NORTH Dakota | Health & Human Services
Be Legendary.

Rapid HIV & Competency Policy Template

Rev. 08/2021

CTR Site HIV & HCV Competency Policy

The CTR program requires all CTR sites to have a competency policy for rapid HIV and HCV testing. This policy should include a competency assessment process that occurs at least annually. CTR sites are encouraged to utilize this document as a resource to developing their own competency policy.

Competency Assessment

CLIA does not require policies for assessing personnel competency for waived testing. Although not a requirement per CLIA law, evaluation of competency of testing personnel is an important part of good laboratory practice, ensuring that patient test results are correct to assist in making an accurate patient diagnosis. Providing regular training, appropriate education, and evaluating and maintaining competency of testing personnel is essential to achieving accurate test results. Evaluation may occur more frequently during the first year of employment, but annual evaluations are sufficient after the first year unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance can be re-evaluated to include the use of the new test methodology or instrumentation. If your laboratory is accredited, you may need to consult your accrediting organization's standards.

Evaluating Assessment

The procedures for evaluating the competency of the staff must include but are not limited to:

1) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing.
2) Monitoring the recording and reporting of test results.
3) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.
4) Direct observation of performance of instrument maintenance and function checks.
5) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.
6) Assessment of problem solving skills.

At least one of the above six evaluating methods should be utilized each year for competency assessment. Different methods can be utilized each year. The method used at the CTR is determined by the CTR site.

Assessment Tools

The following tools have been developed and included in this document to aid CTR sites in evaluating testing and personnel competence:

1. Written Quiz for HIV and HCV rapid testing.
2. Interpretation Quiz for HIV and HCV rapid testing.
3. Observation Checklist for HIV and HCV rapid testing.

Documenting Assessment

Also available is a template for a Competency Certificate. This can be utilized to document each time an individual is assessed. This certificate is for the assessment of HIV and HCV rapid testing simultaneously. CTR sites should modified as necessary.

Action Items

CTR sites should designate an individual responsible for ensuring competency is performed. This individual shall write a plan and decide which evaluating methods are going to be utilized. This individual shall determine when the yearly competency shall be assessed.

CTR Sites HIV & HCV Competency Policy Template

Note: CTR Sites may utilize this template for their competency policy. They should complete the policy with their specific CTR site information.

Goal: Ensure staff that are utilizing CLIA waived rapid HIV and HCV tests are competent and accurately performing and interpreting test results.

Agency	
Personnel Responsible for Competency Assessment of CTR Staff	
Personnel Requiring Competency Assessment:	
Rapid Tests Utilized by Agency	Chembio SURE CHECK® HIV 1/2 Assay Orasure QRAQUICK® HCV Rapid Test

Competency Assessment

New Employees

New employees will be assessed prior to performing rapid testing on patients. New employees will abide by training instructions also dictated by the manufacturers and the NDDoH CTR program. New employees shall complete the *Staff Development and Training* form for the CTR program.

All Employees

Competency will be assessed annually for all employees. Annual competency will occur in **SPECIFIC TIME PERIOD**.

Evaluation Assessment

A variety of tools maybe utilized to evaluate competency. The **responsible party** will choose one of the six methods recommended each year.

Records

Record of competency assessment will be kept for a minimum of two years. These records will be maintained by the **overall responsible party**. The HIV.STD.Hepatitis Prevention Coordinator will review competency assessments at biannual site visit. The **overall responsible party** will ensure each staff completing an assessment receives appropriate documentation that assessment was satisfactory and complete.

Date Policy Approved:

Date Policy Revised:

Chembio SURE CHECK® HIV 1/2 Assay Quiz

Employee Name: _____ Date: _____

Instructions: Circle True or False for Each Question. The reviewer will determine if the assessment is satisfactory or unsatisfactory.

1. The Chembio SURE CHECK® HIV 1/2 Assay kit may be stored at room temperature.	True	False
2. The Chembio SURE CHECK® HIV 1/2 Assay device should remain in an unopened pouch until ready to perform a test.	True	False
3. Venous whole blood samples may be collected in tubes containing citrate, heparin, or EDTA	True	False
4. Venous whole blood samples may be frozen.	True	False
5. Venous whole blood specimens may be stored at room temperature up to 3 days.	True	False
6. The Fingerstick Sample is collected with the device by holding the Sampler tip to the first drop of blood.	True	False
7. The Running Buffer vial should snap 2 times as the device tip is pushed firmly through the foil cover of the vial.	True	False
8. Any pink or purple line in the test area should be called preliminary positive for antibodies for HIV-1 and/or HIV-2.	True	False
9. The Chembio SURE CHECK® HIV 1/2 Assay should be read at 25 minutes. Do not read result after 30 minutes.	True	False
10. You may test patient specimens if the temperature of the testing area falls outside of the 18° to 30°C (46° to 86°F) provided that you run Kit Controls beforehand to ensure proper performance. If the controls perform properly then you may proceed with running patient specimens.	True	False

Reviewed by: _____ Date: _____

Assessment: Satisfactory or Unsatisfactory

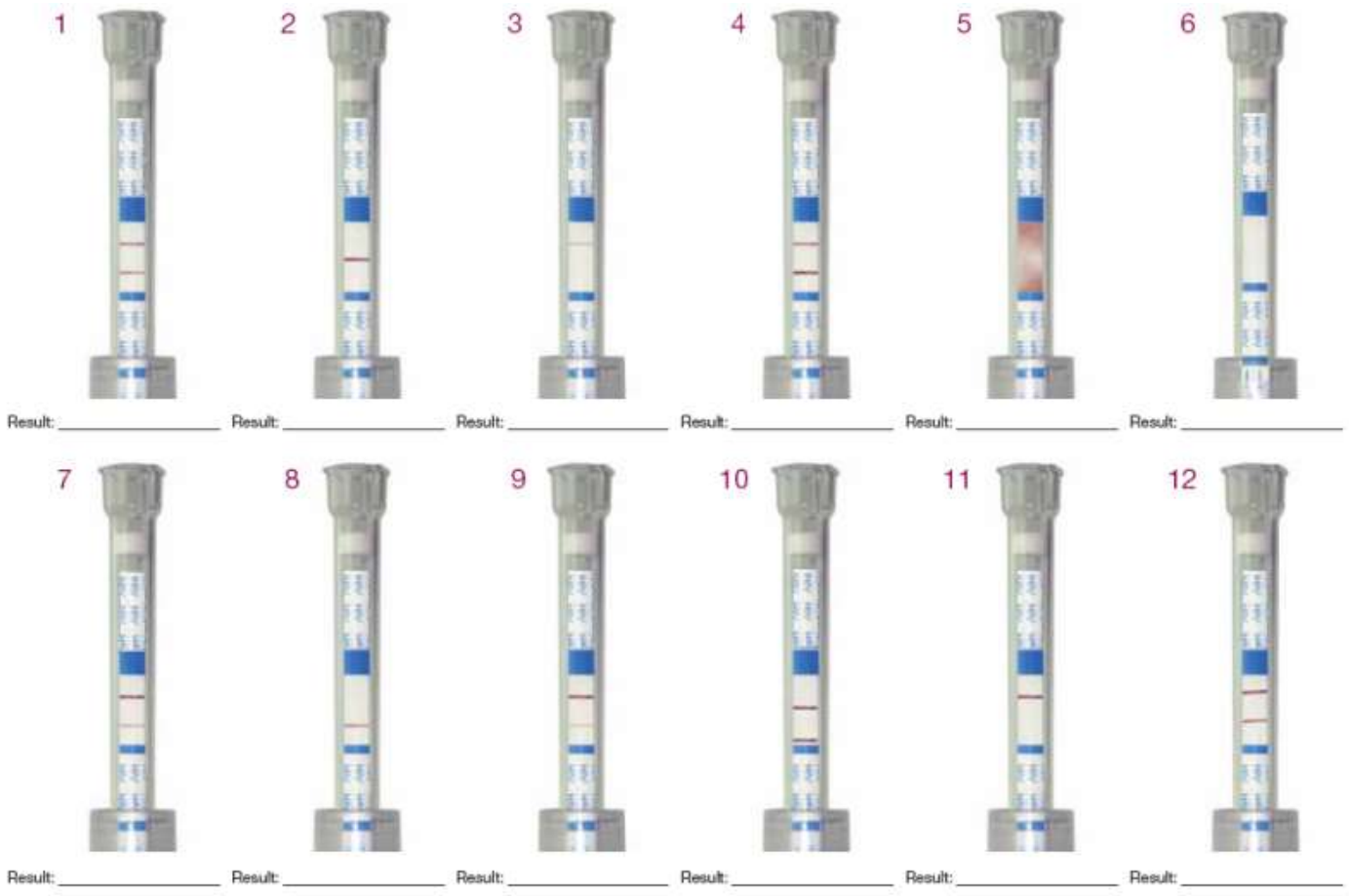
Chembio SURE CHECK® HIV 1/2 Assay Quiz – ANSWER KEY

Question	Answer
1. The Chembio SURE CHECK® HIV 1/2 Assay kit may be stored at room temperature.	**TRUE**
2. The Chembio SURE CHECK® HIV 1/2 Assay device should remain in an unopened pouch until ready to perform a test.	**TRUE**
3. Venous whole blood samples may be collected in tubes containing citrate, heparin, or EDTA.	**TRUE**
4. Venous whole blood samples may be frozen. *Note: Whole blood that is frozen cannot be tested.*	**FALSE**
5. Venous whole blood specimens may be stored at room temperature up to 3 days. *Note: If specimens are not tested immediately, whole blood specimens can be refrigerated at 2º to 8º C for three days.*	**FALSE**
6. The Fingerstick Sample is collected with the device by holding the Sampler tip to the first drop of blood. *Note: Always wipe away the first drop of blood with gauze after a fingerstick.*	**FALSE**
7. The Running Buffer vial should snap 2 times as the device tip is pushed firmly through the foil cover of the vial. *Note: The device will "snap" 3 times when properly seated in the buffer cap.*	**FALSE**
8. Any pink or purple line in the test area should be called preliminary positive for antibodies for HIV-1 and/or HIV-2.	**TRUE**
9. The Chembio SURE CHECK® HIV 1/2 Assay should be read at 25 minutes. Do not read result after 30 minutes. *Note: The assay should between 15 to 20 minutes. Do not ready after 20 minutes.*	**FALSE**
10. You may test patient specimens if the temperature of the testing area falls outside of the 18° to 30°C (46° to 86°F) provided that you run Kit Controls beforehand to ensure proper performance. If the controls perform properly then you may proceed with running patient specimens.	**TRUE**

Chembio SURE CHECK® HIV 1/2 Assay Interpretation Quiz

Employee Name: _____ Date: _____

<u>Instructions:</u> Write the Result on the line below each Test Device. Record Results as: Non-Reactive (NR), Reactive (R), or Invalid (INV). The reviewer will determine if the assessment is satisfactory or unsatisfactory.



Reviewed by: _____ Date: _____

Assessment: Satisfactory or Unsatisfactory

Chembio SURE CHECK® HIV 1/2 Assay Interpretation Quiz – ANSWSER KEY

1. **Report as Reactive/Preliminary Positive**
   - Control line present
   - Test line present

2. **Report as Invalid**
   - No Control line present
   - Test line out of alignment

3. **Report as Nonreactive/Negative**
   - Control line present
   - No test line present

4. **Report as Reactive/Preliminary Positive**
   - Control line present
   - Test line present

5. **Report as Invalid**
   - No Control line present

6. **Report as Invalid**
   - No Control line present
   - Device not fully seated in stand (blue bottom line should line up with clear line in the stand)

7. **Report as Reactive/Preliminary Positive**
   - Control line present
   - Test line present

8. **Report as Invalid**
   - No Control line present
   - Test line present

9. **Report as Reactive/Preliminary Positive**
   - Control line present
   - Test line present

10. **Report as Invalid**
    - Control line present
    - Test and control line out of alignment

11. **Report as Nonreactive/Negative**
    - Control line present

12. **Report as Reactive/Preliminary Positive**
    - Control line present
    - Test line present
    - Test line within tolerance

Orasure QRAQUICK ® HCV Rapid Test Quiz

Employee Name: _____ Date: _____

Instructions: Circle True or False for Each Question. The reviewer will determine if the assessment is satisfactory or unsatisfactory.

1. The OraQuick® HCV Rapid Antibody Test may be stored at freezer temperatures.	**True**	**False**
2. The OraQuick® HCV Rapid Antibody Test should be read at 15 minutes. Do not read result after 20 minutes.	**True**	**False**
3. The OraQuick® HCV Rapid Antibody Test can performed on all age groups include infants.	**True**	**False**
4. Specimen collection loops used in the performance of the OraQuick® HCV Rapid Antibody Test can be utilized for more than one patient.	**True**	**False**
5. If any of the liquid in the developer vial spills, you must obtain a new test device as the result may in an invalid test result.	**True**	**False**
6. To ensure accurate results, the test device must be inserted into the developer solution vial within 120 minutes after introducing the specimen into the developer solution.	**True**	**False**
7. All new users must read the product insert prior to utilizing the OraQuick® HCV Rapid Antibody Test.	**True**	**False**
8. The OraQuick® HCV Rapid Antibody Test has been approved for use with saliva specimens.	**True**	**False**
9. A control line will appear on all valid tests, whether or not the sample is reactive or non-reactive for anti-HCV.	**True**	**False**
10. Controls must be performed under the following circumstances: 1), whenever a new shipment of test kits is received, 2) each new operator prior to performing testing on patient specimens and 3) if the temperature of the test kit storage area falls outside of 2° – 30°C (36°-86° F).	**True**	**False**

Reviewed by: _____ Date: _____

Assessment: Satisfactory or Unsatisfactory

Orasure QRAQUICK ® HCV Rapid Test Quiz – ANSWER KEY

Question	Answer
1. **The OraQuick® HCV Rapid Antibody Test may be stored at freezer temperatures.** *Note: HCV rapid tests shall be stored at room temperature.*	**False**
2. **The OraQuick® HCV Rapid Antibody Test should be read at 15 minutes. Do not read result after 20 minutes.** *Note: Read the results between 20 and 40 minutes.*	**False**
3. **The OraQuick® HCV Rapid Antibody Test can performed on all age groups include infants.** *Note: This test is approved for individuals 15 years and older. This test is not approved for pregnant women.*	**False**
4. **Use all specimen collection loops test devices and develop solution vials only once and dispose of properly.**	**True**
5. **If any of the liquid in the developer vial spills, you must obtain a new test device as the result may in an invalid test result.**	**True**
6. **To ensure accurate results, the test device must be inserted into the developer solution vial within 120 minutes after introducing the specimen into the developer solution.** *Note: The test device must be inserted into the developer solution vial within 60 minutes after introducing the specimen into the developer solution.*	**False**
7. **All new users must read the product insert prior to utilizing the OraQuick® HCV Rapid Antibody Test.**	**True**
8. **The OraQuick® HCV Rapid Antibody Test has been approved for use with saliva specimens.** *Note: The OraQuick® HCV rapid antibody test is approved for fingerstick whole blood and venipuncture whole blood specimens only.*	**False**
9. **A control line will appear on all valid tests, whether or not the sample is reactive or non-reactive for anti-HCV.**	**True**
10. **Controls must be performed under the following circumstances: 1), whenever a new shipment of test kits is received, 2) each new operator prior to performing testing on patient specimens and 3) if the temperature of the test kit storage area falls outside of 2° – 30°C (36°-86° F).**	**True**

OraSure QraQuick® Rapid HCV Antibody Interpretation Quiz

Employee Name: _____ **Date:** _____

<u>Instructions:</u> Write the Result on the line below each Test Device. Record Results as: Non-Reactive (NR), Reactive (R), or Invalid (INV). The reviewer will determine if the assessment is satisfactory or unsatisfactory.

1. 
_____

2. 
_____

3. 
_____

4. 
_____

5. 
_____

6. 
_____

7. 
_____

8. 
_____

Reviewed by: _____ **Date:** _____

Assessment: Satisfactory or Unsatisfactory

OraSure QraQuick® HCV Rapid Antibody Interpretation Quiz – ANSWSER KEY

1. **Report as Non-Reactive**
   - Control line present
   - No Test line present

2. **Report as Invalid**
   - No Control line present
   - No Test line present
   - Red Background obscures results

3. **Report as Invalid**
   - No control line present.
   - Test line incomplete. Partial lines are invalid results.

4. **Report as Reactive**
   - Control line present.
   - Test line present.

5. **Report as Reactive**
   - Control line present.
   - Test line present.

6. **Report as Invalid**
   - No Control line present. Without a control line, test is invalid.

7. **Report as Invalid**
   - Partial Control line present.
   - Partial Test line present.
   - Partial lines are invalid results.

8. **Report as Reactive**
   - Control line present.
   - Test line present. Even if the line is faint in the test zone, the result is reactive.

Testing Personnel Competency Assessment

Test Method: □ **Chembio SURE CHECK® HIV 1/2 Assay**
□ **Orasure Oraquick® HCV Rapid Anitbody Test**

Procedure	Satisfactory	Unsatisfactory	Not Applicable	Comments/Corrective Actions
Observation of Test Performance:				
Patient Preparation				
Specimen Handling/Processing				
Testing				
Recording/Reporting Results				
Assessment of Test Performance Using Known Samples				
Review of Records:				
Patient/Quality Control Log Sheet Records				
Proficiency Testing Records				
Assessment of Problem Solving Skills				

Evaluator:_____ **Date:**_____

Employee:_____