MISSION
Insert agency’s Mission, services offered, etc.

OVERVIEW
The purpose of this protocol is to provide guidance and procedures for conducting Hepatitis C (HCV) rapid testing using the OraQuick® HCV Rapid Antibody Test. The OraQuick® HCV Rapid Antibody Test will be conducted at Insert where testing will take place as part of our screening initiative. It shall be the policy and procedure of the Insert Agency Name to perform HCV Rapid Testing on individuals identified as having associated risks and Select appropriate agency-specific option: to refer those found to have reactive rapid antibody results to a healthcare provider willing to perform diagnostic testing, HCV RNA or to conduct HCV RNA testing for those with a reactive antibody test.

Insert Agency Name must offer testing in accordance with the NYS HCV Testing Law (i.e., all persons born between 1945 and 1965), to those with risk factors associated with HCV (e.g. injection drug use, blood transfusion prior to 1992, etc.), to those presenting with symptoms and to those that request testing. The OraQuick® HCV Rapid Antibody Test is an immunoassay test for the detection of HCV antibodies in human finger stick and venipuncture whole blood. The Rapid HCV test can be performed manually and visually read within 20 minutes.

CLIENT ELIGIBILITY
All patients determined to be at risk for HCV will be encouraged to be tested. The OraQuick® HCV rapid antibody test is FDA approved for use on persons who meet the following eligibility criteria:

- Must not be pregnant
- Must have risk factor for HCV or signs or symptoms of HCV
- Must be at least 15 years of age (Insert Agency Policy on Consent for Minors. Parental consent is required for patients <18 years of age unless patient meets the medical treatment of a minor exception criteria outlined in PHL §2504.)

LABORATORY DIRECTOR
In accordance with NYS Guidance for following Standard Practices in Laboratory Medicine, the Laboratory Director or designee is responsible for oversight of all the HCV rapid testing program activities. Insert Medical Director or Designee Name will serve as the Laboratory Director and oversee all clinical/medical aspects of the testing program. The Laboratory Director is responsible for:
Training of staff performing tests and annual evaluation to demonstrate continued ability and knowledge to perform the test (competency assessment);
Maintaining an up to date procedure manual for all laboratory tests performed.
Making sure all tests are performed as written in the manufacturer’s package insert or device user’s guide;
Maintaining completed and accurate records of tests performed; and
Complying with other state and federal laws, including reporting of communicable diseases and other public health concerns (e.g. lead testing).

Insert Medical Director or Designee Name and Select appropriate agency-specific option will provide standing orders or will provide patient-specific orders for performing an OraQuick® HCV Rapid Antibody Test. HCV Testing will be conducted by qualified trained staff; staff will be annually in-serviced with a competency review. Insert Staff Name will serve as Coordinator of HCV Testing initiative including program coordination, ordering of supplies, forms, documentation and reports.

STAFF TRAINING
(Insert agency-specific information on staff training and monitoring staff proficiency.)

Staff conducting the OraQuick® Rapid HCV Test will receive initial device training by Insert Staff Name/Title or an OraSure Technologies Representative. Then at minimum, an annual competency assessment should be conducted on all testers to ensure proficiency in conducting the rapid antibody HCV test and performing controls.

All staff will be fully trained in the collection and handling of a specimen for HCV rapid testing. Staff will also be trained in the delivery of appropriate counseling messages. Job orientation and training will be documented for each staff member. Before an employee is permitted to perform a rapid test on a client, their ability to follow protocol will be demonstrated and documented. This assessment will be carried out by the program supervisor at periodic intervals following the training and will be documented.

All staff participating in the HCV Testing program will be trained in the following:

- Overview of hepatitis C, including counseling messages.
- Conducting an OraQuick® Rapid HCV Test and External Control.
- Specimen collection procedure for HCV rapid testing.
• Disposal of biohazardous materials.
• Reporting results to the patient and provider ordering the test.
• Process for providing and tracking referrals.
• Reporting requirements to HCV Rapid Testing Program.

EQUIPMENT AND MATERIALS REQUIRED FOR HCV RAPID TESTING:
• Package Insert
• Rapid package with a divide pouch containing: Test device and developer solution
• Reusable Test Stands
• HCV controls
• Specimen Collection Loops
• Timer
• Biohazard waste container
• Sterile lancet
• Antiseptic wipe
• Sterile gauze pads
• Band-Aid
• Disposable gloves
• Disposable absorbent workspace cover
• Refrigerator
• Thermometers
• Flat stable surfaces for testing
• Information pamphlet

SPACE WHERE TESTING IS PERFORMED
(Insert where testing will take place.)

Rapid HCV testing in clinical and/or nonclinical settings can be done anywhere that confidentiality of participants can be assured (e.g. private area or room) and where a specimen can be collected per minimal standards as outlined by the Occupational Safety and Health Administration (OSHA). The setting must have a flat surface, acceptable lighting, and the ability to maintain temperatures for performing the test in the range recommended by the test manufacturer. Participants must be able to stay long enough to be counseled and tested and to receive their results.
ENVIRONMENTAL CONDITIONS
OraQuick® HCV rapid test kits will be stored in an area with a temperature range of 2-30°C (degrees Celsius), 36-86°F (degrees Fahrenheit).

- Temperature of the test kit storage area will be taken daily (including weekends and holidays) and documented on the HCV Temperature Log.
- When using the OraQuick® HCV rapid test kits, the testing environment temperature will be in the range of 15-37°C, 59-99°F.
- A thermometer will be maintained in each testing areas to ensure recommended testing temperature range of 15-37°C, 59-99°F.
- Testing room temperature will be taken on days when testing is conducted and documented on the HCV Temperature Log or Patient Testing Log for each testing site.

HCV Kit Controls will be maintained in a refrigerator with a temperature range of 2-8°C, 36-46°F.

- Temperature will be taken daily (including weekends and holidays) and documented on HCV Control Storage Temperature Log. If corrective actions are required, a notation will be entered and signed with date of completion.
- Once opened, Kit Controls should be discarded after eight weeks. To ensure valid supply of kit controls, once opened each box should be clearly labeled with the expiration date, date opened and discard date (eight weeks from open date or expiration date, whichever comes first).

TRANSPORTING TESTING SUPPLIES
(Insert agency policy on transporting Test Kits off-site.)

Procedures are in place for transporting test kits to and from off-site testing venues. Procedures should include information on how kits are packaged, transported, and temperatures taken to ensure proper transport.

QUALITY CONTROL
The OraQuick® HCV Rapid Antibody Test Kit Controls are quality control reagents for use only with the OraQuick® HCV Rapid Antibody Test.

Internal Quality Control: The OraQuick® HCV Rapid Antibody Test has a built-in procedural control that demonstrates assay validity. A reddish-purple line in the Control Zone (C Zone) of the Result Window indicates that a specimen was added and that the fluid migrated appropriately through the Device. The Control line will appear on all valid tests, whether or not the sample is reactive or non-reactive for anti-HCV.
External Quality Control: The OraQuick® HCV Rapid Antibody Test Kit Controls are human plasma based reagents. The Kit Controls are specifically formulated and manufactured to ensure proper performance of the test. The HCV Positive Control will produce a reactive reddish-purple line at the Test (T) Zone. The HCV Negative Control will generate a non-reactive test result (no reddish-purple line at the Test (T) Zone). Use of kit control reagents manufactured by any other source will not meet the requirements for an adequate quality assurance program for the OraQuick® HCV Rapid Antibody Test.

Run the External Controls under the following circumstances:

- Each new operator prior to performing testing on patient specimens,
- When opening a new test kit lot,
- Whenever a new shipment of test kits is received,
- If the temperature of the test kit storage area falls outside of 2-30°C, 36-86°F,
- If the temperature of the testing area falls outside of 15-37°C, 59-99°F, and
- Controls will be run at least monthly and more often as needed based on testing volume, and as directed by the Laboratory Director. (See guidance below)

Additional manufacturer guidance on frequency of running external controls based on test volume: In addition to the specific circumstances listed above, testing sites should determine the optimal frequency for running controls based on test volume. When external controls provide incorrect results, none of the tests that were run since the last control can be considered valid. Those tested since the last control ran correctly will need to be called back for retested (unless diagnostic testing was conducted). High volume testing sites, and especially those that offer anonymous testing, should plan to run controls more often. Each site needs to decide how often to run controls based on its own situation and testing practices.

The CDC’s original guidelines recommend facilities that test 25 or more subjects a day should run controls every day. Low volume sites, such as those testing fewer than 25 subjects per month, should run external controls every two to four weeks at a minimum. Controls should be run more often if new lots or shipments are opened or if storage or testing temperatures fluctuate.

If Control Kit fails during testing of the control, Insert Staff Name/Title will repeat test using new Test Device, developer solution vial and control specimen. (Ensure
If Control Kit does not perform a second time, Insert Staff Name/Title will discontinue testing and contact the Laboratory Director and OraSure Technologies Representative.

**Documentation of Controls:**
All documentation will be on the HCV Rapid Antibody Quality Control (QC) Log:

- Date and time of control testing
- Initials of staff person running the control
- Lot number and expiration date of test kit
- Lot number and expiration date of control
- Control results
- Corrective action taken if control were unacceptable

**COLLECTION REQUIREMENTS AND SPECIMEN REJECTION CRITERIA:**

**SPECIMEN COLLECTION AND TESTING PROCEDURE**
The OraQuick® HCV Rapid Antibody Test can be used for testing fingerstick whole blood specimens and venipuncture whole blood specimens. Refer to the specific testing procedure below.

**FINGERSTICK WHOLE BLOOD AND VENIPUNCTURE WHOLEBLOOD PROCEDURE**

**STEP 1: COLLECT**

**STEP 1A: FINGERSTICK WHOLE BLOOD**
1. Using an antiseptic wipe, clean the finger of the person being tested. Allow the finger to air dry. Using a sterile lancet, puncture the skin just off the center of the finger pad. Hold the finger downward and apply gentle pressure beside the point of the puncture. Avoid squeezing the finger to make it bleed (see picture 5). Wipe away the first drop of blood with a sterile gauze pad and allow a new drop of blood to form.
2. Obtain an unused Specimen Collection Loop by the handle (see picture 6). Place the rounded end of the Loop on the drop of blood (see picture 7) and verify that the Loop is completely filled with blood (see picture 8). **NOTE:** If the Loop is dropped or comes in contact with any other surface, discard it in a biohazard waste container. Obtain a new Loop for the collection of the blood specimen.

3. **STEP 1B: VENIPUNCTURE WHOLE BLOOD**

1. Using standard venous phlebotomy procedures collect a whole blood specimen using a tube containing any of the following anticoagulants: EDTA, sodium heparin, lithium heparin, or sodium citrate. **Other anticoagulants have not been tested and may cause an inaccurate result.** If the specimens are not tested at the time of collection, the whole blood may be stored at 2°-8°C (36°-46°F) for up to 7 days or at 15°-30°C (59°-86°F) for up to 3 days.

2. Prior to testing, mix the blood tube gently by inversion several times to ensure a homogeneous specimen. Obtain an unused Specimen Collection Loop by the handle (see picture 9). Insert the rounded end of the Loop into the tube of blood (see picture 10), and verify that the Loop is completely filled with blood (see picture 11). **NOTE:** If the Loop is dropped or comes in contact with any other surface, discard it in a biohazard waste container. Use a new Loop for the collection of the blood specimen.

**STEP 2: MIX**

1. Immediately insert the blood-filled end of the Loop all the way into the Developer Vial (see picture 12). Use the Loop to stir the blood sample in the Developer Solution (see picture 13). Remove the used Loop from the Solution and discard in a biohazard waste container.

2. Verify that the Solution is pink in color, indicating that the blood was thoroughly mixed into the Solution (see picture 14). If the Solution is not pink, discard all test materials in a biohazard waste container. Start the test over using a new Pouch and a new blood sample. **NOTE:** To ensure accurate results, the Test Device
must be inserted into the Developer Solution Vial within 60 minutes after introducing the specimen into the Developer Solution.

STEP 3: TEST
1. Remove the Device from the Pouch. **DO NOT** touch the Flat Pad (*see picture 15*). Verify that an Absorbent Packet is included with the Device (*see picture 16*). If no Absorbent Packet is present, or if the Absorbent Packet is damaged, discard the Device and obtain a new Pouch for testing.

2. Insert the Flat Pad of the Device all the way into the Developer Vial containing the blood sample (*see picture 17*), and verify that the Flat Pad touches the bottom of the Developer Vial. The Result Window on the Device should be facing towards you (*see picture 18*).

3. Start timing the test (*see picture 19*). **DO NOT** remove the Device from the Developer Vial while the test is running. A pink color will migrate up the Result Window, and will gradually disappear as the test develops (*see picture 20*). Read the result in a fully lighted area after 20 minutes, but no more than 40 minutes.

4. Refer to the *Test Result and Interpretation of Test Result* section in this package insert.

GENERAL TEST CLEAN-UP
1. Dispose of the used test materials and gloves in a biohazard waste container.
2. When using gloves, change gloves between each test to prevent contamination.
3. Use a freshly prepared 10% solution of bleach to clean up any spills.

**TEST RESULTS AND INTERPRETATION OF TEST RESULT:**
Refer to the Result Window on the Test Device.
A test is **REACTIVE** if:
- A line appears in the C Zone and a line appears in the T Zone. Lines may vary in intensity. The test is reactive regardless of how faint these lines appear (see pictures 21, 22 and 23).

A **REACTIVE** test result means that HCV antibodies have been detected in the specimen. Patient is presumed to be infected with HCV. Individuals with a reactive result in the OraQuick® HCV Rapid Antibody Test should undergo appropriate clinical follow-up, per CDC recommendations for supplemental testing.

A test is **NON-REACTIVE** if:
- A line appears in the C Zone and NO line appears in the T Zone (see picture 24).

A **NON-REACTIVE** test result means that HCV antibodies were not detected in the specimen. Patient is presumed not to be infected with HCV.

A test is **INVALID** if:
- **NO** line appears in the C Zone (see picture 25), or
- A pink background obscures the results during the 20- to 40 minute read times (see picture 26), or
- Any partial line on one side of the C or T Zones (see pictures 27 and 28).

An **INVALID** test result means that there was a problem running the test, either related to the specimen or to the Device. **An INVALID result cannot be interpreted.** Repeat the test with a new Pouch and a new specimen. Contact OraSure Technologies’ Customer Service if you are unable to get a valid test result upon repeat testing.

**Criteria for corrective action**
- Test Device is expired.
- Test Device not packaged with absorbent package.
- Area being tested does not fall between 15°-37°C, 59°-99°F.
- Reading test results earlier or later than 20 minutes or later than 40 minutes.
RECORDKEEPING:
Recordkeeping is an important part in laboratory testing, showing that the HCV rapid test was performed properly and all required steps were completed.

- Storage Temperature Logs will be maintained and recorded daily for test kits and controls (refrigerated and unrefrigerated).
- Testing Room Temperature Logs will be maintained and recorded on days when testing occurs at all sites. Documentation of temperature readings can be maintained on a separate log for each testing site and/or on the patient log at the time of testing.
- Control Logs will be maintained and controls will be run per manufacturer recommendations (minimum monthly). Logs must include the time, date, staff person running and reading the control, the kit lot number and expiration date, the control lot number and expiration date, results, and corrective action taken if control was unacceptable.
- Select appropriate agency-specific option: Log books, electronic medical records or patient’s charts will be used to maintain and track point of care testing information. Required elements will include the kit lot number and expiration date, date test performed, test result and staff who performed the test. (See guidance below)
  - For ease of monthly aggregate data collection and reporting, a sample patient log is available for tracking of results and basic demographics to meet Limited Service Laboratory and NYS HCV Rapid Testing Program reporting requirements.
- All temperature, control and patient logs will be reviewed at minimum monthly by Insert Staff Name/Title.
- Annual review of all HCV Rapid Testing Program logs, testing records, staff competency reviews, and policy and procedures will be conducted by the Insert Laboratory Director Name.

REFERRAL FOR DIAGNOSTIC TESTING AND LINKAGE TO CARE:
For clients, whose test results are Non-Reactive, counselors will address personal HCV risk reduction and the need for repeat testing in the future if the HCV exposure was recent. Counselors will also provide referrals to in-house prevention and health care programs and/or other community based service organizations.

For clients, whose test results are Non-Reactive counselors will:
- Inform client they are probably not infected with Hepatitis C.
Recommend retesting if individual engaged in risky behavior in the last 6 months.
Remind client that non-reactive results do not protect them from getting HCV in the future.
Provide basic liver and hepatitis education.
Ensure that the client has accurate information about steps necessary to prevent infection.
Elicit and correct misperceptions about HCV transmission risk and address strategies for prevention of other sexually transmitted disease or blood borne infections.
Ensure that the client knows where and how to obtain more information and services.
Assess the need for and provide, or make referrals for, other prevention services.

A Reactive result means that HCV antibodies have been detected and further diagnostic testing (HCV RNA) is necessary to confirm or rule out active HCV infection.

For clients, whose test results are Reactive counselors will:

- Select the appropriate agency-specific option: Refer the client to Insert Referral Agency’s Name for HCV diagnostic testing (HCV RNA) and medical evaluation or collect additional specimen for HCV RNA testing. Client may choose to see primary care provider, if already established with a care provider.
- Provide psychological support and referral for additional counseling if required.
- Provide basic liver and hepatitis education.
- Ensure that the client knows where and how to obtain more information and services.
- Assess the need for and provide, or make referrals for, other prevention services.
- Ensure that the client has accurate information about steps necessary to prevent transmission.
- Elicit and correct misperceptions about HCV transmission risk and address strategies for prevention of other sexually transmitted disease or blood borne infections.
- Track all referral appointments and document outcomes in the client file.
Data Entry
Program data is submitted monthly to the AIDS Institute via the HCV Rapid Testing Program application found on the Health Commerce System (HCS). Testing logs are submitted to Insert Staff Title who aggregates, inputs, and submits all aggregate and client level data reports. Data is due to the AIDS Institute, HCV Rapid Testing Program by 30 days after the month ends. Insert Staff Title will respond to feedback on data quality from the HCV Rapid Testing Program staff on a routine basis or as needed.

Laboratory Director Signature: ____________________________

Date Reviewed: ________________