Public Health Division
Infectious Disease Bureau
Hepatitis Program

Protocol and Standing Orders for Public Health Nurses and Staff with Current Certification to conduct **Rapid Testing for the Hepatitis C Virus (HCV) using the Oraquick® Test Device**

February 2019

Contents

New Mexico Department of Health
Public Health Division
Protocol

Rapid Testing for the Hepatitis C Virus (HCV) using the Oraquick® Test Device

Introduction

There are approximately 35,000 - 45,000 New Mexicans with chronic infection with the hepatitis C virus (HCV). Between 2007 and 2012, there were 22,252 reported cases of HCV and roughly 2,600 confirmed positive cases each year. A high proportion – perhaps half - of New Mexicans who are infected with hepatitis C do not know their status. Rapid Testing can overcome this challenge by performing the test and providing results during a single visit. This test is particularly advantageous when testing at rural clinics, public venues, outreach sites, or community events.

The Oraquick® HCV Rapid Antibody Test is the only rapid, point-of-care test for the detection of antibodies to HCV approved by the U.S. Food and Drug Administration (FDA). The test provides results in 20 minutes. The FDA approved the test to utilize whole blood specimens via finger stick. The test was granted a waiver by the FDA under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) in 2011, which allows it to be used in non-laboratory facilities.

Service Population

HCV Rapid Testing can be offered as an option by any test site which also offers conventional HCV testing using a blood draw which is submitted to a laboratory. Trained staff can offer clients the option of a Rapid Test, especially to those individuals who are transient or less likely to return for results for personal reasons such as fear about their status, transportation challenges, or competing personal priorities.

The Oraquick® HCV Rapid Antibody Test is intended by the manufacturer for use in persons at-risk for hepatitis C and is not recommended for screening of the general population. Therefore, it should normally only be offered to individuals with known risk factors that match NMDOH priorities and protocols. Based on the Hepatitis Program's protocol, NMDOH considers the following populations to be at risk and therefore good candidates for this testing:

- Currently injecting substances
- Ever injected substances, including those who injected once or a few times many years ago
- Have certain medical conditions, including persons:
    - who received a transfusion of blood, blood components, or an organ transplant before July 1992
    - who have HIV infection, OR
    - with acute or chronic hepatitis B infection

- Individuals using intranasal cocaine and/or other non-injected illicit substances

In addition, any individual born between 1945 and 1965 is eligible for testing regardless of risk factors if they have indicated they have never received a previous HCV test.

The Oraquick® HCV Rapid Antibody Test is solely a screening tool, so all reactive tests must be confirmed. Persons who are exposed to HCV and clear the virus will still have reactive results to this antibody test; this is fairly frequent as roughly one-quarter of persons infected with HCV will clear the virus. Confirmatory testing normally utilizes a qualitative HCV RNA or other viral load test to determine if an individual is currently infected with HCV. PHD does not normally offer this test due to cost, so having a place for referrals is essential prior to offering testing.

Persons who previously tested negative for hepatitis C but who identify active ongoing risks factors for hepatitis C acquisition should be offered re-testing to screen for newly acquired infection. The most significant risk factor would be current injection of substances.

Persons listed below should generally be referred to an outside medical provider for their testing.

- Any individual at occupational risk of exposure
- Routine testing of sexual and household contacts to hepatitis C
- Routine testing of persons with tattoos or body piercings received at licensed facilities
- General population
- Persons with multiple sex partners
- Children born to HCV positive mothers

For testing regarding potential accidental needle-sticks please refer to the PHD Infection Control for Healthcare Worker protocol.

Procedure and Methodology

All staff, volunteers, and contracted professionals must complete the current NMDOH HIV/HCV Counseling and Testing Training. This approved 3-day training includes the Essentials of Oraquick® HCV Rapid Antibody Test, and HCV Counseling, Testing & Referral. The HIV/HCV Counseling and Testing Training must be completed with a passing proficiency prior to offering/administration of Oraquick® HCV Rapid Antibody Test. This course is based on the Center for Disease Control and Prevention (CDC): *HCV Counseling and Testing Manual (2013).* The training is provided through the NMDOH HIV Prevention Program and is free of charge. All participants who complete the training will receive a Training Certification Card to document their fulfillment of this requirement.

Prior to testing, the tester should ask the client about prior testing for HCV or diagnosis of HIV infection – If a client has been previously diagnosed as having been exposed to HCV or is currently infected with HCV, ensure the client is linked to care. If the client is not linked to care then provide appropriate referrals for confirmatory testing or treatment.

1. Documentation and Reporting

Hepatitis C is one of over 90 diseases and conditions that are required to be reported under New Mexico Statutes Annotated 1978 Section 9-7-6(E) and in conformity with Chapter 24, Article 1 ("the Public Health Act"), sections 24-1-3C, 24-1-7, and 24-1-15. All positive HCV test results, including both standard lab tests and reactive rapid HCV antibody results, are therefore reportable by law to NMDOH.

Results should be reported within 72 hours of notification of **reactive** test results. The Confidential Rapid Hepatitis C Reporting Form (Appendix A) must be filled out completely and faxed to NMDOH ERD, 505-827-0013.

As with all laboratory tests run by PHD either in Public Health Offices (PHO) or during outreach, rapid point-of-care tests such as Oraquick® HCV Rapid Antibody Test must be documented in BEHR. Therefore, the client should be registered in BEHR prior to running the test. For clinicians and nurses performing these tests, a regular BEHR note for this service must be entered.

When rapid point-of-care tests are run by staff who are not clinicians or nurses, the documentation is slightly different. This applies to Disease Prevention Specialists (DPS), other health educators, and any other staff running rapid tests. A regular BEHR note must still be created, however, the "owner" of the note must be a clinician who can sign off and close the note. It is recommended that the "BEHR down" protocol be followed when conducting outreach testing.

The Rapid HCV Testing Log (Appendix D) is the form used to record every rapid HCV test run by PHD team members. Copies of these logs must be submitted on

a monthly basis, either directly to the NMDOH Hepatitis Program or to the assigned contact in each Public Health Region such as the HIV Health Educator.

2. Required Materials & Test Administration

Please see the PHD Laboratory Standard Operating Procedures for required materials and test administration.

Note: although the Oraquick® HCV Rapid Antibody Test is FDA-approved and CLIA waived for sample collection via venipuncture, **this alternative sample collection process is not approved or recommended for PHD.**

3. Test Result and Interpretation

Please see the PHD Laboratory Standard Operating Procedures for test resulting and interpretation.

1. Rapid test **INVALID:** an invalid test result means there was a problem running the test either related to the specimen or to the test device. An invalid result cannot be interpreted.
    - Offer to repeat the rapid test with a new test kit and new specimen using the same type of specimen.
        i. If the second rapid test is invalid, re-test the client by a conventional blood test.
        ii. If the patient declines the second rapid test, re-test the client by a conventional blood test.
    - Conduct quality assurance procedures. External controls must be run after two consecutive invalid test results to verify the test kits are functioning properly before any other rapid tests are conducted.
2. Rapid test **NON-REACTIVE:** a non-reactive test means hepatitis C antibodies were not detected in the specimen.

    <u>Window period</u>
    There is an amount of time after HCV infection occurs before antibodies are detectable by the antibody test. This time is called the “window period.” HCV antibody can be detected in the blood within four to ten weeks after infection. The average window period for the development of HCV antibodies is eight to nine weeks. Ninety out of 100 people exposed to HCV develop antibodies after three months, and 97 out of 100 people have detectable levels of antibodies by six months after infection. If an individual’s exposure falls within in this time frame or is continuous (e.g., ongoing injection of substances) the Window Period is a concern. If client is being tested because of exposure within past 6 months, referral for HCV nucleic acid testing or follow-up antibody testing is recommended.

3. Rapid test **REACTIVE:** a reactive test means hepatitis C antibodies were detected in the specimen and indicate infection (current or resolved) pending confirmatory testing.
    - Refer the client to a healthcare provider to get a confirmatory test to determine if they are currently infected.
    - Refer to the Oraquick® HCV Rapid Antibody Test Algorithm in Attachment A.

    Record **REACTIVE** test results on the Confidential Rapid HCV Reporting Form and submit this report in a confidential fashion to the NMDOH Epidemiology and Response Division (ERD).

4. Safety Precautions

Please see the PHD Laboratory Standard Operating Procedures for general and specific test safety precautions.

For additional Safety Precautions see NMDOH Blood Borne Pathogens Training.

5. Quality Control Procedures

Please see the PHD Laboratory Standard Operating Procedures for test quality control procedures.

Refer to Attachment C for the External Controls Log.

PUBLIC HEALTH DIVISION STANDING ORDER FOR NURSES

PROGRAM: Hepatitis Prevention Program, Infectious Disease Bureau

CLINICAL PROTOCOL/MANUAL TITLE: **Rapid Testing for the Hepatitis C Virus (HCV) using the Oraquick® Test Device**

Purpose: to identify individuals with HCV and refer for comprehensive care, both for individual treatment and for prevention of further spread of HCV.

Policy: Under these standing orders, eligible nurses and other healthcare professionals, where allowed by state law, may perform HCV screening.

Procedure:

1. Determine the client meets one (or more) of the following criteria:
    a. Is a current or former IV substance user; OR
    b. Is positive for HIV; OR
    c. Received a blood transfusion or organ transplant prior to 1992; OR
    d. Has acute or chronic Hepatitis B infection; OR
    e. Is a non-injection substance user who shares intranasal or inhalant equipment; OR
    f. Was born between 1945 and 1965 and has have never received a previous HCV test.
2. Obtain consent from client for HCV screening.
3. Collect and process blood according to "Methodology" as described in the **PHD Rapid Testing with Hepatitis C Virus (HCV) using the Oraquick Test Device** protocol.

2. Interpret results as per "Methodology" of the PHD protocol.

3. ***Reactive screening results:*** Refer patient to a provider that can order and follow up with confirmatory testing. Encourage patient to have a confirmatory test drawn immediately, and begin education and referral for care.

4. Document each patient's result in the medical chart. Task the Regional Health Officer to sign the medical chart note in BEHR for all reactive tests for nurses, and for all records for non-licensed staff.

For any issues not covered by this order, please contact the Regional Health Officer or other designated prescribing clinician for further guidance.

Place this standing order with your Hepatitis AND your Standing Orders Notebook.

This standing order shall remain in effect until rescinded.

Licensed Prescriber	NPI	Signature	Date

Christopher Novak NW Region (Acting)	1508834110		
Thomas Massaro NE Region	1760551394		
Eugene Marciniak SE Region (Acting)	1407830458		
Eugene Marciniak SW Region	1407830458		

References

OraQuick® HCV Rapid Antibody Test – Package Insert – Produced by OraSure Technologies, Inc., 220 East First Street, Bethlehem, PA 18015. Dated 2013

Attachments

Attachment A. Confidential Rapid Hepatitis C Reporting Form

Attachment B. Rapid HCV Antibody Test Algorithm

Attachment C. Test Temperature Log

Attachment D. External Quality Controls Log

Attachment E. Antibody Test Result Log

Attachment F. PHD Clinical Protocol Approval Sheet

Attachment G. Acknowledgement and Receipt of New/Revised Protocol

Attachment A. Confidential Rapid Hepatitis C Reporting Form

Confidential Rapid HCV Reporting Form

Instructions: Fax completed form to: 505.827.0013 or mail to:

Infectious Disease Epidemiology Bureau
1190 St. Francis Drive, N1350
P.O. Box 26110
Santa Fe, NM 87502-6110

Site ID #_____ Test #:_____

Name of Person Conducting Test:_____ Phone: (____)_____

Date of Test:_____/_____/_____

Client Information:

Last Name:_____ First Name:_____ Middle Name:_____

DOB:___/____/____ Gender at Birth: □ Male □ Female; Current Gender Identity: □ Male □ Female □ Declined

Street Address:_____

City:_____ State:_____ Zip:_____

Phone Number(s): Home (____)_____ Work: (____)_____ Cell: (____)_____

Ethnicity: □ Hispanic □ Non-Hispanic □ Don't Know □ Declined

Race: □ American IN/AK Native □ African American/Black □ Asian □ White □ Native HI/Pac Islander □ Declined

Risk Factors:

□ Past or present PWID □ HIV positive □ Blood transfusion or organ transplant prior to 1992 □ HBV positive

□ Sharing of intranasal drug equipment □ Born to HCV positive mother □ Household exposure w/HCV positive person

□ Long-term sexual contact w/HCV positive person □ Recipient of clotting-factor prior to 1987

□ Tattoo or body piercing performed in a non-sterile environment or by unlicensed individual

Test Information:

Reason for Testing? _____

Previous HCV test? Yes □ No □ Result? Positive □ Negative □

Is client symptomatic? Yes □ No □ If Yes, date of onset: ____/____/____

If Yes, check all that apply: □ Fatigue □ Abdominal Pain □ Anorexia □ Nausea □ Vomiting □ Other _____

Was client jaundiced? Yes □ No □ If Yes, date of Onset: ____/____/____

Was the client informed of their test results? Yes □ No □ If No explain? _____

Did the client receive HCV counseling? Yes □ No □ If No explain? _____

Was client referred for confirmatory testing? Yes □ No □ If No explain? _____

If Yes, where? _____

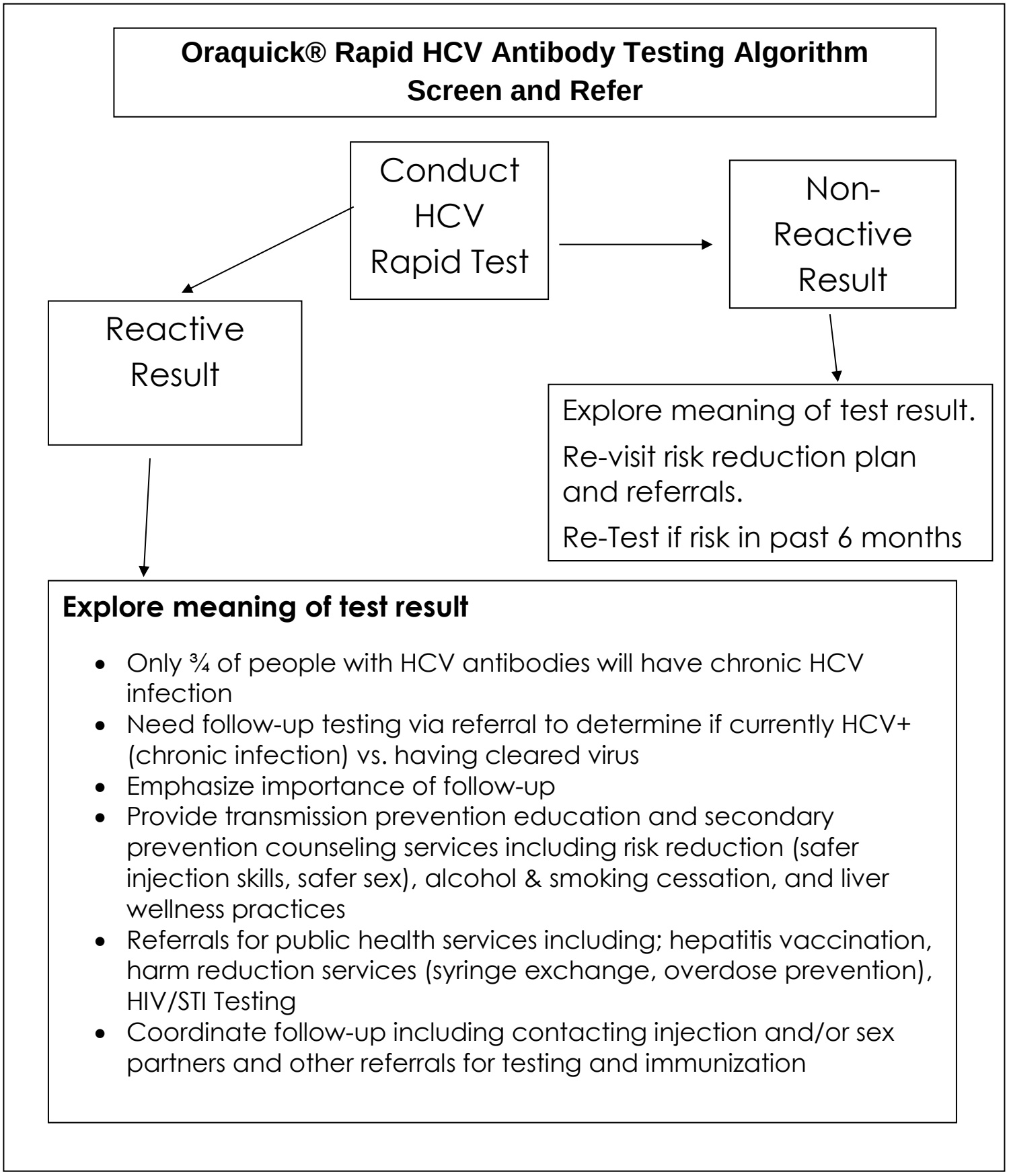
Additional Referrals: □ HBV testing □ SSP □ Overdose prevention □ Health Insurance □ HIV testing

□ Substance use treatment □ STD Testing □ Acu-detox □ Immunization Other _____

EPIDEMIOLOGY AND RESPONSE
1190 St. Francis Drive, N1320 • Santa Fe, New Mexico • 87502-6110
(505) 827-0006 • FAX: (505) 827-0013 • http://www.nmhealth.org Rev.1 4/13/15

SAMPLE

Attachment B. Rapid HCV Testing Algorithm



Attachment C. Oraquick® HCV Rapid Antibody Test Temperature Log

Month and Year:

Storage of External Controls			
Day		Temp	Initials
1	a.m.	°F	
	p.m.	°F	
2	a.m.	°F	
	p.m.	°F	
3	a.m.	°F	
	p.m.	°F	
4	a.m.	°F	
	p.m.	°F	
5	a.m.	°F	
	p.m.	°F	
6	a.m.	°F	
	p.m.	°F	
7	a.m.	°F	
	p.m.	°F	
8	a.m.	°F	
	p.m.	°F	
9	a.m.	°F	
	p.m.	°F	
10	a.m.	°F	
	p.m.	°F	
11	a.m.	°F	
	p.m.	°F	
12	a.m.	°F	
	p.m.	°F	
13	a.m.	°F	
	p.m.	°F	
14	a.m.	°F	
	p.m.	°F	
15	a.m.	°F	
	p.m.	°F	

Testing Storage Area			
Day		Temp	Initials
1	a.m.	°F	
	p.m.	°F	
2	a.m.	°F	
	p.m.	°F	
3	a.m.	°F	
	p.m.	°F	
4	a.m.	°F	
	p.m.	°F	
5	a.m.	°F	
	p.m.	°F	
6	a.m.	°F	
	p.m.	°F	
7	a.m.	°F	
	p.m.	°F	
8	a.m.	°F	
	p.m.	°F	
9	a.m.	°F	
	p.m.	°F	
10	a.m.	°F	
	p.m.	°F	
11	a.m.	°F	
	p.m.	°F	
12	a.m.	°F	
	p.m.	°F	
13	a.m.	°F	
	p.m.	°F	
14	a.m.	°F	
	p.m.	°F	
15	a.m.	°F	
	p.m.	°F	

Testing Room			
Day		Temp	Initials
1	a.m.	°F	
	p.m.	°F	
2	a.m.	°F	
	p.m.	°F	
3	a.m.	°F	
	p.m.	°F	
4	a.m.	°F	
	p.m.	°F	
5	a.m.	°F	
	p.m.	°F	
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	p.m.	°F	
12	a.m.	°F	
	p.m.	°F	
13	a.m.	°F	
	p.m.	°F	
14	a.m.	°F	
	p.m.	°F	
15	a.m.	°F	
	p.m.	°F	

SAMPLE

Note: HCV rapid test must be stored/transported in a temp range of 36° - 86° F and must be operated in a temp range of 59° – 99° F. Controls must be stored in temp range of 36° - 46° F.

Month and Year:

Storage of External Controls			
Day		Temp	Initials
16	a.m.	°F	
	p.m.	°F	
17	a.m.	°F	
	p.m.	°F	
18	a.m.	°F	
	p.m.	°F	
19	a.m.	°F	
	p.m.	°F	
20	a.m.	°F	
	p.m.	°F	
21	a.m.	°F	
	p.m.	°F	
22	a.m.	°F	
	p.m.	°F	
23	a.m.	°F	
	p.m.	°F	
24	a.m.	°F	
	p.m.	°F	
25	a.m.	°F	
	p.m.	°F	
26	a.m.	°F	
	p.m.	°F	
27	a.m.	°F	
	p.m.	°F	
28	a.m.	°F	
	p.m.	°F	
29	a.m.	°F	
	p.m.	°F	
30	a.m.	°F	
	p.m.	°F	
31	a.m.	°F	
	p.m.	°F	

Testing Storage Area			
Day		Temp	Initials
16	a.m.	°F	
	p.m.	°F	
17	a.m.	°F	
	p.m.	°F	
18	a.m.	°F	
	p.m.	°F	
19	a.m.	°F	
	p.m.	°F	
20	a.m.	°F	
	p.m.	°F	
21	a.m.	°F	
	p.m.	°F	
22	a.m.	°F	
	p.m.	°F	
23	a.m.	°F	
	p.m.	°F	
24	a.m.	°F	
	p.m.	°F	
25	a.m.	°F	
	p.m.	°F	
26	a.m.	°F	
	p.m.	°F	
27	a.m.	°F	
	p.m.	°F	
28	a.m.	°F	
	p.m.	°F	
29	a.m.	°F	
	p.m.	°F	
30	a.m.	°F	
	p.m.	°F	
31	a.m.	°F	
	p.m.	°F	

Testing Room			
Day		Temp	Initials
16	a.m.	°F	
	p.m.	°F	
17	a.m.	°F	
	p.m.	°F	
18	a.m.	°F	
	p.m.	°F	
19	a.m.	°F	
	p.m.	°F	
20	a.m.	°F	
	p.m.	°F	
21	a.m.	°F	
	p.m.	°F	
22	a.m.	°F	
	p.m.	°F	
23	a.m.	°F	
	p.m.	°F	
24	a.m.	°F	
	p.m.	°F	
25	a.m.	°F	
	p.m.	°F	
26	a.m.	°F	
	p.m.	°F	
27	a.m.	°F	
	p.m.	°F	
28	a.m.	°F	
	p.m.	°F	
29	a.m.	°F	
	p.m.	°F	
30	a.m.	°F	
	p.m.	°F	
31	a.m.	°F	
	p.m.	°F	

SAMPLE

Note: HCV rapid test must be stored/transported in a temp range of 36° - 86° F and must be operated in a temp range of 59° – 99° F. Controls must be stored in temp range of 36° - 46° F.

Attachment D. Rapid HCV Antibody Test External Quality Control Log

Office Name:	

SAMPLE

Date & Time	Room Temp	Divided Pouch Lot #	Divided Pouch Exp. Date	Kit Controls Lot #	Kit Controls Exp. Date	Date Controls Opened	Control Results	Results Acceptable	Staff Initials	Purpose for running controls/comments	Reviewed by & Date
							☐ Non-Reactive ☐ Reactive	☐ YES ☐ NO			
							☐ Non-Reactive ☐ Reactive	☐ YES ☐ NO			
							☐ Non-Reactive ☐ Reactive	☐ YES ☐ NO			
							☐ Non-Reactive ☐ Reactive	☐ YES ☐ NO			
							☐ Non-Reactive ☐ Reactive	☐ YES ☐ NO			
							☐ Non-Reactive ☐ Reactive	☐ YES ☐ NO			
							☐ Non-Reactive ☐ Reactive	☐ YES ☐ NO			
							☐ Non-Reactive ☐ Reactive	☐ YES ☐ NO			
							☐ Non-Reactive ☐ Reactive	☐ YES ☐ NO			

Please note: Controls must be stored in temp range of 36° - 46° F.
The Controls lot # to be used is located on the box.

Attachment E. Oraquick® Rapid HCV Antibody Test Log

Office Name:	

Date	Staff Initials	Client Name	Client DOB	Contact info	Test Lot #	Test Exp. Date	Test Start Time	Test Area Temp	Test Read Time	Test Result	QA Reviewer Initials and Date	Comments/Notes

SAMPLE

Note: HCV rapid test must be stored/transported in a temp range of 36° - 86° F and must be operated in a temp range of 59° – 99° F.

PUBLIC HEALTH DIVISION
CLINICAL PROTOCOL/MANUAL APPROVAL SHEET

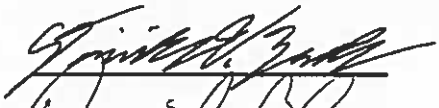
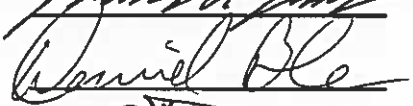
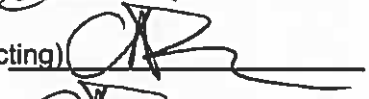
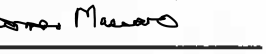
PROGRAM/BUREAU: Hepatitis and Harm Reduction Program (HHRP), Infectious Disease Bureau – February 2019

CLINICAL PROTOCOL TITLE: Rapid Testing for the Hepatitis C Virus (HCV) using the Oraquick® Test Device

Reviewed by: (Must have a signature from at least one clinical user of the Protocol)

Name:	Martin Martinez	Date:	01/29/2019
Name:	Ronald Smith	Date:	01/23/2019
Name:		Date:	/ /

Approved by:

Program Manager		Date:	01/ 31 /2019
Bureau Chief		Date:	01 / 31 / 2019
Bureau Medical Director (acting)		Date:	01 / 29 / 19
PHD Medical Director		Date:	01 / 29 / 19
Regional Health Officer		Date:	01 29 / 19
PHD Chief Nurse	Heather Black	Date:	01 / 29 / 19
PHD Dir of Pharmacy	N/A	Date:	/ /
(Other)		Date:	/ /
(Other)		Date:	/ /

Attachment G

PUBLIC HEALTH DIVISION
ACKNOWLEDGEMENT AND RECEIPT OF NEW/REVISED CLINICAL PROTOCOL

PROGRAM/BUREAU: Hepatitis and Harm Reduction Program (HHRP), Infectious Disease Bureau – February 2019

CLINICAL PROTOCOL TITLE: Rapid Testing for the Hepatitis C Virus (HCV) using the Oraquick® Test Device

I have reviewed the document listed above and I approve it for practice in ___ Region.

Regional Director _____ Date: / /

Regional Health Officer _____ Date: / /

Regional DNS _____ Date: / /

Regional DNS _____ Date: / /

I have received, reviewed, and will follow this Clinical Protocol and its Standing Orders. Staff (Clinicians, PHNs, DPSs, etc.):

Name: _____ Date: / /

Name: _____ Date: / /

Name: _____ Date: / /

Name: _____ Date: / /

Name: _____ Date: / /

Name: _____ Date: / /

Name: _____ Date: / /

Name: _____ Date: / /

Name: _____ Date: / /

Each clinician and PHN must review the document mentioned above and sign this sheet (use additional sheets as necessary). The Nurse Manager will retain the signed copy(ies) of this sheet at the clinic and submit the original(s) to the Director of Nursing Services.