

Field Use of the Rapid Syphilis Health Check (SHC) Test: Quality Assurance Plan

For HIV Prevention and Partner Services (Public Health Follow-Up) Programs

October 2015



Table of Contents

INTRODUCTION TO THE SYPHILIS HEALTH CHECK (SHC)	3
PERSONNEL	5
TEST KIT CARE	7
WARNINGS AND PRECAUTIONS	8
COLLECTION AND STORAGE OF SPECIMENS	9
ASSAY PROCEDURE	11
QUALITY CONTROL	12
INTERPRETATION OF RESULTS	14
OTHER REQUIREMENTS	17
ATTACHMENTS	18
Attachment A: Employee Training Log	
Attachment B: QA External Control and Temperature Log	
Attachment C: Temperature Monitoring Chart	
Attachment D: Employee Competency Evaluation	
Attachment E: QA Checklist	

INTRODUCTION TO THE SYPHILIS HEALTH CHECK (SHC)

CLIA Waiver

A Certificate of Waiver is required to perform this test in a CLIA waived setting. To obtain a Certificate of Waiver, please contact your DSHS Consultant. Additional CLIA waiver information is available at the Centers for Medicare and Medicaid website at www.cms.gov/CLIA or from the Texas Department of State Health Services Lab.

Failure to follow the instructions or modification to the test instructions will result in the test no longer meeting the requirements for waived category.

INTENDED USE (from the package insert)

Syphilis Health Check (SHC) is a qualitative rapid membrane immunochromatographic assay for the detection of *Treponema pallidum* (syphilis) antibodies in human whole blood, serum or plasma. This product can be used as an initial screening test or in conjunction with a non-treponemal laboratory test and clinical findings to aid in the diagnosis of syphilis infection. This test is not intended for use in screening blood or plasma donors.

<http://www.trinitybiotech.com/products/syphilis-health-check-3/>

Criteria for using Syphilis Health Check (SHC) in non-laboratory settings (or in the Field):

- All SHC testing is voluntary and will be performed only with informed consent.
- SHC testing is only available confidentially. Clients may NOT test anonymously.
- If the client tests preliminary positive on the SHC test, the non-treponemal test must also be done confidentially. Clients may NOT test anonymously.
- Establish whether or not the individual has ever tested positive for syphilis
 - Conduct a thorough medical history to determine if the individual has had a syphilis infection in the past.
 - Determine if the individual received treatment for syphilis and date/s of treatment.
 - Note: This test will most likely be positive for those who have ever been infected with syphilis, even if they received treatment.
- If the individual reports a previous history of syphilis, do not conduct a rapid test.

- Perform venipuncture for the standard non-treponemal test (RPR) blood draw to determine whether or not the individual has been re-infected.
- Assess whether or not the patient has any symptoms indicative of syphilis infection (e.g., sore(s) on genitals, anus/rectum or on/near mouth, rash on palms of hands/soles of feet or generalized body rash, patchy hair loss, etc.).
 - If the patient reports symptoms, refer the patient to the local or regional health department for clinical assessment and appropriate treatment.
- Individuals considered to be at increased risk for syphilis vary across the state, please check with your local health department or STD program to determine populations at increased risk for syphilis.
- Generally speaking, high risk populations include:
 - Persons within an affected socio-sexual network identified through Partner Services
 - Men who have Sex with Men (MSM)
 - Individuals who exchange sex for money, drugs, or other goods
 - Persons who inject drugs (PWID)
 - Pregnant women (may have a higher false positivity rate).
 - If you encounter a pregnant woman, ensure that she is receiving prenatal care
 - Ensure a pregnant woman knows she needs to be tested at her first prenatal visit and during her third trimester. She might also be tested at labor/delivery.
 - It is important to identify syphilis infection early in the pregnancy so the pregnant woman can receive prompt and adequate treatment for her syphilis infection.
 - Prompt and adequate treatment will protect the fetus from adverse effects of maternal infection.
- Staff will conduct SHC if no prior history of syphilis is identified.
- If the SHC results are positive, collect a blood specimen via venipuncture for a non-treponemal (RPR) titer.
- **All positive tests are reportable to the local health authority <http://www.dshs.state.tx.us/hivstd/healthcare/reporting.shtm>
 - Upon receipt of the positive test, the local health authority will determine the need for public health follow-up/partner services.
 - If deemed necessary, the individual will be contacted by a disease intervention specialist (DIS) for treatment and partner services.

PERSONNEL

A. Positions:

1. Staff eligible for training in the field use of the rapid syphilis health check include HIV Risk Reduction Specialists (HIV Prevention Programs) and Disease Intervention Specialists (Partner Services/Public Health Follow-Up Programs).
 - a. Staff must be assessed for colorblindness prior to being approved to perform this testing platform.
2. **All** Risk Reduction Specialists and Disease Intervention Specialists in the Public Health Follow-Up/Partner Services programs are eligible for training in the field use of the rapid syphilis test.
3. Staff who perform the test will be responsible for: quality control, identifying appropriate individuals for whom the test is appropriate, conducting the test, maintaining appropriate documentation, and reporting positive tests to the local health authority.

B. Trainings

Staff will be trained to:

- Identify individuals who meet the criteria for testing
- Perform quality controls on testing kits
- Collect specimens for the SHC test
- Read the results on the testing platform
- Interpret test results based on the individual's history
- Perform venipuncture for the draw of non-treponemal (RPR) test
- Follow all related procedures required by the Laboratory Director, the HIV Program Director, or the test manufacturer's representative.
 - The HIV Prevention Program Director or First Line Supervisor (FLS) for DIS will maintain documentation of all staff training.

C. Personnel Assessment

The competency of all staff will be reviewed annually. All newly trained staff will be reviewed at minimum two (2) times per year for the first year after training. Supervisor will review/observe the following:

- Assessment of the individual's history of testing and/or treatment for syphilis;
- Specimen collection including site preparation, collection of the specimen, specimen handling, and conducting of the test;
- Interpretation of test results and appropriate follow-up;
- Discussion about appropriate syphilis treatment and partner services for reactive test results;
- Accurate recording of the SHC result;

- Documentation of quality control checks to include: assessment of test performance by testing previously analyzed samples, blind samples, or proficiency testing.

Programs must maintain documentation of staff members' orientation to testing procedures, periodic procedure reviews, and competency checks. A list of staff who receive training and who are approved to perform the SHC test will be maintained by the Program Supervisor. (See Attachment A)

D. Procedure Reviews

The SHC test procedures will be reviewed annually by the Laboratory Director or the HIV Program Director to ensure approved procedures are current and appropriate.

TEST KIT CARE

A. Materials

- Test kits
- Controls

B. MATERIALS REQUIRED BUT NOT PROVIDED

- Timer - 20 min.
- Syphilis Health Check (SHC) Control Sets, which can be ordered through your STD program consultant or directly from Trinity Biotech at (800) 325-3424.

C. Where/How Stored

- ALLSHC kit components should be stored at (4° - 30°C). Test cassettes should be stored in their sealed pouch. Do not freeze the test kit.

D. Expiration Dates

- The SHC kit is stable until the expiration date on the package label.

E. Documentation

- Kit storage temperatures will be recorded each day testing is performed. The temperature chart is attached. (See attachments B and C).

WARNINGS AND PRECAUTIONS

1. Persons performing the SHC test must be tested for colorblindness before performing the test.
2. Do not use the buffer or cassette after the expiration date printed on the outside of each foil pouch.
3. Do not use test cassette if foil pouch is opened or defective.
4. Make sure the materials in the kit are at room temperature before use.
5. Always wear gloves when performing the SHC.
6. This test is designed for the detection of current or previous syphilis infection.
7. Read instructions carefully before using this test.
8. Place the cassette on a clean flat surface facing up.
9. Only use the pipette included in the kit.
10. A positive test must be followed by [or reflexed to] a laboratory non-treponemal syphilis assay with titer information.
11. Trained judgment is necessary for interpreting the test results.
12. A positive SHC result may not be used to establish a diagnosis of a current syphilis infection.
 - The positive result may reflect a prior treated infection.
 - A negative result can exclude a diagnosis of syphilis except for cases of incubating or early primary disease where syphilis antibodies are not yet detectable.
13. Blood specimens may be potentially infectious. Avoid contact with skin by wearing gloves and proper laboratory attire. Properly handle and discard all used test devices in an approved biohazard container.
14. Avoid any contact between hands and eyes or nose during specimen collection and testing.
15. Test cassettes are single use only.
16. Adding sample and buffer in the wrong order will result in an incorrect result.
17. Test buffer and controls contain sodium azide as preservative which is a poison and may be harmful if swallowed. Seek medical help if buffer is swallowed.

COLLECTION AND STORAGE OF SPECIMENS

For Finger Stick Whole Blood Collection:

1. Apply gloves and gently squeeze the chosen finger towards the tip and wipe the end of the finger with an alcohol wipe and a sterile pad.
2. Alcohol will affect the test. Let the finger dry thoroughly prior to collecting the specimen.
3. Two drops of whole blood (50 μ L) is required to perform the test.
4. Stick fingertip with a lancet.
5. The first drop of blood should be wiped clean with a sterile pad. **NOTE:** The first drop should NOT be used to avoid any potential interference from the alcohol.
6. Gently squeeze the finger towards the tip to collect two more drops of blood.
7. Using the fixed volume pipette provided in the kit, touch the end of the pipette to the drop of blood.
8. Holding the pipette horizontally, allow the blood to flow into the pipette on its own, making sure there are no air bubbles, empty spaces, or gaps in the specimen. If air bubbles, empty spaces, or gaps are present, collect another sample.
9. It may be necessary to gently squeeze the finger to get one or more additional drops of blood.

For Venous Whole Blood Collection:

1. The serum or plasma specimen should be collected aseptically (sterile) under the standard laboratory conditions, avoiding hemolysis (destruction of red blood cells).
2. Fresh samples should be used for testing.
3. If the test is to be run within 8 hours after collection, the specimen should be stored in the refrigerator (2° to 8°C).
4. If testing is NOT performed within 8 hours, the sample must be converted to serum or plasma and can be stored refrigerated (2 - 8°C) up to 5 days.
5. If testing is delayed more than 5 days, serum and plasma specimens should be frozen. The frozen specimen must be completely thawed, thoroughly mixed and brought to room temperature prior to testing. Avoid repeated freezing and thawing.

6. Draw venous whole blood sample into a syringe or a vacuum collection tube containing the additive EDTA (ethylenediaminetetraacetic acid) as an anticoagulant (clot preventer) for plasma or a red top tube for serum.
7. Remove tube cap and touch the end of the pipette included in the kit to the blood in the tube by slightly tipping the tube and holding the pipette so the tip is in the blood.
8. Draw the blood up into the end of the pipette (> 2 drops) making sure there are no air bubbles, empty spaces, or gaps in the specimen.
 - a. If a whole blood (with red cells) sample is used, TWO drops of whole blood (50 μL) is needed for the assay.
 - b. If the red blood cells are separated, then ONE drop of serum or plasma (25 μL) is required to perform this test. If air bubbles, empty spaces, or gaps are present, collect another sample.
9. Replace cap on tube.

ASSAY PROCEDURE

1. Allow samples and the SHC test devices to come to room temperature prior to testing.
2. Remove the reaction device from its protective wrapper by tearing along the notch.
3. Label device with the patient's name or control number.
4. Fill the pipette with specimen (whole blood, serum, or plasma).
5. Hold the pipette vertically, dispense one drop (25 μ l) of serum or plasma into the sample well (small circle).
 - a. If whole blood is used, dispense two drops (50 μ l) into the sample well.
6. Allow sample to be absorbed into the pad.
7. Add 4 full drops of Diluent (200 μ l) to the sample well (small circle). One more drop can be added, if the sample does not flow down the membrane. **DO NOT USE WATER OR OTHER LIQUIDS.**
8. Set the cassette on a flat surface and incubate at room temperature (20 - 26°C) for 10 minutes.

Read the results after 10 - 15 minutes. **PLEASE NOTE: Do not read test results if test is processed longer than 15 minutes. At this point the test is invalid because the test may be inaccurately interpreted as reactive.**

QUALITY CONTROL

A. **Built-in Controls:**

SHC contains built-in quality control features.

A pink line in the Control Zone should always be seen and shows:

- 1) enough specimen is added
- 2) proper flow is obtained.

If this pink control line is missing, the test was not run correctly or failed to function correctly.

The test is invalid and the test should be repeated using a new cassette.

B. **External Controls:**

The Positive and Negative Controls, which are provided separately from the manufacturer, should be run according to the laboratory requirements.

These controls should be run like an unknown patient specimen, at a minimum, in the following circumstances:

- Each new lot.
- Each new shipment (even if from the same lot previously received).
- Each new operator (an individual who has not run the tests for at least two weeks).
- Monthly, as a continued check on storage conditions.
- Whenever problems are identified (e.g., storage, operator, or other).
- As required by your laboratory's standard quality control procedures.

If the controls do not give expected results (Positive or Negative), patient results must NOT be reported, and the test should be re-run.

If the SHC test does not show any Control or Test line in the window or there is a smudged or partial line, the test cassette should be discarded. Do not report the results. Run the test again with a new cassette and follow the procedure exactly.

If the second SHC test does not show lines, please contact Technical Services at 866-358-9282.

C. **Procedure for failed assay**

- If the SHC test is invalid, repeat the test with a fresh device.
- If the repeat SHC test is invalid, run external controls.

- If controls are not within limits, discontinue using the devices in that lot number and report the problem to your supervisor.
- Collect a sample from the individual for laboratory testing.

For any other concerns regarding Syphilis Health Check, please call 800-325-3424 8am -6pm EST.

Problems may also be reported using the MedWatch reporting system <http://www.fda.gov/Safety/MedWatch/HowToReport/> or

Call 1-800-FDA-1088 (1-800-332-1088).

INTERPRETATION OF RESULTS

A. Negative

One pink/red line of any intensity appears in the “C” control area and no visible line in the test area is considered a negative result. This indicates a Non-Reactive result that is interpreted as Negative for syphilis antibodies.

B. Positive

A pink/red line of any intensity appears in the “C” control area and a pink/red line of any intensity appears in the device window adjacent to “T” Test. This indicates a Reactive result that is interpreted as Presumptive Positive for syphilis antibodies. Any visible red/pink line adjacent to the “T” is considered positive. All positive tests must be reported to the local health authority.

C. Invalid

If there is no color line visible in the “C” control area, whether or not there is a line in the “T” test area, the test is invalid and cannot be interpreted. In this case, repeat the test with a fresh specimen using a fresh device.

Contact Trinity Biotech at 800- 325- 3424 if you are unable to produce a valid result upon repeat testing.

IMPORTANT: In addition to the pink line by the Control mark, ANY line that is seen near the Test mark of the cassette at the 10-minute time is considered a positive result. The intensity of the line does not matter.

The following Table provides an algorithm to aid in interpreting and reporting syphilis serology results for diagnosis of T. Pallidum infection status, using both a treponemal test and a non-treponemal test.

A positive SHC result is not diagnostic of syphilis without additional non-treponemal serologic testing and a full clinical evaluation. A new venous whole blood specimen must be obtained for further testing.

Treponemal Result (SHC, IGG, TPPA, FTA-ABS)	Non-treponemal Result (RPR, VDRL)	Report/Interpretation of Results *except neonates or infants*
Negative (Nonreactive) No further testing indicated	Not done	<ol style="list-style-type: none"> 1. Not infected 2. Previous history with treatment during incubation or early primary syphilis stage 3. Incubating or early primary syphilis <p>If there is a known syphilis exposure, recommend repeat testing within one month.</p> <p>Recommend repeat testing (3 months) if there is no known exposure and risks behaviors are present.</p>
Negative (Nonreactive) No further testing indicated	Nonreactive	<ol style="list-style-type: none"> 1. Not infected 2. Previous history with treatment during incubation or early primary syphilis stage 3. Incubating or early primary syphilis <p>If there is a known syphilis exposure, recommend repeat testing within one month.</p> <p>Recommend repeat testing (3 months) if there is no known exposure and risks behaviors are present.</p>
Negative (Nonreactive) No further testing indicated	Reactive	<ol style="list-style-type: none"> 1. Biological False Positive (BFP) secondary to other medical conditions 2. Incubating or early primary syphilis <p>Recommend repeat testing (non-treponemal, and treponemal by other test method).</p>

Treponemal Result (SHC, IGG, TPPA, FTA-ABS)	Non-treponemal Result (RPR, VDRL)	Report/Interpretation of Results *except neonates or infants*
Positive (Reactive)	Nonreactive	<ol style="list-style-type: none"> 1. Previously treated infection 2. Untreated late latent infection (e.g., if no history of previous treatment reported) <p style="text-align: center;"><i>Additional testing with clinician may be recommended with reported infection, symptom and/or treatment history.</i></p>
Positive (Reactive)	Reactive	<ol style="list-style-type: none"> 1. Current infection/re-infection 2. Serofast (adequately treated previous infection) 3. Inadequately treated infection 4. Persistent infection <p style="text-align: center;"><i>Clinical assessment and additional testing may be recommended.</i></p>

***HIV-infected individuals may have delayed sero-conversion, albeit rarely.**

OTHER REQUIREMENTS

A. CLIA license

- A current CLIA license will be maintained.

B. Hazardous Waste Disposal Plan

- Refer to Agency Infection Control Plan.
- Staff will bring hazardous waste containers used in the field to the health center for proper disposal.

C. Exposure Control Plan

- Refer to Agency Infectious Control Manual for complete information.
- All staff must be trained on and use Universal Precautions.
- Staff must carry hand sanitizer for use at outreach sites and washes hands at appropriate times.
- Gloves are provided as personal protective equipment.
- Safety equipment is provided for protecting against needle sticks.

ATTACHMENTS

**ATTACHMENT A:
EMPLOYEE TRAINING LOG**

Employee Name Title	Date of Hire	Date of Termination	Training to date	Training Date
			PCPE/HCV	
			Syphilis Rapid Health Check Test	
			OraQuick Rapid Test	
			FCT	
			Uni-Gold Rapid Test	

ATTACHMENT B:

EXTERNAL CONTROLS AND TEMPERATURE LOGS

		1 st Quarter		2 nd Quarter		3 rd Quarter		4 th Quarter	
		External Controls	Temp Log						
	Run appropriately								
	Within limits								
	Corrective action taken								
	Run appropriately								
	Within limits								
	Corrective action taken								
	Run appropriately								
	Within limits								
	Corrective action taken								
	Run appropriately								
	Within limits								
	Corrective action taken								
	Run appropriately								
	Within limits								
	Corrective action taken								

ATTACHMENT C:
RAPID SYPHILIS HEALTH CHECK (SHC)
TEMPERATURE MONITORING CHART

Month:

RRS:

	STORAGE TEMP				TESTING TEMP				Comments
	Max	Min	Current		Max	Min	Current		
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									

All SYPHILIS HEALTH CHECK kit components should be stored at (4° - 30°C). Test cassettes should be stored in their sealed pouch.

Note: If temperature is out of range, controls must be run before using the test.

ATTACHMENT D:

Rapid Syphilis Health Check (SHC)

Employee Competency Evaluation

Employee's Name: _____

Date: _____

Rapid Syphilis Health Check (SHC)

Using the parameters below, rank the competency demonstrated by the employee in each of the following tasks:

Numerical Parameters
1= Failed to follow directions for task
2= Several errors in technique/procedure
3= Few errors/instruction for each task
4= No errors/instruction for each task
N/A= Not applicable

____ Employee validated test kit was appropriate for use (read expiration date, checked packaging).

____ Employee accurately discussed syphilis testing and treatment history with the patient and how that can influence the test results.

____ Proper sample was collected.

____ Proper testing technique was used.

____ Employee knows the time frame for reading the test.

____ Test was read at the appropriate time.

____ Test result was interpreted correctly.

____ Employee ran controls according to schedule.

____ Employee documented storage and testing temperatures according to protocol.

For reactive test results:

___ Employee performed appropriate follow-up activities.

___ Employee explained Public Health Follow-Up.

___ Employee made appropriate referrals for additional testing or clinical services.

Conclusion:				
Overall performance of employee (average of all task evaluated)	1	2	3	4
Is retraining necessary?	Yes		No	
Note: Overall satisfactory performance does not mean retraining is not necessary. Each task is evaluated individually for retraining purposes. Retraining is required on each task that has a score less than 3.				

Evaluation done by: _____

ATTACHMENT E:
QUALITY ASSURANCE CHECKLIST

- Procedure reviewed at least annually

- All staff had annual competency review

- Quality control logs reviewed quarterly

- Temperature logs reviewed quarterly