

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

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

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INTRODUCTION TO THE SYPHILIS HEALTH CHECK (SHC)

CLIA complexity: WAIVED for Fingertick Whole Blood Specimens ONLY

This document outlines SHC test performance and quality control procedures using fingerstick whole blood specimens in a CLIA waived setting. It does not include use of the SHC on venous whole blood specimens which requires a separate CLIA license for non-waived (moderate complexity) testing.

CLIA Certificate of Waiver

A CLIA 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 DSHS Laboratory. 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: for *in vitro* diagnostic use only (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. Additional information can be found on the manufacturer's website at www.diagnosticsdirect2u.com.

Criteria for using 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.

- Establish whether 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 (rapid plasma reagin) blood draw to determine whether the individual has syphilis.

- Assess whether the patient has symptoms indicative of syphilis (e.g., sore(s) on genitals, anus/rectum or on/near the 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 vulnerability for syphilis vary across the state, please check with your local health department or STI program to determine populations at increased vulnerability for syphilis. Vulnerable populations may include:
 - Persons within an affected socio-sexual network identified through Partner Services
 - Men who have Sex with Men (MSM)
 - Persons who exchange sex for money, drugs, or other goods
 - Persons who inject drugs (PWID)
 - Pregnant women (may have a higher false positivity rate).
 - Ensure a pregnant woman is receiving prenatal care and knows she needs to be tested at her first prenatal visit, during her third trimester, and at 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.

- 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.

- Report all positive tests to the local health authority.
dshs.texas.gov/hivstd/reporting
 - 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 Prevention Specialists (HIV Prevention Programs) and Disease Intervention Specialists (Partner Services/Public Health Follow-Up Programs).
2. Staff who perform the test will be responsible for identifying individuals for whom the test is appropriate, conducting the test, ensuring quality control, maintaining appropriate documentation, and reporting positive tests to the local health authority.

B. Training

Staff will be trained to:

- Identify individuals who meet the criteria for testing
- Perform quality controls (built-in and external) on testing kits
- Collect fingerstick 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.

Note: Staff must be assessed for colorblindness prior to being approved to perform this testing platform.

The HIV Prevention Program Director or First Line Supervisor (FLS) for DIS will maintain documentation of all staff training. Programs may also contact the Diagnostic Direct representative for training assistance

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. The 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 fingerstick 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;
- Performance and documentation of external quality control checks

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 responsible for agency's CLIA Certificate of Waiver and Program Director to ensure approved procedures are current and appropriate.

MAINTENANCE of TEST KITS and CONTROL SETS

A. Materials

- Test kits (SHC test devices, disposable plastic fixed volume pipettes, diluent in a dropper bottle containing saline buffer, detergent, and sodium azide (NaN₃, 0.1%),package insert)
- SHC Control Sets, which can be ordered through your STD program consultant.

B. Materials Required-Not Provided

- Timer - 20 minutes

C. Materials Optional

- Thermometer

D. Where/How Stored

- All SHC kit components should be stored at +4° to +30°C. Test cassettes should be stored in a sealed pouch. Do not freeze the test kit.
- SHC control sets should be stored refrigerated at +2 ° C to +8 ° C. Allow to warm to room temperature before use in the assay. Refrigerate after use. Controls are stable for 12 months after first opening when stored at +2 ° C to +8 ° C between each use. Do NOT freeze.

E. Expiration Dates

- The SHC kit is stable until the expiration date on the package label.
- The SHC control set is stable until the expiration date printed on the label. Do not use after the expiration date.

F. Documentation

Kit and control set 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 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 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) are 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 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.

ASSAY PROCEDURE

1. Allow the SHC test devices to come to room temperature prior to testing. Fingertick whole blood samples should be used immediately after collection.
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 (fingertick whole blood).
5. Hold the pipette vertically, 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 (15 - 30°C) for 10 minutes.
9. 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.

INTERPRETATION OF RESULTS

A. Negative (Non-Reactive)

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 (Reactive)

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 which is interpreted as presumptive positive for syphilis antibodies. A 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.

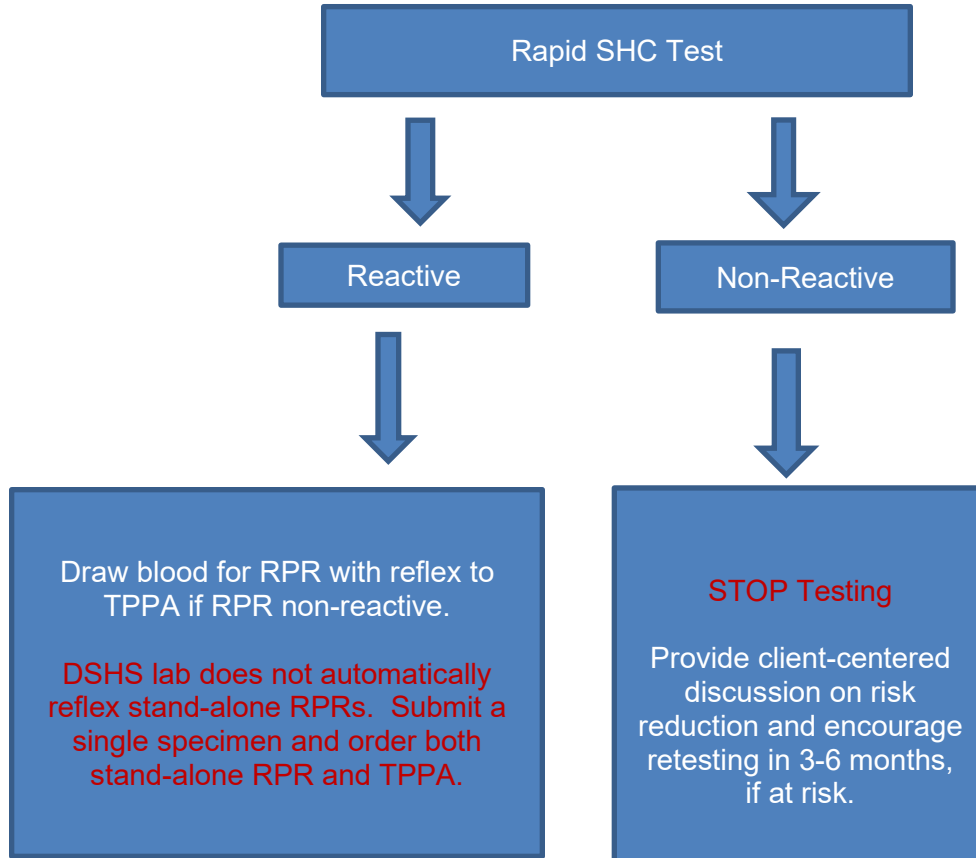
Contact Diagnostics Direct Technical Assistance at 866-358-9282 if you are unable to produce a valid result upon repeat testing.

IMPORTANT: In addition to the pink line by the Control mark, ANY line which 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.

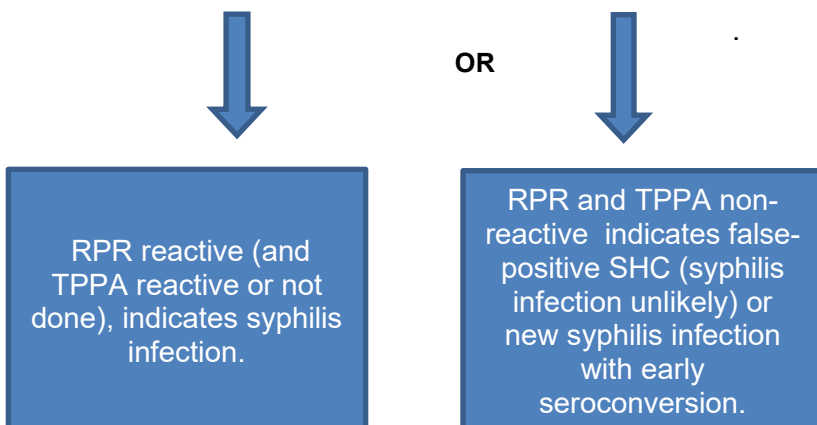
A positive SHC result is not diagnostic of syphilis without additional non-treponemal serologic testing and a full clinical evaluation. A new venous whole blood specimen must be obtained for further testing.

Rapid Syphilis Health Check (SHC) Test Reverse Algorithm

Use only for clients with no previous history of syphilis.



Interpret results based on the reverse algorithm.



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

Treponemal Result (SHC, IGG, TPPA, FTA-ABS)	Non-treponemal Result (RPR, VDRL)	Report/Interpretation of Results *except for 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 risk 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 risk behaviors are present.</p>

Treponemal Result (SHC, IGG, TPPA, FTA-ABS)	Non-treponemal Result (RPR, VDRL)	Report/Interpretation of Results <i>*except for neonates or infants*</i>
Negative (Nonreactive) No further testing indicated	Reactive	1. Biological False Positive (BFP) secondary to other medical conditions 2. Incubating or early primary syphilis Recommend repeat testing (non-treponemal, and treponemal by another test method).
Positive (Reactive)	Nonreactive	1. Previously treated infection 2. Untreated late latent infection (e.g., if no history of previous treatment reported) <i>Additional testing with clinician may be recommended with reported infection, symptom and/or verification of treatment history.</i>
Positive (Reactive)	Reactive	1. Current infection/re-infection 2. Serofast (adequately treated previous infection) 3. Inadequately treated infection 4. Persistent infection <i>Treatment verification, clinical assessment and additional testing may be recommended.</i>

Evaluation and treatment must be in accordance with the [CDC STI Treatment Guidelines](#).
 Additional resource-[Syphilis Monograph: The Diagnosis, Management and Prevention of Syphilis](#).

***Individuals living with HIV may have delayed sero-conversion, albeit rarely.**

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 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 SHC control set package insert and laboratory requirements.

Instructions for use:

1. The SHC positive and negative controls are liquid and are ready to use.
2. Bring to room temperature before use.
3. Add ONE drop (25 microliters) of the control (positive or negative) into the sample well of the cassette and proceed in the same way as for a patient's sample by adding 4 drops of the buffer diluent (included in the SHC test kit).
4. Read the result after 10 minutes. The result can be read for up to 15 minutes. Do not read after 15 minutes.

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)
- Monthly, as a continued check on storage conditions.
- Whenever problems are identified (e.g., storage, operator, or other)

In addition, controls may also be run as required by your laboratory's standard quality control procedures and as directed by your Laboratory Director.

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 Diagnostics Direct 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 other concerns regarding Syphilis Health Check, please call Diagnostics Direct Technical Services at 866-358-9282.

Problems may also be reported using the MedWatch reporting system www.fda.gov/Safety/MedWatch/HowToReport/ or 1-800-FDA-1088 (1-800-332-1088).

OTHER REQUIREMENTS

A. CLIA

- A current CLIA Certificate of Waiver 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 Standard Precautions.
- Staff must carry hand sanitizer for use at outreach sites and wash hands at appropriate times.
- Gloves are provided as personal protective equipment.
- Safety equipment is provided for protecting against blood borne pathogen exposure, including, but not limited to safety devices on lancets and needles.

ATTACHMENTS

ATTACHMENT A:
EMPLOYEE TRAINING LOG

Employee Name Title	Date of Hire	Date of Termination	Training to date	Training Date
			Foundations of Testing and Navigation (FNT)	
			Syphilis Rapid Health Check Test & Controls	
			Point of Care Test Training	

ATTACHMENT B:

EXTERNAL CONTROLS AND TEMPERATURE LOGS

		1 st Quarter		2 nd Quarter		3 rd Quarter		4 th Quarter	
		External Controls	Temp Log	External Controls	Temp Log	External Controls	Temp Log	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:

Evaluation Completed By: _____

Rapid Syphilis Health Check (SHC)

Area Observed	Rating*
1. Validated test kit was appropriate for use (read expiration date, checked packaging).	
2. Accurately discussed syphilis testing and treatment history with the patient and how that can influence the test results.	
3. Proper sample was collected.	
4. Proper testing technique was used.	
5. Knows the period for reading the test.	
6. Test was read at the appropriate time.	
7. Test result was interpreted correctly.	
8. Ran external controls according to schedule.	
9. Documented storage and testing temperatures according to protocol.	
For reactive test results:	
10. Performed appropriate follow-up activities.	
11. Explained Public Health Follow-Up.	
12. 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 which has a score less than 3.	

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

Rating: 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

ATTACHMENT E:
QUALITY ASSURANCE CHECKLIST

- Procedure reviewed at least annually by Laboratory Director and Program Manager

- All staff had annual competency review

- Quality control logs reviewed quarterly

- Temperature logs reviewed quarterly