client should not eat, drink (even water), smoke, chew gum, or rinse mouth for 5 minutes prior to specimen collection.
2. Demonstrate to the client how the oral specimen should be collected by using a demonstration device, swab, or tongue depressor.
3. Have the client remove the paddle from the pouch
4. Do not allow the client to touch the flat pad of the paddle
5. Direct the client to place the flat pad above the teeth against the outer gum. Instruct the client to gently swab completely around the outer gums, both upper and lower, one time around, using the flat pad. (Note: Both sides of the pad may be used during this procedure.)
6. Do NOT allow the person to swab the roof of the mouth, the inside of the cheek or the tongue.

*Testing:*

1. Instruct the client to insert the flat pad end of the device into the developing solution with the result window facing forward.<sup>2</sup>
2. Write the starting time on the testing log. It also may be helpful to set a timer for 20 minutes.
3. Read the result of the test after 20 minutes but not more than 40 minutes from the time the device was placed in the solution.
4. Write the time you read the result on the testing log.

*Reading the result:*

Results should be read “straight on” without moving or tipping the device.

A valid test result must have a reddish-purple line next to the “C” (Control) triangle. If there is no line present at this area, the test is invalid and no result can be interpreted. In this case, the client must be tested again.

- A line at only the “C” triangle, and not at the “T” (Test) triangle, is interpreted as a non-reactive or negative test result. The client is either not infected with HIV, or it is too soon to tell. If the client has had a risk exposure within the last 3 months, the client should be re-tested 3 months after the exposure.
- Lines at both the “C” and “T” area are interpreted as a reactive test result. A Western blot test must be conducted on a second specimen to determine whether the client is infected with HIV.

To view examples of each of these readings – including invalid tests – look at the last page of the “*Step-by-Step Instructions for OraQuick Rapid HIV-1 Antibody Test.*”

Typically, only one staff person should read the test result. However, in the event that one staff person identifies a reactive test (i.e. sees a line at the T triangle) and another staff person does not see a “T” line and identifies the test as non-reactive – the test should be considered reactive and confirmatory testing should be done.

*Assessing Invalid Results:*

A test is invalid when at 20 minutes:

- The result window has a red background that has not cleared
- There is no reddish purple line next to the “C” triangle
- Any of the lines are not inside the “C” or “T” triangle areas

A test is also considered invalid if it is not read within the 20–40 minute time period.

To assess why a test may be invalid, staff should review their procedures to determine that the test was conducted properly (see “Troubleshooting” p. 58). A second test

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<sup>2</sup>If the device must be transported, the client can place the device into the open foil pouch. The absorbent packet must be first removed, and the client should place the device into the pouch horizontally – paddle first. The staff person may then keep the device horizontal until it is placed in the developing solution. The device must be placed in the vial within 10 minutes of the oral collection.

should be conducted. If this test is also invalid, external quality controls should be run. If the expected results are not obtained, staff should contact Kathleen Krchnavek at 608-267-3583 or the Wisconsin State Laboratory of Hygiene Retrovirus Lab at 608-262-2366. If it appears that devices are defective, the OraSure customer service department should be contacted at 1-800-672-7873.

*Documentation of the Result:*

1. Check the Test ID sticker and client code/initials on the test device and vial. Be certain that both the vial and the device within the vial have the same ID number and client code/initials. If these identifiers are not the same on both components of the test, staff cannot determine which client is associated with the test. Re-tests would need to be done on all clients associated with the identifiers.
2. Complete documentation of the *OraQuick Testing Log* including read time and results.
3. Record the date of the test and the Client Name or anonymous code on the agency "OraQuick Rapid HIV Result" which is printed on the agency letterhead. (Appendix B). This form should also be printed with the name of an agency staff person to contact in case the client has questions regarding their result after leaving the agency.
4. Place a checkmark next to the appropriate paragraph indicating whether the result was non-reactive or reactive.
5. Provide the client with the written result.

*Clean up:*

1. Dispose of sharps (lancets, needles) in a sharps container and all other used test materials (capped vial, paddle, loops, used gauze and gloves, etc.) in a trash bag.
2. Clean any spills with a surface disinfectant (EPA-registered, hospital grade, intermediate activity disinfectant such as Dispatch, Virex TB, or Cavicide).
3. Remove gloves if used, and wash hands after every test is performed. Use new gloves for each client.

**Confirmatory Testing**

All clients receiving a reactive OraQuick result should immediately have a specimen collected for a confirmatory test - the Western blot - to determine whether they have HIV infection. A blood or oral fluid (OraSure) specimen should be obtained from the client and sent to the Wisconsin State Laboratory of Hygiene (WSLH) for Western blot testing. If agency staff have the capacity to do phlebotomy, a blood test is preferable to an oral fluid test for confirmatory testing.

If staff used venipuncture whole blood for OraQuick testing, a new tube of blood must be obtained for confirmatory testing. Staff should not use the same tube of blood that was used for OraQuick testing due to the possibility of specimen contamination.

Specimens should be sent to WSLH with the lab slip - EvaluationWeb Form C. Under "Test Requests" on this form, mark **Confirmation of a rapid test**. Whether the specimen is oral fluid or blood should also be marked under "Specimen Type."

For blood specimens, WSLH will run an initial EIA test on the specimen for quality assurance purposes. This EIA result will not be reported on the WSLH result form. WSLH will run a Western blot regardless of whether the EIA is reactive or non-reactive. For oral fluid specimens, WSLH will conduct standard EIA/Western blot testing. WSLH will run a Western blot regardless of whether the EIA is reactive or non-reactive. Both the EIA and Western blot results will be reported for oral fluid specimens.

### *Discordant Results*

When the Western blot is negative following a reactive rapid test:

- If the initial sample sent to the lab was blood, test the client again with conventional blood testing (EIA/WB) in one month to be certain that the client is not seroconverting. If testing staff are concerned that the client may not return for the follow-up test, this test could be done immediately.
- If the initial sample sent to the lab was oral fluid (OraSure), draw a blood specimen immediately for conventional testing (EIA/WB).

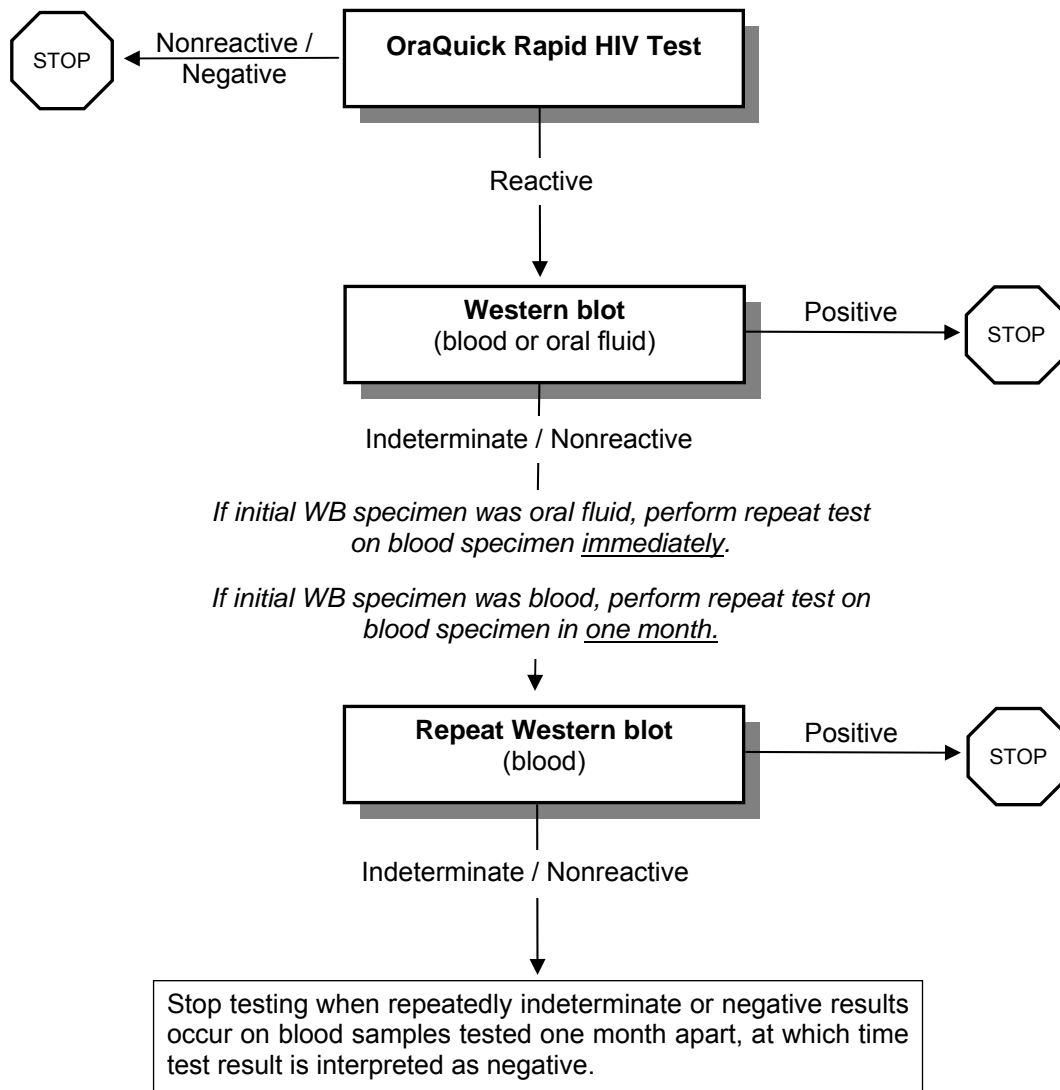
When the Western blot is indeterminate following a reactive rapid test:

- If the initial sample obtained was blood, retest the client with a conventional blood test (EIA/WB) in one month. If the second Western blot is still indeterminate, the client is considered not infected.
- If the initial sample obtained was oral fluid, test the client again using a conventional blood test (EIA/WB) immediately. If this second Western blot is still indeterminate, the client should be retested (EIA/WB) in one month. If this third result is indeterminate, the client is considered not infected.

The above descriptions are illustrated by the algorithm on the next page.

When a rapid test is reactive and the Western blot is negative or indeterminate, the Wisconsin State Laboratory of Hygiene will test the specimen for the presence of HIV-2 with an HIV-2 EIA. Most specimens will be negative on the HIV-2 EIA. However, in the rare occurrence that the HIV-2 EIA is reactive, the specimen will be sent to another laboratory for an HIV-2 Western blot. On average, this occurs at the Wisconsin State Laboratory of Hygiene once or twice a year from all of the specimens they test for HIV.

# OraQuick Rapid HIV Testing Algorithm



## Summary comments on initial and repeat testing

All indeterminate or nonreactive Western blot test results of oral fluid or blood specimens must be followed by EIA/Western blot testing of blood

- Indeterminate or nonreactive Western blot test results of oral fluid must be followed by immediate EIA/Western blot testing of blood
- Indeterminate or nonreactive Western blot test results of blood must be followed by repeat EIA/Western blot test of blood in one month.

Repeatedly indeterminate Western blot test results of blood samples tested one month apart are interpreted as negative.

## CONSENT FOR ANONYMOUS OR CONFIDENTIAL HIV TESTING

Completion of this form is required for testing to take place. ALL information recorded on this form is confidential and not shared without your consent except as provided by law. See Supplemental Information on the reverse side of this form.

I want to be tested for the human immunodeficiency virus (HIV), the virus that can cause AIDS.

I understand:

- The benefits and possible risks of testing.
- Additional counseling and assistance with health care and other services are available if I need them.
- My HIV test results will be kept confidential. If I have a confidential HIV test (with my name listed), I understand that Wisconsin statutes allow my test results to be released only to the persons or under the circumstances listed on the back of this form.

In addition, I understand that if I choose a rapid HIV test,:

- If the test result is non-reactive, the result is interpreted as negative and is available today.
- **If the test result is reactive, I am agreeing to a second (confirmatory) test that will be performed to determine whether I have HIV infection. This second test requires that a blood or oral sample be collected today to be sent to an off-site laboratory. Results will be available 1-2 weeks from today.**
- Only a positive result from the confirmatory test would indicate that I have HIV infection.

I have read the above information. It has been explained to me. My questions have been answered. I agree to be tested for HIV. I have indicated below the type of test to which I am agreeing.

I want my test to be anonymous (without my name being listed).

\_\_\_\_\_  
**CODE** - Test Subject

\_\_\_\_\_  
Date Signed

\_\_\_\_\_  
**SIGNATURE** – Witness

\_\_\_\_\_  
Date Signed

I want my test to be confidential (with my name listed).

Test Subject \_\_\_\_\_

Telephone Number \_\_\_\_\_

Address \_\_\_\_\_

Date of Birth \_\_\_\_\_

\_\_\_\_\_  
**SIGNATURE** - Test Subject

\_\_\_\_\_  
Date Signed

\_\_\_\_\_  
**SIGNATURE** –Person Legally Authorized to Consent on Behalf of Test Subject

\_\_\_\_\_  
Date Signed

\_\_\_\_\_  
Telephone Number of Signee

\_\_\_\_\_  
Relationship to Test Subject

\_\_\_\_\_  
**SIGNATURE** – Witness

\_\_\_\_\_  
Date Signed

**SUPPLEMENTAL INFORMATION FOR THE CONSENT FOR HIV TESTING FORM*****There are three possible HIV test results:***

- A **negative test result** means that a person is probably not infected with HIV. However, if a person has been recently exposed to HIV, it may be too soon to find out if infection has occurred. Re-testing may be necessary.
- A **confirmed positive test result** means that a person is infected with HIV and is able to spread the virus to others by having unprotected sex or sharing needles. If a person has not tested positive before, it is recommended that another test be done to verify the result.
- An **indeterminate test result** is neither negative nor positive. The person should be tested again as soon as possible. No test is 100% accurate. Additional testing may be needed or recommended.

***Redisclosure:***

Wisconsin law requires that HIV test results can only be given to people who are authorized to have access to these results or in the limited circumstances specified in statute 252.15(5)(a).

The following are persons who may receive name-associated HIV test results under certain circumstances under Wisconsin statute 252.15 (5) (a). There are penalties for illegal release of HIV test results.

The person tested; and if the person is incapacitated, the person designated as the agent in the health care power of attorney;

The person's health care provider, including a health care provider who provides emergency care to the person tested;

An agent or employee of the tested person's health care provider who provides patient care or handles specimens of body fluids or tissues or prepares or stores patient health care records;

A blood bank, blood center or plasma center that subjects a person to a test;

A health care provider who procures, processes, distributes or uses a human body part for the purpose of ensuring medical acceptability of the donated body part;

The State Epidemiologist or his/her designee for the purpose of communicable disease investigation or control or epidemiologic surveillance;

A funeral director or to other persons who prepare a corpse for burial or other disposition; or to a person who performs or assists in an autopsy;

Health care facility staff committees or accreditation or health care services review organizations for conducting program monitoring, evaluations and reviews;

Under a court order;

A person who conducts research, if the researcher :

- Is affiliated with the tested person's health care provider, and
- Has obtained permission to perform the research from an institutional review board, and
- Provides written assurance that the information will not be released and will not identify the person tested without informed consent;

A person rendering emergency care to a victim if significantly exposed;

A coroner or medical examiner or assistant if :

- The HIV-infected status is relevant to the determination of cause of death, or
- During direct investigation the coroner, medical examiner or appointed assistant is significantly exposed to the subject;

A sheriff; jailer; keeper of a prison, jail or house of correction; for the purpose of assigning private cells;

If the test results were positive and the tested patient is now deceased, persons known by the deceased patient's physician to have had sexual contact or shared intravenous drug equipment with that patient;

A person who consents for testing an individual who is under 14 years of age, or declared incompetent by a court, or is unable to communicate because of a medical condition;

An alleged victim or victim of sexual assault, the victim or alleged victim's parent or guardian and the victim or alleged victim's healthcare provider;

To a person who is significantly exposed, as defined by state statute, through certain occupations;

To a foster parent or treatment foster parent or the operator of a group home, child caring institution or correctional facility in which a child is placed.

If the person is a prisoner, the prisoner's health care provider and medical and intake staff of the prison or jail.

Smith HIV Testing Agency  
111 Main Street  
Hereandnow, WI 53704

HIV staff contact: Jane Smith, R.N.  
608-555-4516

**OraQuick Rapid HIV Result**

Date of OraQuick test: \_\_\_\_\_

Client Name or Code: \_\_\_\_\_

\_\_\_\_\_ Your OraQuick test result was non-reactive. This result means that either you do not have HIV infection or you have been exposed too recently to find out if infection has occurred. If you have had risk exposure in the last three months, you should repeat the test three months after your last exposure to be sure that you are not infected.

\_\_\_\_\_ Your OraQuick test result was reactive. A confirmatory test is required to determine whether you have HIV infection. A blood or oral fluid specimen from you will be submitted for confirmatory testing today and results of this test will be available within one to two weeks. While you are waiting for your confirmatory result, you should be sure to avoid transmitting the virus to others in case you are infected.

If you have any questions regarding your test result, please contact the person at the phone number listed above.

Sixteenth Street Community Health Center  
HIV Outreach Center  
437 East Lincoln Avenue  
Milwaukee, WI 53207

Para más información llame a Maria Garcia  
414-810-9541

**Resultado rápido del VIH**

Fecha de la prueba de OraQuick: \_\_\_\_\_

Nombre o clave del paciente: \_\_\_\_\_

\_\_\_\_\_ Su prueba de OraQuick no es reactiva. Este resultado significa que Ud. no tiene infección de VIH o que se ha expuesto muy recientemente para saber si ha ocurrido. Si Ud. se ha puesto en riesgo durante los últimos tres meses, es necesario hacer la prueba tres meses después de su última exposición para asegurar que no está infectado.

\_\_\_\_\_ Su resultado de la prueba de OraQuick es reactivo. Una prueba confirmatoria es necesaria para determinar si Ud. tiene la infección del VIH. Una muestras de sangre o fluido oral será mandado para una prueba confirmatoria hoy y los resultados de esta prueba serán disponibles dentro de dos semanas. Mientras que aguarda por su resultado confirmatorio, es necesario evitar transmisión del virus a otros en caso de que Ud. esté infectado.

Si tiene alguna pregunta acerca de su resultado, favor de llamar a la persona cuyo nombre aparece arriba.

**Appendix C**

**OraQuick Testing Log**

Agency: \_\_\_\_\_ Location: \_\_\_\_\_  
 OraQuick Device Lot Number (on pouch): \_\_\_\_\_ OraQuick Device Expiration Date: \_\_\_\_\_  
 OraQuick Control Lot No. (on box) \_\_\_\_\_ OraQuick Control Exp. Date \_\_\_\_\_ Date Opened: \_\_\_\_\_ Toss Date \_\_\_\_\_

Test #	Date	Test ID.sticker or +/- Control	Staff Initials	Absorbent packet?	Temp°	Spec. Type B/O	Start Time	Read Time	Internal Control Valid Y/N	Result pos/neg/Inv	Spec. sent for WB?	Result of WB pos/neg/ind NA	Comments

<b>Instructions for OraQuick Testing Log</b>	
<b>Agency</b>	Fill in name of Agency
<b>Location</b>	Fill in location of testing: e.g. clinic; South City Satellite Clinic; Smith Chemical Dependency Center
<b>OraQuick Device Lot No. and Expiration Date</b>	Fill in Lot Number (on pouch) and Expiration Date for the shipment of devices in use.
<b>OraQuick Control Lot No. and Expiration Date:</b>	Fill in Lot Number (on box) and Expiration Date of most recent control performed.
<b>Date Opened and Toss Date</b>	At <i>Date Opened</i> fill in the date that the controls were opened. At <i>Toss Date</i> fill in the date the controls are to be disposed. (Controls expire 56 days after opening)
<b>Test #</b>	Begin numbering with 1,2,3,4... EVERY time a control is run, regardless of the reason. When the number gets to 25, run another control. Run routine controls every 25 tests or once a month, whichever comes first.
<b>Date</b>	Fill in date of OraQuick test
<b>Test I.D Sticker or +/- Control</b>	<ul style="list-style-type: none"> <li>• If testing a Positive Control, fill in "+ Control"</li> <li>• If testing a Negative Control, fill in " - Control"</li> <li>• If testing a client specimen, fill in Test ID number (or use sticker) <b>and</b> the client code or initials.</li> </ul>
<b>Staff Initials</b>	Fill in the initials of staff conducting the OraQuick test
<b>Absorbent Packet?</b>	Write whether the absorbent packet was in the test device pouch (Y=yes; N=no). If the dessicant is not present, dispose of the test.
<b>Temperature</b>	Fill in the current temperature of the testing site
<b>Specimen Type</b>	Write "B" for blood or "O" for oral
<b>Start Time</b>	Write the exact time that the device was placed in the developing solution.
<b>Read Time</b>	Write the exact time that the result was read.
<b>Internal Control Valid</b>	<ul style="list-style-type: none"> <li>• If a line is present at the "Control" triangle, write "Y" for yes.</li> <li>• If the area at the "Control" triangle is blank, write "N" for no – the test is invalid. (Explain your next steps under the comment section).</li> </ul>
<b>Result</b>	<ul style="list-style-type: none"> <li>• For a non-reactive OraQuick result – write "neg"</li> <li>• For a reactive OraQuick result – write "pos"</li> <li>• For a invalid OraQuick – write "inv"</li> </ul>
<b>Specimen sent for Western Blot</b>	<ul style="list-style-type: none"> <li>• If yes – write "Y"</li> <li>• If no – write "N"</li> <li>• If not applicable (in the case of controls) – write "NA"</li> </ul>
<b>Result of Western Blot</b>	<ul style="list-style-type: none"> <li>• For a positive Western blot - write "pos"</li> <li>• For a negative Western blot – write "neg"</li> <li>• For an indeterminate Western blot – write ind</li> <li>• If not applicable (in the case of controls) – write NA</li> </ul>
<b>Comments</b>	<ul style="list-style-type: none"> <li>• If conducting either a Positive or Negative Control, indicate reason.</li> <li>• If test is invalid, indicate next steps</li> <li>• If rapid test is reactive, indicate whether client received confirmatory test results and/or next steps.</li> </ul>

**Appendix D**

**OraQuick Inventory Log – Test and Controls**

Log each box of tests or external controls received.

<u>Item Received</u> (Tests or Controls)	<u>Date Received</u>	<u>Lot No #</u>	<u>Exp. Date</u>	<u>No. of Tests in Box *</u>	<u>Date when item first used</u>

\*Applies to test shipments only.

**Appendix E**

**Temperature Log**

Thermometer location \_\_\_\_\_

Acceptable temperature range\* \_\_\_\_\_

Month/Year \_\_\_\_\_

Day	Initials	High Temp	Low Temp	Corrective action taken when temperature is out of range
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				
16				
17				
18				
19				
20				
21				
22				
23				
24				
25				
26				
27				
28				
29				
30				
31				

\* The acceptable range for test kit storage is 2 to 27° C or 35 to 80° F and the acceptable range for control storage is 2 to 8°C or 36 to 46° F.

Reviewed by \_\_\_\_\_

Date reviewed \_\_\_\_\_

## Appendix F

### Example Training Checklist for the OraQuick Rapid Antibody Test

**Employee:** Name

**Instructions:** Fill in dates when the trainee observes and performs each objective or procedural step, as applicable. (If a trainee will not perform a specific task, enter N/A for not applicable.) The trainee should initial when he/she feels the objective/procedure has been mastered and the trainer when he/she thinks the trainee has met the objective or performs the specific procedure competently.

Objective/Procedural Step	Date Observed by Trainee	Date Performed by Trainee	Trainee's initial and date	Trainer's initial and date
Read OraQuick package insert and protocol	N/A			
Read Biohazard Exposure Control Plan	N/A			
Determine if requirements for acceptable testing environment are met (e.g., temperature, lighting, level work space)				
Practice test with negative and positive external controls				
Give person getting tested the "Subject Information" brochure				
Label test device components and appropriate paperwork				
Collect fingerstick specimen, put loop into vial and mix correctly				
Insert test device, time test, read result				
Dispose of lancet and other biohazardous waste appropriately				
Record results on report form and testing log sheet				
Record internal and external quality control (QC) results on testing log				
Evaluate a new OraQuick test kit lot number and record results on testing log				
Report test result to the person being tested (one negative and one preliminary positive)				
Collect specimen for confirmatory testing				
Send confirmatory test specimen to laboratory and document submission				
Receive laboratory results and record results				
Explain what to do if results of external controls show a problem				

# Clearview HIV 1/2 Stat-Pak

## Introduction

Testing with Clearview HIV 1/2 Stat-Pak consists of dispensing a whole blood specimen in the well of a test device and then adding a running buffer solution to the well. The buffer solution assists the movement of the specimen through the test device. The test result is read 15-20 minutes after the specimen and buffer have been dispensed.

Stat-Pak is FDA approved to identify both HIV-1 and HIV-2 infection. In clinical studies by the manufacturer, Stat-Pak had a sensitivity to detect HIV-1 of 99.7% and a specificity of 99.9%. This means that the test correctly identified 99.7% of the people in the trial who were HIV-1 infected, and 99.9% of those who were not infected with HIV-1.

Some individuals who are not infected with HIV will have reactive results with Stat-Pak (false positives). Reactive results should not be considered definitive until confirmatory testing is completed.

In addition, a small number of people who are infected with HIV will have negative test results (false negatives) with Stat-Pak. Individuals with HIV infection who are taking highly active antiretroviral therapy (HAART) may have false negative results with the Stat-Pak test.

## Materials Required for Testing

The following materials are provided to the site:

- The Clearview HIV 1/2 Stat-Pak test. The test is packaged in boxes of 20 and labeled with a Master Lot Number and expiration date outside of the box.
- Running buffer solution – one vial per box . (buffer should only be used with tests from the same Master Lot Number).
- Specimen collection loops
- Subject information pamphlets
- Package insert
- External controls (set of HIV-1 positive, HIV-2 positive and negative)

The following materials are not provided to the site but are required:

- Latex, vinyl or nitrile disposable gloves
- Timer or watch capable of timing up to 20 minutes (more than one timer may be useful if running several tests simultaneously)
- Clean, disposable, absorbent workspace cover (“chux” pad)
- Trash bags
- Surface disinfectant to clean up accidental spills(EPA-registered, hospital grade, intermediate activity disinfectant such as Dispatch, Virex TB, or Cavicide)
- Alcohol-based waterless hand cleanser

- Laboratory grade thermometers- ideally minimum/maximum thermometers which record the high and low temperature since the last reading - to measure storage temperature of test devices and controls and temperature of testing location.
- Refrigerator dedicated to storage of biohazardous materials
- Required forms (see appendices A-E)
- Sterile retractable lancets or phlebotomy supplies and blood tubes. Lancets should have a depth that ranges from 1.8 mm to 2.4 mm. Blood tubes must contain any of the following anticoagulants: EDTA (lavender top), sodium heparin (green top), or sodium citrate (light blue top).
- Alcohol wipes
- Sterile gauze pads (2"x2")
- Small adhesive bandages
- Biohazard sharps container

Also, a flashlight may be helpful to illuminate the result window in case the result is difficult to read.

### **Conditions for Testing**

The following conditions must be present to use Stat-Pak:

- Sufficient lighting to safely and accurately perform the test and read the result.
- A level, clean surface where testing can be performed.
- Storage temperature of tests and buffer between 46° and 86° Fahrenheit.
- Operating temperature (temperature during testing) between 64° and 86° Fahrenheit.
- Space that assures confidentiality for both testing and counseling. Ideally the test is set up in an area apart from the client and where no other individuals can read the result.

### **Use of External Quality Controls**

The Wisconsin AIDS/HIV Program supplies each site with external quality controls that verify whether the tests are working properly or staff are properly performing the test.

Each set consists of three vials –

- HIV-1 positive control
- HIV-2 positive control\*
- negative control.

The positive controls contain a solution of heat inactivated human plasma positive for antibodies to HIV-1 or HIV-2 respectively that will cause a reactive result when used with the Stat-Pak test.

The negative control contains a solution of normal human plasma negative for antibodies to HIV-1 and HIV-2 that will create a non-reactive result when tested.

To run controls, run the test using the solution in a control vial rather than a client specimen. If the test does not show the expected result of the control used, either the testing process was not performed correctly or the test is defective. Staff should thoroughly review all of their testing procedures prior to assuming that the device is defective (See “Troubleshooting” p. 58).

**\*Please Note:** only the HIV-1 positive control and the negative control should be used to run controls. It is not necessary – and the Program does not recommend – using the HIV-2 positive control.

External quality controls should be run under the following conditions:

- When a staff person has been trained to use the Stat-Pak test, prior to testing client specimens.
- When a new box of tests is opened at the testing site.
- If the temperature of the test storage area falls outside 46°-86° Fahrenheit.
- If the temperature of the testing area falls outside 64°-86° Fahrenheit.
- Including any of the above reasons, external controls should be conducted at least once every 20 tests or once a month – whichever occurs first.

When controls are run, these tests should be documented on the *Stat-Pak Testing Log*. If more than one box of tests are being used simultaneously in an agency, staff must assure that controls are run on each box.

External quality controls do not need to be run in distinct venues provided the testing conditions outlined above have been met. The external controls must be refrigerated (temperature must be between 36-46° Fahrenheit). Controls do not need to be warmed prior to use.

Controls expire two years after production. Controls can be used repeatedly, but must be disposed of by the expiration date. Dispose of the controls in a biohazardous waste container.

If the results of the controls are not as expected, assess all possible reasons for the failure of the controls (see Trouble-shooting guidelines on p. 58).

- If you have not determined the reason for the failure, run the controls again using a new box of tests.
- If the controls fail again, open a new set of controls and run them.
- If the controls fail again, discontinue testing and contact Kathleen Krchnavek, HIV Testing Technology Specialist at 608-267-3583 or [krchnka@dhfs.state.wi.us](mailto:krchnka@dhfs.state.wi.us) for further guidance.

When controls fail, all results prior to the last control run are suspect.

## **Shelf-Life and Storage of Test and Control Kits**

The Stat-Pak test kits expire two years after production. The expiration date is marked the outside of the box, on the test pouch, and on the buffer. Tests must be *stored* between 46°-86° Fahrenheit. Because of this temperature range, tests should not be stored in the refrigerator. Tests must be *run* between 64°-86° Fahrenheit.

External quality controls expire two years after production, and must be stored between 36°-46° Fahrenheit.

To assure that the proper storage temperature is maintained for test and control kits, a thermometer should be placed in the storage areas (e.g. a refrigerator for the controls, a closet for the tests). Agency staff should log test and control storage temperatures each day that testing is performed.

If storage temperature falls outside of this range for either the tests or controls:

- a set of external controls should be run on the tests in question, or
- the external controls in question should be run on tests that have been kept at the appropriate temperature range.

If the proper result is received, the item in question may be used. However, the agency should report this to Kathleen Krchnavek at 608-267-3583 or [krchnka@dhfs.state.wi.us](mailto:krchnka@dhfs.state.wi.us) to discuss if further assessment should be done.

If the expected results are not obtained the tests or controls in question should be disposed.

## **Assuring Proper Testing Temperature**

The temperature in the area where the test will be performed must be within the range of 64°-86° Fahrenheit. Staff must use a thermometer to determine whether the temperature is within the specified range. If the temperature is out of this range, staff should not conduct testing.

## Testing Steps

The following is a summary of the steps required to complete a Stat-Pak test with a whole blood specimen, (either fingerstick or venipuncture). Detailed instructions are described in the package insert and in the “*Clearview HIV1/2 Stat-Pak Test Procedure – Quick Reference Instructions.*” included with this protocol. Staff must read and understand both of these documents prior to testing clients.

### *Preparation:*

1. Cover the area with a workspace cover and set up the materials needed for blood collection.
2. Document the Master Lot number (on the test box) on the *Stat-Pak Testing Log* when opening a new box.
3. Check expiration date of test pouch. If expired, dispose and obtain a new pouch that is not expired.
4. Check to make sure there is an absorbent packet in the test pouch. If none is present discard the pouch and get a new one.
5. Test should be at room temperature - between 64° - 86° Fahrenheit – before using the test.
6. Remove the Stat-Pak test from the pouch and place it on a flat surface.
7. Open the pouch and label the test with a test ID sticker and write the client code or initials on the sticker.
8. Put on disposable gloves.

### *Collection:*

#### *Fingerstick whole blood specimens*

1. Clean the patient’s finger with an alcohol wipe and allow it to dry thoroughly.
2. Using a sterile retractable lancet (depth range: 1.8 mm – 2.4 mm), puncture the skin just off the center of the finger pad.
3. Discard lancet in a sharps container.
4. Hold hand palm-side up, but pointing downward toward the floor to facilitate blood flow. Apply gentle pressure beside point of puncture. Avoid squeezing the finger to make it bleed.
5. Wipe away the first drop of blood with a sterile gauze pad. Allow a new drop of blood to form.
6. Touch the sample loop to the drop of blood, allowing the opening of the loop to fill with blood.

#### *Venipuncture whole blood specimens*

1. Using standard phlebotomy procedures, collect a whole blood sample using a tube containing any of the following anticoagulants: EDTA (lavender top), sodium heparin (green top), or sodium citrate (light blue top). **Other anticoagulants have not been tested and may give an incorrect result.**
2. Blood can be tested up to one day at room temperature and up to three days refrigerated. Do not freeze blood.

3. Prior to testing, mix the blood tube by inversion several times to ensure a homogenous sample.
4. Carefully open the tube of blood. Use personal protective equipment such as a face shield or goggles to protect face from a blood splash.
5. Put the sample loop into the tube of blood allowing the opening of the loop to fill with blood. After filling the loop, do not knock the loop against the side of the tube.

### *Testing*

1. Holding the sample loop vertically, touch it to the pad in the center of the sample well (labeled “S”) of the device. You will need to apply some pressure to the loop. The blood specimen will flow onto the pad.
2. Dispense the buffer by holding the bottle vertically (not at an angle) above the well of the device and squeeze three (3) free falling drops of buffer slowly into the well.
3. Read the test result between 15 and 20 minutes after the addition of the buffer.
  - Reactive test results may be observed and read earlier than 15 minutes.
  - To verify a non-reactive test result, wait the entire 15 minutes after starting the test. Do not read after 20 minutes.

### *Reading the result*

Read the result directly over the result window.

A valid test result must have a pink/purple line next to the “C” (Control) area. If no line is present at this area, the test is invalid and no result can be interpreted. The client must be tested again.

- A line at only the “C” area, and no line at the “T” (Test) area, is interpreted as a non-reactive or negative test result. The client is either not infected with HIV, or it is too soon to tell. If the client has had a risk exposure within the last 3 months, the client should be re-tested 3 months after the exposure.
- Lines at both the “C” and “T” area are interpreted as a reactive test result. A Western blot test must be conducted on a second specimen from the client to determine whether the client is infected with HIV.

**Note:** “Shade” off of the result window may appear to be a line in the result window. Be certain to read the result directly over the result window and verify that a pink/purple line is at the appropriate area(s) of the window.

Typically, only one staff person should read the test result. However, in the event that one staff person identifies a reactive test and another staff person does not see a “T” line and identifies the test as non-reactive – the test should be considered reactive and confirmatory testing should be done.

### *Assessing Invalid Results:*

A test is invalid at 15 minutes when:

- There is no pink/purple line next to the “C” area
- Any of the lines are outside the “C” or “T” areas (above or below)

A test is also considered invalid if it is not read within the 15-20 minute time period.

To assess why a test may be invalid, staff should review their procedures to determine that the test was conducted properly (see “Troubleshooting” p.58). A second test should be conducted. If this test is also invalid, external quality controls should be run. If the expected results are not obtained, staff should contact Kathleen Krchnavek at 608-267-3583 or the Wisconsin State Laboratory of Hygiene Retrovirus Lab at 608-262-2366. If it appears that devices are defective, the Stat-Pak customer service department should be contacted at 1-800-637-3717

*Documentation of the Result:*

6. Check the test ID sticker and client code/initials on the test. Be certain that it matches with the person to whom you are about to give results.
7. Complete documentation of the *Stat-Pak Testing Log* including read time and results.
8. Record the date of the test and the Client Name or anonymous code on the agency “Stat-Pak Rapid HIV Result” (Appendix B), printed on the agency letterhead. This form should also be printed with the name of an agency staff person to contact in case the client has questions regarding their result after leaving the agency.
9. Place a checkmark next to the appropriate paragraph indicating whether the result was non-reactive or reactive.
10. Provide the client with the written result.

*Clean up:*

4. Dispose of sharps (lancets, needles) in a sharps container and all other used test materials (device, loops, used gauze and gloves, etc.) in a trash bag.
5. Clean any spills with a surface disinfectant (EPA-registered, hospital grade, intermediate activity disinfectant such as Dispatch, Virex TB, or Cavicide).
6. Remove gloves, and wash hands after every test is performed. Use new gloves for each client.

**Confirmatory Testing**

All clients receiving a reactive Stat-Pak result should immediately have a specimen collected for a confirmatory test - the Western blot - to determine whether they have HIV infection. A blood or oral fluid (OraSure) specimen should be obtained from the client and sent to the Wisconsin State Laboratory of Hygiene (WSLH) for Western blot testing. If agency staff have the capacity to do phlebotomy, a blood test is preferable to an oral fluid test for confirmatory testing.

If staff used venipuncture whole blood for Stat-Pak testing, a new tube of blood must be obtained for confirmatory testing. Staff should not use the same tube of blood that was used for Stat-Pak testing due to the possibility of specimen contamination.

Specimens should be sent to WSLH with the lab slip – EvaluationWeb Form C. Under “Test Requests” on this form, mark **Confirmation of a rapid test**.

For blood specimens, WSLH will run an initial EIA test on the specimen for quality assurance purposes. This EIA result will not be reported on the WSLH result form. WSLH will run a Western blot regardless of whether the EIA is reactive or non-reactive.

For oral fluid specimens, WSLH will conduct standard EIA/Western blot testing. WSLH will run a Western blot regardless of whether the EIA is reactive or non-reactive. Both the EIA and Western blot results will be reported.

### *Discordant Results*

When the Western blot is negative following a reactive rapid test:

- If the initial sample sent to the lab was blood, test the client again with a conventional blood test (EIA/WB) in one month. If testing staff are concerned that the client may not return for the follow-up test, this test could be done immediately.
- If the initial sample sent to the lab was oral fluid (OraSure), test the client again with conventional blood test (EIA/WB) immediately.

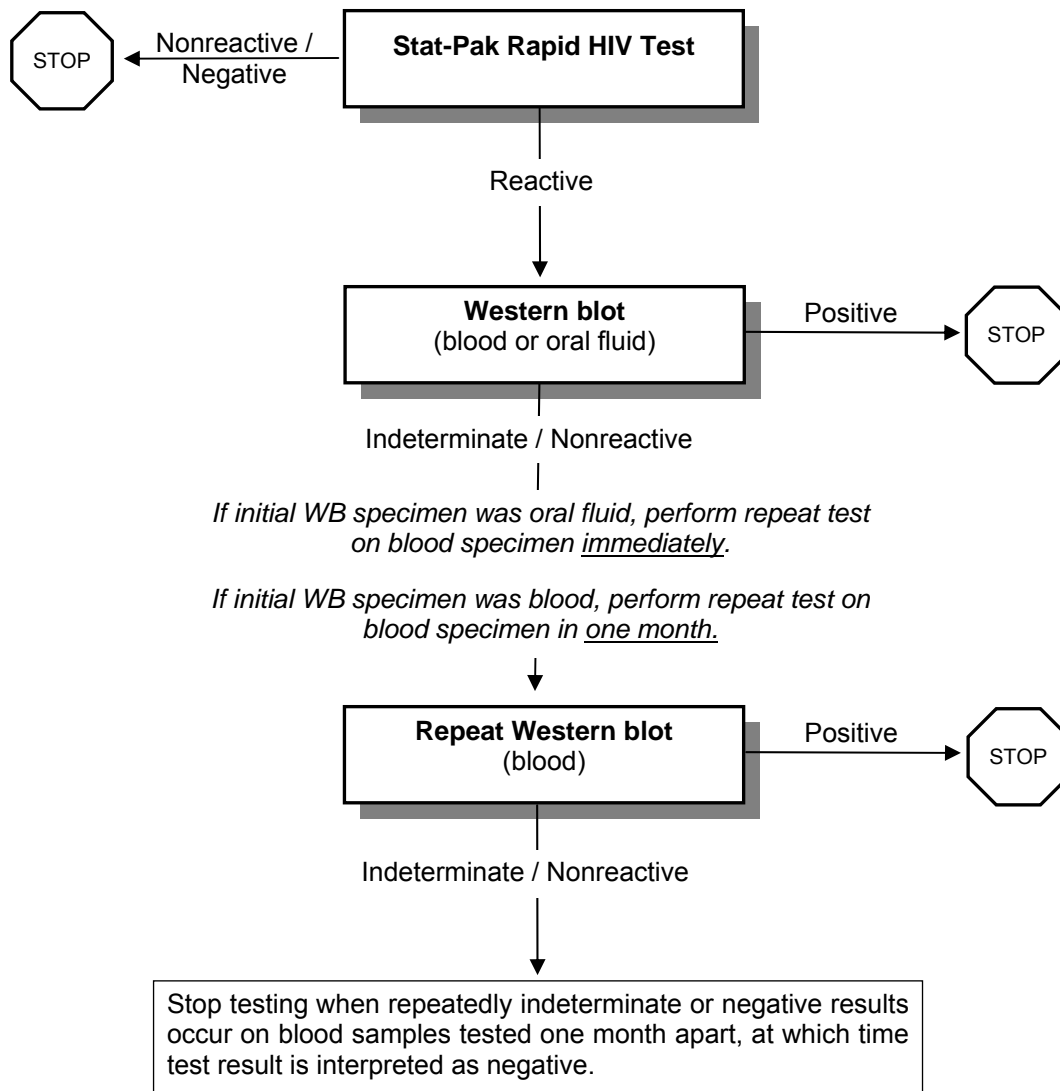
When the Western blot is indeterminate following a reactive rapid test:

- If the initial sample sent to the lab was blood, test the client again with a conventional blood test (EIA/WB) in one month. If the second Western blot is still indeterminate, the client is not infected.
- If the initial sample obtained was oral fluid (OraSure), test the client again with a conventional blood test (EIA/WB) immediately. If this second Western blot is still indeterminate, the client should be retested (EIA/WB) in one month. If this third result is indeterminate, the client not infected.

The above descriptions are illustrated by the algorithm on the next page.

When a rapid test is reactive and the Western blot is negative or indeterminate, the Wisconsin State Laboratory of Hygiene will test the specimen for the presence of HIV-2 with an HIV-2 EIA. Most specimens will be negative on the HIV-2 EIA. However, in the rare occurrence that the HIV-2 EIA is reactive, the specimen will be sent to another laboratory for an HIV-2 Western blot. On average, this occurs at the Wisconsin State Laboratory of Hygiene once or twice a year from all the specimens they will test for HIV infection.

# Stat-Pak Rapid HIV Testing Algorithm



## Summary comments on initial and repeat testing

All indeterminate or nonreactive Western blot test results of oral fluid or blood specimens must be followed by EIA/Western blot testing of blood

- Indeterminate or nonreactive Western blot test results of oral fluid must be followed by immediate EIA/Western blot testing of blood
- Indeterminate or nonreactive Western blot test results of blood must be followed by repeat EIA/Western blot test of blood in one month.

Repeatedly indeterminate Western blot test results of blood samples tested one month apart are interpreted as negative.

## CONSENT FOR ANONYMOUS OR CONFIDENTIAL HIV TESTING

Completion of this form is required for testing to take place. ALL information recorded on this form is confidential and not shared without your consent except as provided by law. See Supplemental Information on the reverse side of this form.

I want to be tested for the human immunodeficiency virus (HIV), the virus that can cause AIDS.

I understand:

- The benefits and possible risks of testing.
- Additional counseling and assistance with health care and other services are available if I need them.
- My HIV test results will be kept confidential. If I have a confidential HIV test (with my name listed), I understand that Wisconsin statutes allow my test results to be released only to the persons or under the circumstances listed on the back of this form.

In addition, I understand that if I choose a rapid HIV test,:

- If the test result is non-reactive, the result is interpreted as negative and is available today.
- **If the test result is reactive, I am agreeing to a second (confirmatory) test that will be performed to determine whether I have HIV infection. This second test requires that a blood or oral sample be collected today to be sent to an off-site laboratory. Results will be available 1-2 weeks from today.**
- Only a positive result from the confirmatory test would indicate that I have HIV infection.

I have read the above information. It has been explained to me. My questions have been answered. I agree to be tested for HIV. I have indicated below the type of test to which I am agreeing.

---

I want my test to be anonymous (without my name being listed).

\_\_\_\_\_  
CODE - Test Subject

\_\_\_\_\_  
Date Signed

\_\_\_\_\_  
SIGNATURE – Witness

\_\_\_\_\_  
Date Signed

---

I want my test to be confidential (with my name listed).

Test Subject \_\_\_\_\_

Telephone Number \_\_\_\_\_

Address \_\_\_\_\_

Date of Birth \_\_\_\_\_

\_\_\_\_\_  
SIGNATURE - Test Subject

\_\_\_\_\_  
Date Signed

\_\_\_\_\_  
SIGNATURE –Person Legally Authorized to Consent  
on Behalf of Test Subject

\_\_\_\_\_  
Date Signed

\_\_\_\_\_  
Telephone Number of Signee

\_\_\_\_\_  
Relationship to Test Subject

\_\_\_\_\_  
SIGNATURE – Witness

\_\_\_\_\_  
Date Signed

## SUPPLEMENTAL INFORMATION FOR THE CONSENT FOR HIV TESTING FORM

### There are three possible HIV test results:

- A **negative test result** means that a person is probably not infected with HIV. However, if a person has been recently exposed to HIV, it may be too soon to find out if infection has occurred. Re-testing may be necessary.
- A **confirmed positive test result** means that a person is infected with HIV and is able to spread the virus to others by having unprotected sex or sharing needles. If a person has not tested positive before, it is recommended that another test be done to verify the result.
- An **indeterminate test result** is neither negative nor positive. The person should be tested again as soon as possible.

No test is 100% accurate. Additional testing may be needed or recommended.

### Redis closure:

Wisconsin law requires that HIV test results can only be given to people who are authorized to have access to these results or in the limited circumstances specified in statute 252.15(5)(a).

The following are persons who may receive name-associated HIV test results under certain circumstances under Wisconsin statute 252.15 (5) (a). There are penalties for illegal release of HIV test results.

The person tested; and if the person is incapacitated, the person designated as the agent in the health care power of attorney;

The person's health care provider, including a health care provider who provides emergency care to the person tested;

An agent or employee of the tested person's health care provider who provides patient care or handles specimens of body fluids or tissues or prepares or stores patient health care records;

A blood bank, blood center or plasma center that subjects a person to a test;

A health care provider who procures, processes, distributes or uses a human body part for the purpose of ensuring medical acceptability of the donated body part;

The State Epidemiologist or his/her designee for the purpose of communicable disease investigation or control or epidemiologic surveillance;

A funeral director or to other persons who prepare a corpse for burial or other disposition; or to a person who performs or assists in an autopsy;

Health care facility staff committees or accreditation or health care services review organizations for conducting program monitoring, evaluations and reviews;

Under a court order;

A person who conducts research, if the researcher :

- Is affiliated with the tested person's health care provider, and
- Has obtained permission to perform the research from an institutional review board, and
- Provides written assurance that the information will not be released and will not identify the person tested without informed consent;

A person rendering emergency care to a victim if significantly exposed;

A coroner or medical examiner or assistant if :

- The HIV-infected status is relevant to the determination of cause of death, or
- During direct investigation the coroner, medical examiner or appointed assistant is significantly exposed to the subject;

A sheriff; jailer; keeper of a prison, jail or house of correction; for the purpose of assigning private cells;

If the test results were positive and the tested patient is now deceased, persons known by the deceased patient's physician to have had sexual contact or shared intravenous drug equipment with that patient;

A person who consents for testing an individual who is under 14 years of age, or declared incompetent by a court, or is unable to communicate because of a medical condition;

An alleged victim or victim of sexual assault, the victim or alleged victim's parent or guardian and the victim or alleged victim's healthcare provider;

To a person who is significantly exposed, as defined by state statute, through certain occupations;

To a foster parent or treatment foster parent or the operator of a group home, child caring institution or correctional facility in which a child is placed.

If the person is a prisoner, the prisoner's health care provider and medical and intake staff of the prison or jail.

**Appendix B-1**

**Smith HIV Testing Agency  
111 Main Street  
Hereandnow, WI 53704**

**HIV staff contact: Jane Smith, R.N.  
608-555-4516**

**Stat-Pak Rapid HIV Result**

Date of Stat-Pak test: \_\_\_\_\_

Client Name or Code: \_\_\_\_\_

\_\_\_\_\_ Your rapid HIV antibody test result was non-reactive. This result means that either you do not have HIV infection or you have been exposed too recently to find out if infection has occurred. If you have had risk exposure in the last three months, you should have a repeat test three months after your last exposure to be sure that you are not infected.

\_\_\_\_\_ Your rapid HIV antibody test result was reactive. A confirmatory test is required to determine whether you have HIV infection. A blood or oral fluid specimen from you will be submitted for confirmatory testing today and results of this test will be available within one to two weeks. While you are waiting for your confirmatory result, you should be sure to avoid transmitting the virus to others in case you are infected.

**If you have any questions regarding your test result, please contact the person at the phone number listed above.**

Sixteenth Street Community Health Center  
HIV Outreach Center  
437 East Lincoln Avenue  
Milwaukee, WI 53207

Para más información llame a: **Maria Garcia**  
**414-810-9541**

### Resultado rápido del VIH

Fecha de la prueba de Stat-Pak: \_\_\_\_\_

Nombre o clave del paciente: \_\_\_\_\_

\_\_\_\_\_ Su prueba de Stat-Pak no es reactiva. Este resultado significa que Ud. no tiene infección de VIH o que se ha expuesto muy recientemente para saber si ha ocurrido. Si Ud. se ha puesto en riesgo durante los últimos tres meses, es necesario hacer la prueba tres meses después de su última exposición para asegurar que no está infectado.

\_\_\_\_\_ Su resultado de la prueba de Stat-Pak es reactivo. Una prueba confirmatoria es necesaria para determinar si Ud. tiene la infección del VIH. Una muestras de sangre o fluido oral será mandado para una prueba confirmatoria hoy y los resultados de esta prueba serán disponibles dentro de dos semanas. Mientras que aguarda por su resultado confirmatorio, es necesario evitar transmisión del virus a otros en caso de que Ud. esté infectado.

Si tiene alguna pregunta acerca de su resultado, favor de llamar a la persona cuyo nombre aparece arriba.

Appendix C

**Stat-Pak Testing Log**

Agency: \_\_\_\_\_ Location: \_\_\_\_\_ Box ID: \_\_\_\_\_ Date Opened: \_\_\_\_\_

Device Lot Number (on box): \_\_\_\_\_ Device Expiration Date: \_\_\_\_\_

Control Lot No. (on box) \_\_\_\_\_ Control Exp. Date \_\_\_\_\_

Date	Testing I.D. sticker or +/- Control	Staff Initials	Absorbent packet?	Temp.°	Start Time	Read Time	Internal control valid?	Result	Spec. sent for WB?	Result of WB pos/neg/ind	Comments -Indicate reason for running control -If test is invalid, indicate next steps -If rapid test is reactive, indicate whether client received confirmatory test results

<b>Instructions for Stat-Pak Testing Log</b>	
<b>Agency</b>	Fill in name of Agency
<b>Location</b>	Fill in location of testing: e.g. clinic; South City Satellite Clinic; Smith Chemical Dependency Center
<b>Box ID</b>	If several boxes will be in use at the same time in the agency - identify each box with a code so that the log is linked to a specific box.
<b>Date Opened</b>	Write in the date when the box was opened for use.
<b>Stat-Pak Device Lot No. and Expiration Date</b>	Fill in Lot Number (on box) and Expiration Date for the shipment of devices in use.
<b>Stat-Pak Control Lot No. and Expiration Date:</b>	Fill in Lot Number (on box) and Expiration Date of most recent control performed.
<b>Date</b>	Fill in date that you are conducting this Stat-Pak test
<b>Test I.D Sticker or +/- Control</b>	<ul style="list-style-type: none"> <li>• If testing a Positive Control, fill in "+ Control"</li> <li>• If testing a Negative Control, fill in " – Control"</li> <li>• If testing a client specimen, fill in 10 digit test ID number (or use sticker) <b>and</b> the client code or initials.</li> </ul>
<b>Staff Initials</b>	Fill in the initials of staff conducting the Stat-Pak test
<b>Absorbent Packet Present</b>	If an absorbent packet is present in the test pouch, mark "Y" and if not, mark "N". If a desiccant packet is not present in the pouch, dispose of the test device.
<b>Temperature</b>	Fill in the current temperature of the testing site
<b>Start Time</b>	Write the time that the tester finished dispensing the specimen and 3 drops of buffer into the sample well of the device.
<b>Read Time</b>	Write the exact time that the result was read.
<b>Internal Control Valid</b>	<ul style="list-style-type: none"> <li>• If a line is present at the Control area, write "Y" for yes.</li> <li>• If the Control area is blank, write "N" for no – the test is invalid. (Explain your next steps under the comment section).</li> </ul>
<b>Result</b>	<ul style="list-style-type: none"> <li>• For a non-reactive result – write "neg "</li> <li>• For a reactive result – write "pos"</li> <li>• For a invalid – write "inv"</li> </ul>
<b>Specimen sent for Western Blot</b>	<ul style="list-style-type: none"> <li>• If yes – write "Y"</li> <li>• If no – write "N"</li> <li>• If not applicable (in the case of controls) – write "NA"</li> </ul>
<b>Result of Western Blot</b>	<ul style="list-style-type: none"> <li>• For a positive Western blot - write "pos"</li> <li>• For a negative Western blot – write "neg"</li> <li>• For an indeterminate Western blot – write ind</li> <li>• If not applicable (in the case of controls) – write NA</li> </ul>
<b>Comments</b>	<ul style="list-style-type: none"> <li>• If conducting either a Positive or Negative Control, indicate reason.</li> <li>• If test is invalid, indicate next steps</li> <li>• If rapid test is reactive, indicate whether client received confirmatory test results and/or next steps.</li> </ul>



**Appendix E**

**Temperature Log**

Thermometer location \_\_\_\_\_

Acceptable temperature range\* \_\_\_\_\_

Month/Year \_\_\_\_\_

Day	Initials	High Temp	Low Temp	Corrective action taken when temperature is out of range
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				
16				
17				
18				
19				
20				
21				
22				
23				
24				
25				
26				
27				
28				
29				
30				
31				

\* The acceptable range for test kit storage is 2 to 27° C or 35 to 80° F and the acceptable range for control storage is 2 to 8°C or 36 to 46° F.

Reviewed by \_\_\_\_\_

Date reviewed \_\_\_\_\_

## Appendix F

### Example Training Checklist for the Stat-Pak Rapid Antibody Test

**Employee:** Name \_\_\_\_\_

**Instructions:** Fill in dates when the trainee observes and performs each objective or procedural step, as applicable. (If a trainee will not perform a specific task, enter N/A for not applicable.) The trainee should initial when he/she feels the objective/procedure has been mastered and the trainer when he/she thinks the trainee has met the objective or performs the specific procedure competently.

Objective/Procedural Step	Date Observed by Trainee	Date Performed by Trainee	Trainee's initial and date	Trainer's initial and date
Read Stat-Pak package insert and protocol	N/A			
Read Biohazard Exposure Control Plan	N/A			
Determine if requirements for acceptable testing environment are met (e.g., temperature, lighting, level work space)				
Practice test with negative and positive external controls				
Give person getting tested the "Subject Information" brochure				
Label test device components and appropriate paperwork				
Collect fingerstick specimen, put loop into vial and mix correctly				
Insert test device, time test, read result				
Dispose of lancet and other biohazardous waste appropriately				
Record results on report form and testing log sheet				
Record internal and external quality control (QC) results on testing log				
Evaluate a new Stat-Pak test kit lot number and record results on testing log				
Report test result to the person being tested (one negative and one preliminary positive)				
Collect specimen for confirmatory testing				
Send confirmatory test specimen to laboratory and document submission				
Receive laboratory results and record results				
Explain what to do if results of external controls show a problem				

## Counseling and Referral – Pre-test, Post-test, and Prevention

### Pre-test (Test-decision) Counseling

Pre-test counseling consists of providing information to the client so that he/she can make an informed choice regarding HIV testing. It also offers an opportunity for discussion with the client regarding their reasons and feelings related to HIV testing, meaning of test results, and transmission risks. As with conventional testing, clients should be offered the option of either anonymous or confidential testing. Staff should also explain the following:

- The differences and methods of conventional testing (blood serum and/or oral fluid) and rapid testing.
- Procedures related to each of the testing options – how the test is done, how long the process takes, timeframes for getting results, meaning of test results, and repeat testing.
- Relevant information regarding the “window period” i.e. the time between possible exposure to the HIV virus and when the test is likely to identify HIV antibody in the patient specimen. Some clients mistakenly believe that the term “rapid test” refers to identifying infection rapidly – that the test can accurately determine whether a risk exposure last night resulted in infection today. Staff must be clear that rapid HIV testing only refers to obtaining results rapidly – not to reducing the time between exposure and identification of infection. If a client has had a recent exposure (< than 3 months) and their test is non-reactive, the client should be re-tested  $\geq$  3 months from exposure.<sup>3</sup>

If the client decides to be tested with a rapid test staff should:

- Provide the client with the “Subject Information” pamphlet supplied by the manufacturer.
- Ensure that the client understands the meaning of test results, including that a reactive result requires that confirmatory testing be performed immediately.
- Assess client’s potential reaction to receiving a reactive rapid test. Staff might ask “How would you feel if this test comes back reactive today? What would you do?” Some clients may realize that they are not prepared to receive their result today and choose to have a conventional test. For those who do choose rapid testing, this discussion will help staff understand and plan for the client’s support needs if their test result is reactive.
- Complete the informed consent form with the client and conduct the test. By completing the informed consent, the client does not need to sign another consent if confirmatory testing is necessary.

---

<sup>3</sup> All HIV antibody tests (serum EIA/Western blot, OraSure, or rapid tests) will convey a reactive result among 95% of infected individuals by 3 months after exposure. However, conventional serum testing will identify infection earlier than either OraSure or rapid testing. If a client is particularly concerned about a recent exposure, conventional serum testing may be able to provide more information to the client. Regardless of which test the client chooses, if the client has had a risk exposure less than 3 months from the test, a re-test is recommended.

## **Post-test Counseling and Referral for Rapid Results**

Post-test counseling consists of providing the results to the client and arranging for any follow-up testing, services, or referrals. What is discussed during this session depends on whether the rapid test was reactive or non-reactive.

### ***Reactive results:***

The following information should be covered when counseling someone with a reactive result. Throughout this process, staff should provide emotional support to assist the client to cope while waiting for the confirmatory test:

1. Interpret the result and assess client understanding of the result.
  2. Explain confirmatory testing.
  3. Obtain commitment from client to return for confirmatory result.
  4. Discuss what client intends to do during waiting time, including disclosure issues.
  5. Encourage client to take precautions to avoid potentially transmitting the virus to others.
  6. Assess need for referrals.
1. *Interpret the result and assess client understanding of the result:* Reactive results are defined as “preliminary positives” by the Centers for Disease Control and Prevention (CDC). However, this term may be confusing since some clients may not understand the word “preliminary,” and “positive” has intense associations with it. By hearing the word “positive” clients may believe they are infected with HIV, regardless of how the staff person describes this screening result.

To more accurately convey that this result is an initial screen and requires confirmatory testing, staff should explain the result in the following manner:

“Your test reacted. We need to do another test to  
find out whether you have HIV infection.”

“Your test result shows that we need to do another test to check  
whether you are HIV-infected.”

Ideally, the client will understand the meaning of the result and the process of confirmatory testing based on your pre-test counseling and explanation of the informed consent form. However, clients with a reactive result may require more explanation of the next steps in the testing process.

Although a reactive result is a screening test, the majority of confirmatory results will indicate HIV infection – especially when the client has been at risk. Therefore, although the client does not have a confirmed result, it may be appropriate for the client to discuss their feelings and begin to deal with the possibility that they may be infected.

Staff should provide the client with written documentation of their result (see Appendix B).

2. Explain confirmatory testing: A specimen for confirmatory testing should be obtained immediately for Western blot testing. If possible, a blood specimen should be drawn. If the staff person does not perform phlebotomy, an oral fluid specimen can be obtained. When OraSure is used to confirm the rapid test result, staff should explain that if the confirmatory test result is negative, additional confirmatory testing with blood will be done to be absolutely certain of their result.

The Western blot result should be available from the Wisconsin State Laboratory of Hygiene within one week.

3. Obtain commitment from client to return for confirmatory result: Staff should set an appointment with the client in one week to receive the confirmatory test result.

If the rapid test was done anonymously, some clients may be willing to give the staff person some identifying information (e.g. a first name) and a phone number to reach them in case the result arrives early. If the client provides this information, staff should verify that the client is willing to have the agency contact them regarding the result if the client does not return.

Some clients who opted for anonymous testing with the rapid test may be willing to have confidential testing for their confirmatory result. In this case, the client should sign the same consent form - now checking the confidential box and dating it - noting on the form that it applies to the confirmatory test.

All confirmatory results should be provided in person to facilitate linkage to further services and provision of emotional support. If it is impossible for the client to return for the confirmatory result, staff should make a strong effort to obtain contact information to follow-up with the client at another site or by phone.

4. Discuss what client intends to do during waiting time, including disclosure issues: Waiting for the confirmatory result will create anxiety for many clients. Staff should discuss how clients intend to cope during this waiting period and whom – if anyone – they intend to tell about their rapid test result. As with someone who has just received a confirmed positive result, staff should discuss with the client who they will trust with the result, and the potential ramifications of disclosing their result widely. If their confirmatory result is negative, the client may also have to contend with people who mistakenly believe that he/she is truly HIV infected.
5. Encourage client to take precautions to avoid potentially transmitting the virus to others: Staff should encourage and support the client in using risk reduction behaviors to avoid potentially transmitting the virus to others. This includes examining the client's possible risk behavior during the waiting period and developing a plan with the client for modifying this behavior.
6. Assess need for referrals: The client may need emotional support during this waiting period. Minimally, staff should offer to be a support to the client by phone or in

person. In addition, the client may need referrals to a mental health counselor, risk reduction specialist, or crisis line. Staff should assess the need for referrals based on the steps defined in the *Basic Counseling Skills for HIV Prevention* and the *HIV Counseling, Testing, and Referral* training courses and in the Wisconsin Division of Public Health - AIDS/HIV Program - Revised HIV Counseling, Testing, and Referral Services Protocol.

Staff should also mention the services that are available to them if their confirmatory test is positive. A brief description of partner counseling and referral services, as well as access to medical evaluation and care, case management, risk reduction counseling, legal services, and the drug reimbursement or health insurance programs should be provided.

### ***Non-reactive results:***

The following information should be covered when counseling someone with a non-reactive result:

1. Interpret the result and discuss possible need for re-testing.
2. Assess need for referrals.

1. *Interpret the result and discuss possible need for re-testing:* A non-reactive result is interpreted the same as for conventional HIV antibody testing. The result is interpreted as negative unless the client has engaged in risk behavior within the last three months. If the client has engaged in risk behavior during this time, staff should recommend a re-test three months after their last exposure.

In rare cases, individuals have been known to seroconvert as late as six months after an exposure. If the client has had an exposure to someone who is known to be HIV positive, it may be advisable to recommend a re-test at six months after this exposure.

2. *Assess need for referrals:* Staff should assess for additional services needed by the client, such as AODA treatment, economic assistance, domestic violence services, housing, STD testing and treatment, and hepatitis vaccination and testing in accordance with CDC guidelines.

### **Prevention Counseling**

Prevention counseling – also referred to as risk reduction counseling - is a critical part of HIV testing, counseling, and referral services for clients at risk for HIV infection. Most agency staff state that integrating prevention counseling with the pre-test (test-decision) process, as is done with conventional testing, continues to be the most effective way to offer risk reduction services with rapid testing. However, some agencies or staff may prefer to offer prevention counseling during the time that the test is developing or during the post-test counseling session after the result is provided. Agency staff should examine their site flow with rapid testing and identify how to offer prevention counseling in a convenient manner for clients and staff.

## **Assuring Quality**

### **Lead Quality Assurance (QA) Staff**

Each agency must designate a lead staff person responsible for assuring quality of their agency's rapid testing. This person will be responsible for assuring that:

- storage and site temperatures are monitored and documented;
- site testing log is completed accurately;
- devices and controls are used prior to expiration;
- the agency has sufficient test devices and controls to provide efficient services to clients; and
- staff are trained and following the protocol.

The lead QA staff person will be the first person notified by other testing staff when a test is invalid or external quality controls fail. This person will work with agency testing staff to determine the basis of the problem and to notify additional agency personnel as needed. Some large agencies will have a hierarchy of administrative staff who oversee quality assurance of testing. Each agency should develop communication mechanisms to assure that staff are made aware of testing problems and problem solving.

When problems arise, the lead QA staff or other administrative staff should contact either Kathleen Krchnavek at 608-267-3583 or the Wisconsin State Laboratory of Hygiene at 608-262-2366. Either of these contacts will provide technical assistance on resolving problems regarding rapid HIV antibody testing. In some circumstances, it may be necessary to contact the test manufacturer to report defective devices or controls.

### **Training**

As stated previously, all staff conducting rapid testing must participate in the following training sessions conducted by the Wisconsin AIDS/HIV Program through the Wisconsin HIV/AIDS Prevention Training Network:

- Foundations for HIV Prevention in Wisconsin
- Basic Counseling Skills for HIV Prevention
- HIV Counseling, Testing, and Referral Services – New Provider Training
- Rapid HIV Antibody Testing (either for OraQuick or Stat-Pak)

The lead quality assurance staff person can assure that staff are competent in rapid testing procedures by observing them in the various steps required for conducting a rapid test, (see Training Checklist – Appendix F).

In addition, all staff must be trained annually in bloodborne pathogen control (“universal precautions”) through their employer. Staff who conduct rapid testing with whole blood must be trained and competent in fingerstick collection of whole blood specimens. The

Wisconsin AIDS/HIV Program will provide opportunities for training on bloodborne pathogen control and fingerstick specimen collection, as needed. It is the responsibility of the agency to assure that staff are proficient and are implementing these activities. To comply with OSHA standards, the agency should document training of staff in bloodborne pathogen control and fingerstick specimen collection. All relevant training and results of competency assessment should be documented in the personnel file.

### **Competency Assessment**

At the completion of Wisconsin AIDS/HIV Program rapid testing training, all participants who intend to conduct rapid testing must successfully complete a competency assessment to assure that they can run tests and interpreting results properly. Each participant must conduct tests on six samples provided by the Wisconsin State Laboratory of Hygiene (WSLH) Proficiency Testing Program.

Staff identifying less than 5 of the 6 samples must participate in remedial training related to problems in conducting or interpreting the test. This may involve one-to-one discussion with the trainer, attending another training, or repeating the competency assessment.

In addition to the competency assessment, the Wisconsin AIDS/HIV Program recommends that the lead QA person at each agency complete the training checklist (see Appendix F) developed by the CDC to assure that staff accurately conduct rapid HIV testing. Lead QA staff should observe the newly trained staff when initially conducting rapid testing with clients.

### **Proficiency Testing**

Proficiency testing (PT) is another way to “test the tester.” Agencies are sent specimens on a periodic basis to test and interpret results. Their performance is scored based on how many tests were interpreted correctly. The goal is for all sites to obtain a score of 100% for each PT event.

Sites will be signed up for proficiency testing through the WSLH Proficiency Testing Program. Agencies are sent a panel of 5 specimens three times a year. Staff at the agency are to test the specimens and send WSLH the results which are scored on accuracy. Ideally, each staff person performing rapid testing will test and interpret at least some of the specimens each year. The lead QA staff at each agency will document that proficiency testing was completed and the staff person who tested and interpreted each specimen. When completed, the specimens should be disposed of in a biohazardous waste container.

The results from each PT event will be sent to both the agency and the Wisconsin AIDS/HIV Program. If an agency fails a PT event, the Wisconsin AIDS/HIV Program will

contact the lead QA staff person to assess the situation. Rapid testing may be halted at the site until the problems with testing or interpreting test results are resolved.

### **Use of External Quality Controls**

Using external quality controls on a consistent basis is an important tool to maintaining quality testing. Please refer to the details of how to use each test's controls in the specific OraQuick or Stat-Pak sections of this protocol.

### **Documentation**

To assure that conditions and key elements of the testing process are in place to assure quality testing, each site is required to complete the following documentation:

- 1) Testing Log – documentation of key information related to each specimen and control run at the site.
- 2) Inventory Log – documentation of when test kits and control kits are received by the agency, their lot numbers, expiration dates, the number of tests within each box, and the date that tests from this box were first used.
- 3) Storage Temperature Logs – documentation of temperature where controls *and* tests are stored.

More detailed information on each of these logs is described below.

1) Testing Log: Each time a test is run on a client specimen or an external control, the testing information must be logged. For each test, the following must be documented:

- Date of test
- Test ID number and client code/initials or positive or negative control
- Initials of staff performing test
- Whether absorbent packet was in the test pouch
- Current temperature of testing area
- When the test was started
- When the test was read
- Whether the internal control on the test device was valid
- Whether the result was reactive or non-reactive
- Whether a client specimen was sent for Western blot testing
- Results of Western blot test
- Comments (e.g. why external controls were run; troubleshooting for invalid results; whether client received confirmatory results; venue where test was done; etc.)

In addition, the lot numbers and expiration dates of both the tests and external quality controls must be documented at the top of the log.

All specimens and controls must be logged chronologically, so that the log provides an accurate history of testing at that location. **A new log should be started every time a new lot of tests or external controls are used.**

For a copy of the log and complete instructions, see Appendix C.

- 2) Inventory Log – Each time a shipment of tests or external quality controls is received by the agency, it should be documented on the log. The log should indicate when the item was received; the lot number; and the expiration date. The log should also indicate the date when devices from this box were first used. Items with the earliest expiration dates should be used first.

For a sample of this log, see Appendix D.

- 3) Storage Temperature Logs - Staff must document storage temperatures of both test kits and the controls on each day tests are performed. The Sample Temperature Log in Appendix E specifies a column for the high and low temperatures since the last reading as indicated on a min/max thermometer. If the temperature falls out of the specified range, staff must document what corrective action was taken.

When temperatures fall out of the required range for storing test kits, staff should run a set of external quality controls. If the expected results are obtained, the tests may be used. If either the tests are invalid or the expected results are not obtained, the tests should be disposed.

When temperatures fall out of the required range for storing external control kits, staff should use that set of controls to run a positive and negative control on test devices that have been stored properly. If the expected results are obtained, the controls may be used. If not, the controls should be disposed. This process should be done for each set of controls exposed to the out-of-range temperatures.

For a sample of this log, see Appendix E.

## **Troubleshooting**

Troubleshooting is a problem-solving process. When a test fails, staff must attempt to determine the source of the problem. Staff must try to answer the question “What went wrong?” The problems may rest with the testing process or conditions, the test device, or the specimen.

The lead QA staff person should be involved in the problem solving process. If the testing process and conditions met all specified requirements, staff must assess if there were problems with the devices. In a rare event, something about the specimen may cause the failure. On the next page is a process for evaluating an invalid test result:

## The Test Was Invalid...Now What?

1. Identify the problem using the following list of potential problem areas.

- Were the tests stored within the proper temperature range?
  - Was the temperature of the testing area within the proper range?
  - Was the test used prior to the expiration date?
  - Was the test kit at room temperature prior to testing?
  - Was the lighting in the testing area adequate for proper testing?
  - Was the absorbent packet present in the test pouch?
  - Was the first drop of blood wiped away and testing performed on the second drop?
  - Was the loop completely filled with blood prior to mixing in the developing solution?
- OraQuick only:**
- Was the vial in the manufacturer stand and on a level surface?
  - Did all of the developing solution remain in the vial (rather than being spilled or splashed out of it)?
  - Were the two holes on the back of the device left uncovered?
  - Did the solution turn pink?

2. If it is determined that any of the above conditions caused the invalid test result, staff should document on the *Testing Log* in the “Comments” section - the troubleshooting process; actions taken; and how staff verified that the corrective action taken addressed the problem. Staff should use the other side of the log if more space is needed.
3. If it is determined that none of the above conditions caused the invalid result, perform a second rapid test either with another client specimen or with a set of external quality controls.
4. If a client specimen was used and the second test is also invalid - run a set of external quality controls.
5. If the control tests come back invalid, discontinue testing. Report the problem to the test manufacturer and to Kathleen Krchnavek, Wisconsin AIDS/HIV Program 608-267-3583 or the Wisconsin State Laboratory of Hygiene Retrovirus Lab – 608-262-2366.

On the next page is a process for evaluating when external controls fail:

## The External Quality Controls Failed...Now What?

1. Identify the problem using the following list of potential problem areas.

- Were the tests stored within the proper temperature range?
- Was the temperature of the testing area within the proper range?
- Were the controls stored between 35°F and 46°F?
- Was the test used prior to the expiration date?
- Were the controls used prior to the expiration date?
- Was the test brought to room temperature prior to testing?
- Was the lighting in the testing area adequate for proper testing?
- Was the absorbent packet present in the test pouch?
- Was the loop completely filled with the control specimen?
- Was a new loop used with each control vial?
- Were the devices labeled correctly? (i.e. positive on a positive control and negative on a negative control)?

### **OraQuick only:**

- Were the OraQuick controls used no more than 8 weeks after they were first opened?
- Did the developing solution remain in the vial (rather than it being spilled or splashed out of it)?
- Were the two holes on the back of the device left uncovered?

2. If it is determined that any of the above conditions caused the external controls to fail, staff should document on the *Testing Log* in the “Comments” section - the troubleshooting process; actions taken; and how staff verified that corrective action taken addressed the problem. Staff should use the other side of the log if more space is needed.
3. If it is determined that none of the above conditions caused the external controls to fail, perform a second rapid test on another client specimen.
4. If the problem resolves with the second set of controls, dispose of the first set of controls.
5. If the problem remains with the second set of controls, contact the test manufacturer and Kathleen Krchnavek at 608-267-3583 or the Wisconsin State Laboratory of Hygiene Retrovirus Lab at 608-262-2366.

## **Record Review**

The lead QA staff person should review all testing documentation at least once per month to assure that testing practices meet the requirements indicated in the manufacturer's package insert and this protocol. The lead staff should also review whether the number of test kits left in inventory is consistent with the number of tests used as documented on the *Testing Log*.

Wisconsin AIDS/HIV staff will review testing documentation (testing logs, temperature logs, etc.) of grantee agencies at annual site visits.

## **Record Storage and Disposal**

Testing logs should be stored in a three ring binder or folder. The logs should be stored in chronological order. Logs should be stored for three years, and then disposed. If the logs have patient identifiers on them, the logs must be stored in a locked file cabinet in a locked room.

Completed informed consent forms should be stored for three years. Name-associated forms should be stored in a locked file cabinet in a locked room.

Temperature and inventory logs should be stored for two years, and then disposed.

For disposal, records with patient identifiers should be shredded. Otherwise, records may be disposed of in trash or recycling containers.

## Obtaining Devices and Controls

Agencies should contact Kathleen Krchnavek at 608-267-3583 or [krchnka@dhfs.state.wi.us](mailto:krchnka@dhfs.state.wi.us) to obtain more tests and external quality controls. Agencies should order needed tests and controls two weeks before current inventories run out.

Agency staff should maintain sufficient inventory of both tests and controls so that rapid testing services are not interrupted.

### **If an agency cannot use all of their tests prior to the expiration date...**

the lead staff person should contact Kathleen Krchnavek to find out whether another site can use the tests prior to expiration so that these tests are not wasted.

Staff should maintain an *Inventory Log* documenting the following (see “Documentation” section on p. 59):

- shipments receipt dates of test kits and controls
- lot numbers
- expiration dates
- when devices from the box were first used

Shipments with the earliest expiration dates should be used first. Tests should be kept in a secure area, and inventory should be reviewed to assure that the number of tests that remain are consistent with the number of tests that have been used.