New Mexico Department of Health
Public Health Division
Protocol

Rapid Testing using Syphilis Health Check™ Device

INTRODUCTION

The Syphilis Health Check™ device from Trinity Biotech is a qualitative rapid assay for the detection of Treponema pallidum (syphilis) antibodies. The device is CLIA-waived only for use with finger stick.

This device is designed for initial screening for syphilis. It cannot be used for diagnosis or syphilis staging. Because it is an antibody test, any person who has previously had syphilis (treated or untreated) may have a reactive result; individuals with a prior history of syphilis should have a blood sample sent to the laboratory for an RPR test.

The test device does not require a blood draw and produces results in less than 15 minutes. Therefore, it is ideally suited for screening in clinics and during community-based outreach in settings with higher prevalence of syphilis.

SERVICE POPULATION

Syphilis Health Check™ is best suited for high risk populations in two different settings.

1) This device can be used in Public Health Offices for rapid screening of high risk individuals. The advantage is that results are received during the same visit, so that persons with reactive tests can immediately receive further testing and/or treatment.

2) This device can be used for screening events held in community settings, including outreach with mobile units or at special events. It is particularly appropriate for venues that include populations with higher rates of syphilis.

Populations with higher rates of syphilis include but are not limited to: 1) gay/bisexual men and other men who have sex with men (MSM), 2) transgender persons with male sexual partners and 3) persons who trade sex for money, drugs and/or other resources. However, any population that has higher rates of syphilis as shown by STD surveillance data is appropriate for this device, including targeting events or settings in zip codes or geographic areas with known outbreaks.

This test is not appropriate for anyone with a prior history of syphilis. When feasible, a record search for the patient in the PRISM system should be used to determine if there is a prior history, whether or not the client recalls having had syphilis.

This test is not an ideal device to use on sexual contacts of known cases of syphilis. Contacts who fall within the exposure period should be treated presumptively. Use of Syphilis Health Check™ could inappropriately discourage such treatment. For example, if a contact receives a rapid test and gets a false negative result because antibodies have not yet developed, the patient and/or provider may be hesitant to give treatment when it would be beneficial.

METHODOLOGY

Syphilis Health Check™ can be run by any Public Health Division (PHD) staff, volunteers and/or interns who complete required training and are certified by the STD Program. The training is a 90 – 120 minute session provided either by Trinity Biotech corporation trainers and/or trainers certified by the STD Program. The class covers all content required for the CLIA waiver for use of this test.

I. Required Materials

a) Supplies provided and packaged with the Syphilis Health Check™ test devices:
   i) 20 test devices (individually pouched)
   ii) Diluent (5.0 ml)
   iii) 20 disposable plastic fixed-volume pipettes
   iv) One package insert
b) Syphilis Health Check™ Kit Controls
c) Timer, stopwatch or watch capable of timing 10 - 15 minutes (use of personal smart phones as a timer is discouraged to ensure clean workspace)
d) Sterile lancet to obtain 50 microliter whole blood sample via fingerstick
e) Clean, disposable, absorbent workspace cover (i.e. chucks or exam drape)
f) Thermometer with high/low temperature
g) Flat work surface and good lighting to process and read tests
h) Biohazard/sharps disposal container and red bags for biohazardous waste
i) Disposable gloves, antiseptic wipes, adhesive bandages and sterile gauze pads

II. Testing Procedures

a) Calibration of Instruments

Not applicable.

b) Temperature Control

The acceptable range for storing and operating the Syphilis Health Check™ test kits and kit controls are as follows.

Activity	Temperature Range
Syphilis Health Check™ **kit storage**	39.2° to 86° F (4° to 30° C)
Syphilis Health Check™ **test operation**	68° to 78.8° F (20° to 26° C)
Syphilis Health Check™ **controls storage**	35.6° to 46.4° F (2° to 8° C)

At the start of each day of testing, the thermometer stored with the test kits should be examined to ensure that they have remained within the acceptable storage range. The high and low temperatures should be recorded on *Form B – Temperature Log*. If kits have been stored in a refrigerator, allow at least 20 minutes to reach operating temperature.

At the start of specimen collection for each test, the current temperature should be reviewed. The acceptable range for test operation is 68° to 78.8° F. The current test area temperature should be noted on the *Form A – Rapid Syphilis Test Results Log*.

If the tests have been outside the acceptable storage temperature range or the test area is outside the operating range, a new set of controls must be run.

c) Test Procedure

Read the Syphilis Health Check™ package insert completely before using the product. Follow instructions carefully. Not doing so may result in inaccurate test results.

i) Work Space: Set up the work space and gather all needed materials. Allow the test kits to come to operating temperature (68° to 78.8° F) before use. Ensure there is a flat and stable table and cover it with a clean, disposable, absorbent workspace cover.

ii) Gloves: Use of gloves is required for all rapid testing and when running controls.

iii) Expiration: Check the expiration date of the test device. Do not use after the expiration date.

iv) Patient Consent: Assess the client's ability to give informed consent and readiness to receive a preliminary reactive result during the testing session. Obtain the client's (or guardian's, if applicable) informed consent. Verbal consent can be documented by completing the test log.

v) Test Device: Open the pouch containing the test device. ***Perform only one test at a time.*** To ensure that the test results are given to the correct individual, label the test device by writing the patient name, initials or BEHR record number on top of the device.

vi) Sample Collection: Use the procedures in the following section to collect a whole blood sample via fingerstick. These procedures also describe how to add the sample to the test device. ***The test kit is CLIA-waived only with fingerstick specimens; venipuncture whole blood samples, serum, and plasma samples may not be used.*** Specimens must be tested immediately after collection.

vii) Run and Time Test: Holding the dropper bottle of diluents in a vertical position, add four (4) full drops (200 microliter) in 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.

Set timer for 10 minutes and set the test cassette device on a flat surface to

incubate at operating temperature (68° to 78.8° F).

Read the results after ten (10) minutes but not more than fifteen (15) minutes incubation time. If the test is not read between 10 and 15 minutes, repeat the test using a new test device.

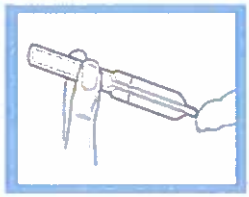
Check if test results are valid. **For the test result to be valid, the sample well must contain full red color AND a control line next to "C" must also be present**. If no red color is seen in the sample well OR there is no control line present, repeat the test with a fresh test device.

d) Sample Collection - Fingerstick Blood

i) Follow appropriate procedures to gather a sample of blood using fingerstick.

- Clean the finger of the person being tested with an antiseptic wipe. Allow to dry thoroughly or wipe dry with a sterile gauze pad.
- Using a sterile lancet capable of producing a 50 microliter sample, puncture the skin just off the center of the finger pad.
- Hold the finger downward. Apply gentle pressure beside the point of puncture. Avoid squeezing the finger to make it bleed.
- ***Wipe away the first drop of blood using a sterile gauze pad, not an alcohol pad.*** Allow a new drop to form.

ii) Collect the blood into the disposable plastic fixed-volume pipette provided with the Syphilis Health Check test devices.

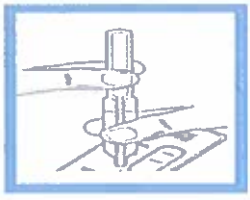


Do so by holding the pipette gently in a horizontal (or slightly above horizontal) position to the sample. ***The specimen may not be adequately drawn if the pipette is held in a vertical position.***

Place the tip of the pipette into the sample, taking care not to squeeze the bulb. Allow the blood to flow into the pipette on its own. Make sure that there are no air bubbles, empty spaces or gaps in the specimen. Maintain this position until the flow of the sample into the pipette has been stopped. The sample should fill to the mark on the pipette.

If sample is not collected to this mark, or if air bubbles, empty spaces or gaps are present, the pipette should be safely discarded and another specimen should be collected from another finger by repeating the sample collection process.

iii) Holding the pipette vertically, squeeze the bulb until the sample is fully dispensed into the sample well. If the sample does not fully dispense, cover the small opening at the mark on the pipette with gloved fingers and then squeeze the bulb until the sample is fully dispensed.



iv) Allow the sample to absorb into the paper in the sample well. Ensure that air bubbles are not introduced into the sample well. Dispose of the pipette in a biohazard waste bag or sharps container. Start timing the test and continue with the general testing procedures.

e) Safety Precautions

Handle blood specimens and materials as if they are capable of transmitting infectious agents. Dispose of all test specimens and materials in the appropriate biohazard container. Lancets should be placed in puncture-resistant containers. Do not pipette by mouth.

Do not eat, drink or smoke in areas where specimens are being handled or testing is being performed.

Wipe all spills thoroughly with a solution of 10% bleach or other appropriate disinfectant.

In case of diluent solution contact with eyes, rinse immediately with plenty of water and seek medical advice. Avoid contact between solution and acids.

III. Quality Control Procedures

The Syphilis Health Check™ device has a built-in procedural control. **For the test result to be valid, the sample well must contain full red color AND a control line next to "C" must also be present.** If no red color is seen in the sample well OR there is no control line present, repeat the test with a fresh test device.

The following external control procedures must be followed as well.

a) Reasons to Run Controls

If controls do not produce the expected results, that invalidates any tests conducted since controls were last run. Therefore, controls should be run with regular frequency to ensure that few tests will be invalidated due to any problems.

Controls should be run routinely, although this schedule varies by site. At a minimum, controls must be run once per month. (Because each user must run controls again if they have not used the test in two weeks, it can be practical to "rotate" among different staff to run controls to reduce the number used overall in each office.)

In addition, controls should be run at least once after completion of 20 tests. It is recommended that controls be run before every large outreach or testing event that may have significant volume.

The kit controls also must be run under the following circumstances:

- Each new operator prior to performing testing on patient specimens. A new operator is defined as an individual who has not run the test for at least two weeks.
- When opening a new lot of test devices.
- Whenever a new shipment of test kits is received.
- If the temperature of the test kit storage area falls outside of the range of 39.2° to 86° F.
- If the temperature of the testing area falls outside the range of 68° to 78.8° F.

b) Control Storage

Controls must be stored in a laboratory refrigerator (i.e. contains no food). The acceptable range for storing the Syphilis Health Check™ kit controls is 35.6° to 46.4° F. Store in an upright position to prevent leakage. The controls must come to operating temperature before running the test with them. Control solutions that are visibly turbid (i.e. cloudy) should be discarded in accordance with safety procedures.

When opening each box of controls, the box must be labeled with the initials of the person opening the box. In addition, the expiration date on the box should be circled.

Controls must be discarded 12 months after they are opened. Therefore, when opening the box containing the controls, this discard date (12 months from the current date) must be written on the box. Dispose of unused portions of opened Kit Control vials upon the expiration date or discard date, whichever is sooner.

c) Control Test Procedure

(1) Each kit control contains two vials, one (1) to produce a negative result and one (1) to produce a positive result. Both of these controls should be run at the same time.

(2) The Positive Control will produce a positive test result and has been manufactured to produce a faint test line. The Negative Control will produce a negative test result.

(3) The results are interpreted in the same way as test results, except that the sample well will not have a red color.

(4) If the tests with the controls do not produce the expected results as described in the kit control package insert, they may be run a second time or the test kits may be run with another set of controls.

If these also do not produce the expected results, report the problem to the Director of Nursing Services (DNS), Regional Health Officer (RHO) and/or STD Program Manager. Notify and return the entire stock of Syphilis Health Check™ with the same lot number and shipping date to the STD Program. Identify all individuals tested with kits from the lot number and shipping date since the last set of successful controls were run in case notification is necessary.

IV. Interpretation and Provision of Test Results

Read the results after ten (10) minutes but not more than fifteen (15) minutes incubation time. If the test is not read between 10 and 15 minutes, repeat the test using a new test device.

Check if test results are valid. **For the test result to be valid, the sample well must contain full red color AND a line next to "C" must also be present.** If no red color is seen in the sample well OR there is no control line present next to "C", repeat the test with a fresh test device.

See ***Attachment B: Interpretation of Valid Results*** for illustrations of negative and preliminary positive results.

Once read, the test and disposable workstation should be disposed into a biohazard container. ***Do not show the client the testing device.***

a) **Negative:** A red line of any intensity appears next to the letter "C", a full red color appears in the Sample Pad and no red line is present at the Test "T" area.

   A negative test means that the test was non-reactive and Treponema pallidum (syphilis) antibodies were not detected.

b) **Preliminary Positive:** A red line of any intensity appears next to the letter "C" (for control), a full red color appears in the sample port and a red line of any intensity appears in the device window's Test area marked with "T" (for test).

   A preliminary positive test result is interpreted as a presumptive positive for Treponema pallidum (syphilis) antibodies.

   For all preliminary positive results, a blood draw should be conducted with the sample sent to the state's Scientific Laboratory Division (SLD) for further testing including an RPR test. Further testing is normally needed before treatment is provided.

   See ***Attachment C: Screening/Testing Algorithm*** for flow chart of required follow-up testing after a preliminary positive result.

c) **Invalid:** The test result is invalid if a red color is not seen in the Sample Pad. The test result is also invalid if there is no red line next to the letter "C".

   An invalid result means there was a problem running the test with the specimen or device. ***This result can not be interpreted.*** The test should be repeated.

   The client should be informed that this indicates operator error or an issue with the test kits themselves; it should not be interpreted as an indication of the possible syphilis infection status of the patient.

V. Limitations of Procedure

a) Reading the test result earlier than 10 minutes or later than 15 minutes may yield erroneous results.

b) A non-reactive (negative) test result does not preclude the possibility of recent exposure to syphilis. High risk clients should be encouraged to return for retesting when three months has lapsed since their last sexual contact.

c) The intensity of the line next in the test areas on the device is not an indication of the level of antibody in the specimen.

VI. Documentation

a) As with all laboratory tests run by PHD either in Public Health Offices (PHO) or during outreach, rapid point-of-care tests such as Syphilis Health Check™ 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.

b) When rapid point-of-care tests are run by staff who are not clinicians or nurses, this 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.

c) Syphilis is a reportable STD in New Mexico. Therefore, all preliminary positive results on the Syphilis Health Check™ device must be reported to the NMDOH STD Program.

This can be done by the staff member who ran the test by ensuring that this lab is entered into the PRISM database system. This should be done the same day that the test is run. This will ensure that the case is well documented for follow-up before the confirmatory test results are received.

ATTACHMENTS

Attachment A: Public Health Division Standing Order for Nurses
Attachment B: Interpretation of Valid Results
Attachment C: Screening/Testing Algorithm
Attachment D: PHD Clinical Protocol Approval Sheet
Attachment E: Acknowledgement and Receipt of New/Revised Protocol

Form A: Syphilis Health Check™ Test Results Log
Form B: Syphilis Health Check™ Test Temperature Log
Form C: Syphilis Health Check™ Test External Controls Results Log

Attachment A

PUBLIC HEALTH DIVISION
STANDING ORDER FOR NURSES

PROGRAM: STD Program, Infectious Disease Bureau

CLINICAL PROTOCOL/MANUAL TITLE: Rapid Syphilis Testing using Health Check™ Device

Purpose: This device is designed for initial screening for syphilis. Because it is an antibody test, any person who has previously had syphilis (treated or untreated) may have a reactive result. Follow Standing Orders for screening for syphilis reinfection in these individuals, including using a blood sample sent to the laboratory for an RPR test.

Because the test device does not require a blood draw and produces results in less than 15 minutes, it is ideally suited for screening in clinics and during community-based outreach in settings with higher prevalence of syphilis.

Policy: Under these standing orders, eligible nurses and other healthcare professionals employed by the New Mexico Department of Health, where allowed by state law, may perform syphilis screening on any who meet any of the criteria below.

Procedure: please see "Methodology" section of the attached "**Rapid Testing using Syphilis Health Check™ Device**" protocol for detail of test administration and service population.

1. Collect and process blood according to "Methodology" as above.
2. Interpretation of results per "Methodology" as above.
3. ***Positive results:*** encourage patient to have a confirmatory test drawn immediately, and refer for medical treatment immediately.
4. Document each patient's result in the medical chart.

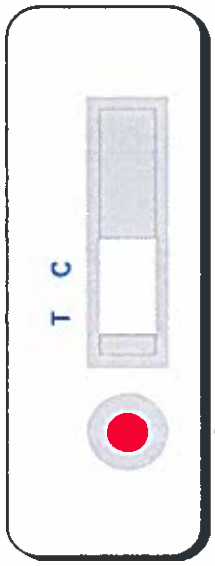
This policy and procedure shall remain in effect for all patients of the New Mexico Department of Health until rescinded.

IDB Medical Director's signature: _____ 2/19/16

Effective date: 1/29/16

Attachment B

ILLUSTRATION OF VALID RESULTS



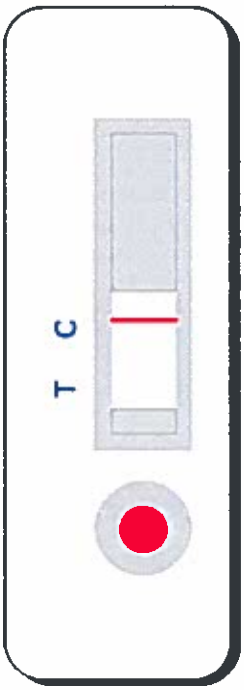
For a fingerstick test result to be valid, there must be a control line present and full red color in the sample well.

Test must be read between 10-15 Minutes

Control Line Area

Test Line Area

Sample Well



Negative

Valid Test Result

Control Line Present

Test Line Absent

Full Red color in the sample well

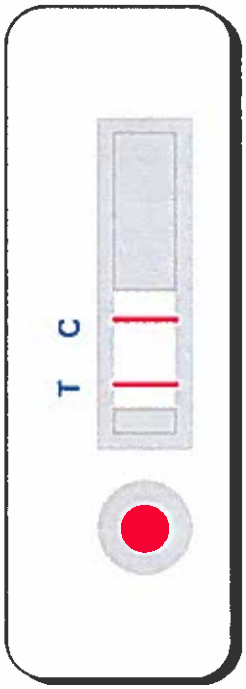
Positive

Valid Test Result

Control Line Present

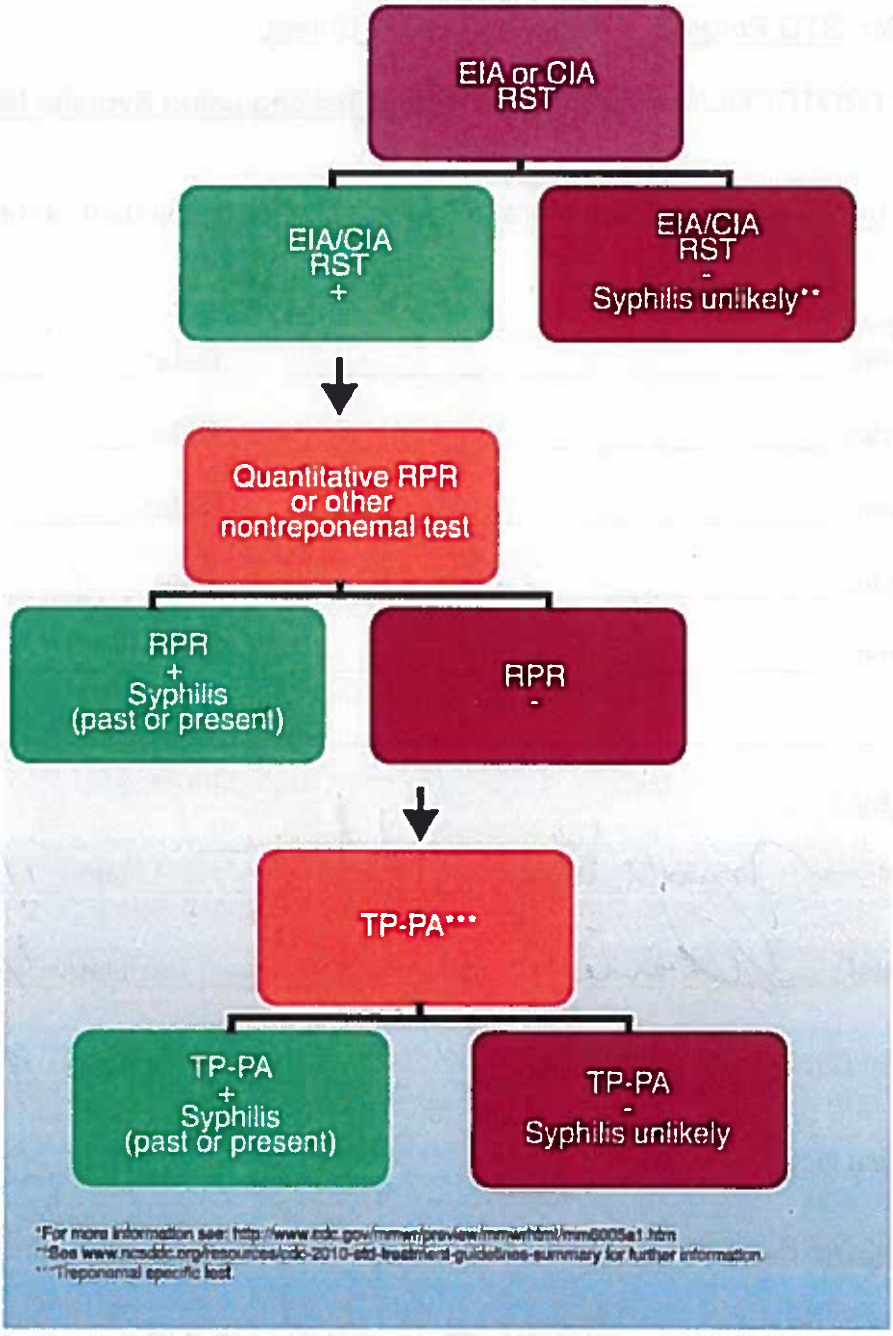
Test Line Present

Full Red color in the sample well



Attachment C

SCREENING/TESTING ALGORITHM



EIA = Elisa screening test
RST = Rapid Syphilis Test (such as Syphilis Health Check)

Source: National Coalition of STD Directors (NCSD)

Attachment D

PUBLIC HEALTH DIVISION
CLINICAL PROTOCOL/MANUAL APPROVAL SHEET

PROGRAM: STD Program, Infectious Disease Bureau

CLINICAL PROTOCOL/MANUAL TITLE: Rapid Testing using Syphilis Health Check™ Device

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

User Reviews:

Name: _____ Date: _____

Name: _____ Date: _____

Name: _____ Date: _____

Name: _____ Date: _____

Name: _____ Date: _____

Approved by:

Program Manager _____ Date 1/28/16

Bureau Chief _____ Date 1/29/16

IDB Medical Director _____ Date 1/29/16

PHD Medical Director _____ Date 2/1/16

Regional Health Officer _____ Acting NE Region Date 2/1/16

Director of Nursing Services _____ DNS Date 2/17/16

PHD Chief Nurse _____ Date 2/19/16

Attachment E

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

PROGRAM: STD Program, Infectious Disease Bureau

CLINICAL PROTOCOL/MANUAL TITLE: Rapid Testing using Syphilis Health Check™ Device

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

Regional Director	Date
Regional Health Officer	Date
Regional Director of Nursing Service	Date
Regional Director of Nursing Service	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	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.