ANTI-HCV SCREENING by ORAQUICK® HCV RAPID ANTIBODY TEST

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

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

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

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

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

QUALITY CONTROL:

EXTERNAL QUALITY CONTROL:

ORAQUICK® *HCV* RAPID ANTIBODY CONTROL TEST KIT CONTAINS:

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

ORAQUICK® *HCV* VISUAL REFERENCE PANEL CONTAINS:

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

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

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

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

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

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

How to Perform Quality Control?

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

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

INTERNAL QUALITY CONTROL

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

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

TEST PROCEDURE:

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

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

II. Using a sterile lancet, puncture the skin off the center of the finger pad.
III. Hold the finger downward. Apply gentle pressure beside the point of the puncture. Avoid "squeezing" or "milking" the finger to obtain blood.
IV. Wipe away the first drop of blood with a sterile gauze pad. Allow a new drop to form.
V. Take a clean, unused Specimen Collection Loop, and fill the loop completely with blood.
VI. Immediately insert the blood-filled end of the loop into the solution in the vial and stir the blood sample into the solution (preferably in a back and forth motion).
VII. Make sure that the solution appears pink. If blood did not fully fill the loop, or if the solution is not pink, discard the test materials and start again with a new pouch, new lancet, and fresh fingerstick.

8. Insert the flat pad of the test device (labeled with the client's ID) into the developer solution. Make sure that the pad touches the bottom of the vial and that you can see the result window.
9. Start timing the test. Record the start time on the test log sheet.
10. Read the results after at least 20 minutes, but not more than 40 minutes have passed. Record the read time on the test log. If the test is not read within 40 minutes, discard the test materials and start again. The test is invalid.

TEST INTERPRETATION:

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

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

11. Record test results:

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

Expected Values:

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

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

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

Procedural Notes:

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

Limitations of the Procedure:

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

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

References:

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

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