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Evaluation of Rapid Syphilis Testing Using the Syphilis Health Check in Florida, 2015–2016

Jennifer Richards, MPH [DrPH student],

Florida Agricultural and Mechanical University, Institute of Public Health, Tallahassee, FL.

James Matthias, MPH [Associate Service Fellow],

STD and Viral Hepatitis Section, Florida Department of Health, Tallahassee, FL.

Charlotte Baker, DrPH, MPH, CPH [Assistant Professor],

Department of Population Health Sciences, Virginia Polytech Institute and State University, Blacksburg, VA.

Craig Wilson [Section Administrator],

STD and Viral Hepatitis Section, Florida Department of Health, Tallahassee, FL.

Thomas A Peterman, MD, MSC [Medical Officer],

Division of STD Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention, Atlanta, GA.

C Perry Brown, DrPH, MSPH Professor,

Institute of Public Health, Florida Agricultural and Mechanical University, Tallahassee, FL.

Matthew Dutton, PhD [Associate Professor],

Economic, Social, and Administrative Pharmacy, Florida Agricultural and Mechanical University, Tallahassee, FL.

Yussif Dokurugu, DrPH, MPH [Assistant Professor]

Institute of Public Health, Florida Agricultural and Mechanical University, Tallahassee, FL.

Abstract

The Syphilis Health Check (SHC) had low estimated specificity (91.5%) in one Florida county. We investigated use of SHC by a range of Florida publicly-funded programs between 2015 and 2016 to estimate specificity, positive predictive value (PPV), field staff acceptance, and impacts on programmatic outcomes. All reported SHC results were extracted from routinely collected program data. Field staff were surveyed about SHC's utility. Analyses investigated differences between SHC and traditional syphilis testing outcomes. Of 3,630 SHC results reported, 442 were reactive; 92 (20.8%) had prior diagnoses of syphilis; 7 (1.6%) had no further testing. Of the remaining 343; 158 (46.0%) were confirmed cases, 168 (49.0%) were considered false-positive, and 17 (5.0%) were not cases but not clearly false-positive. Estimated specificity of SHC was 95.0%. Overall, 48.5% of positives became confirmed cases (PPV). PPV varied according to

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jenniferl.richards@famu.edu.

prevalence of syphilis in populations tested. Staff (90%) thought SHC helped identify new cases but expressed concern regarding discordance between reactive SHC and lab-based testing. Programmatic outcomes assessment showed shorter time to treatment and increased numbers of partners tested for the SHC group; these enhanced outcomes may better mitigate the spread of syphilis compared to traditional syphilis testing alone, but more research is needed.

BACKGROUND

The U.S. Food and Drug Administration granted the first-ever Clinical Laboratory Improvement Amendments waiver for a rapid treponemal syphilis screening test, Syphilis Health Check, in December 2014 (FDA, 2014). Accurately identifying new cases of syphilis, administering timely treatment, and securing timely partner notification for testing and treatment are cornerstones of successful public health interventions to control the spread of syphilis.

The SHC may facilitate these interventions, but very few studies have investigated its performance in the field. One small cohort study found that sensitivity was 71.4% and specificity was 91.5%, significantly lower than the >98% specificity reported for SHC (Matthias et al., 2016). Findings from a larger United States cohort study using 2014 – 2016 data to investigate the performance of SHC showed that sensitivity ranged from 88.7% to 95.7% and specificity ranged from 93.1% to 93.2%, depending on the method of confirmatory test result consensus used (Pereira et al., 2018). Other studies have found mixed results with a range of sensitivity (61.1% to 92.0%), specificity (92.7% to 99.6%), and positive predictive value (9.4% to 97.5%) (Jafari et al., 2013; Seña, White, & Sparling, 2010; Toskin et al., 2017).

Few studies have assessed the acceptability of the SHC among healthcare workers and patients (Ansbro et al., 2015; Swartzendruber, Steiner, Adler, Kamb, & Newman, 2015), and none have been from the United States. A rapid point of care test could reduce clinic waiting time, allow same-day treatment, facilitate outreach testing, and allow substitution of finger-stick for venipuncture (Ansbro et al., 2015; Swartzendruber et al., 2015). Faster identification of new syphilis cases could decrease time to treatment and facilitate partner treatment.

Purpose

Florida has multiple syphilis testing sites across the state and routinely captures testing and case management information, including time to treatment and numbers of partners named, tested, infected, and treated. We aimed to describe the results of SHC testing in Florida after a state-wide implementation and the impact on programmatic outcomes. Moreover, we surveyed the staff that used SHC to identify benefits and challenges to using it in the field.

METHODS

Data Extraction and Study Population

All records for adults tested with SHC from 08/01/2015 through 12/31/2016 were extracted, de-identified, and compiled. The SHC was performed by health department staff who had been trained in administering the SHC. Test settings varied based on program needs. Data included syphilis testing location, test type, test results, case/non-case determination, treatment, and partner services outcomes. We excluded persons who required testing for congenital syphilis or neurosyphilis, as the SHC test is not appropriate for determining these types of syphilis. This was a program evaluation of standard routine public health practices using de-identified programmatic data. Thus, it was determined not to be human subjects research.

SHC Reactivity Rate Determination

All 67 Florida health departments were given the opportunity to receive SHC kits for rapid syphilis testing free of charge. Each health department self-selected whether to use the SHC at its site or not. If a health department did request SHC kits to use, the only stipulation was that the health department had to report all SHC test results to the health department of the county in which the patient resides. Training of field staff for use of the SHC was provided by the SHC distributor. All tests reported in this study were done by health departments. A total of 35 Florida counties conducted SHC testing. For inter-county comparison, data was stratified by volume of SHC tests given for the top 11 SHC-using counties and combined for the small volume remaining in the other 24 counties. The top 11 counties, in order of greatest number of SHC tests conducted to the least, were Orange, Miami-Dade, Escambia, Lee, Alachua, Polk, Duval, Leon, Hillsborough, Palm Beach, and Brevard.

The performance of the SHC was investigated at both statewide and county levels. Variables of interest were SHC test result status (positive or negative), agreement or discordance between SHC results and traditional testing (non-treponemal and/or treponemal) results, new syphilis cases identified from SHC testing, and new syphilis cases treated as the result of positive SHC test results.

We excluded from the analyses any SHC test results that were done on persons with a history of past syphilis or when there were no associated confirmatory test results. The prevalence of syphilis among persons appropriately tested was estimated as the number of new syphilis cases reported divided by the number of persons tested. The Council for State and Territorial Epidemiologists (CSTE) case definition for reported syphilis cases was used to determine new cases.(Sosa, 2017) Specific to this study, new cases were assessed and classified by local program staff. For this evaluation, SHC reactive tests without both a reactive treponemal and non-treponemal test or a diagnosis of primary syphilis by a provider were considered inconclusive. Positive predictive value (PPV) was calculated after excluding persons with inconclusive results on additional testing. Thus, PPV was the new cases divided by the sum of the new cases plus the false positives, times 100. Specificity was estimated by considering all negative SHC to be true negatives. No false negative SHC were identified because persons who tested negative on the SHC were not retested. The specificity

is the number of true negatives divided by the sum of the true negatives plus the false positives, times 100.

Programmatic Outcomes Assessment Comparing SHC with Traditional Syphilis Testing

In order to identify programmatic benefits of the SHC, we conducted analyses comparing cases identified using the SHC administered by health department staff with cases identified at public health departments using traditional syphilis testing in the 11 Florida counties that did the most SHC testing during the defined study period for 2015 and 2016. Treatment data were collected by health department staff from syphilis investigations conducted by healthcare providers. Timeliness of treatment was calculated by subtracting the recorded date of treatment from the date of specimen collection. The outcome variables were timeliness of treatment, number of named partners, number of named partners tested, number of named partners infected, and number of infected partners treated (see Variables of Interest, Appendix 1).

Survey Interviews of Field Staff

Field staff interviews were conducted from 09/27/2017 through 10/19/2017 using a 27-question survey instrument to assess the value of the SHC as a screening test and its effectiveness as a tool to prevent the spread of syphilis (see Survey Instrument, Appendix 2). Survey participants were not chosen at random, rather they were chosen based on expertise with the SHC. Participants consisted of one program manager and those field staff who had the most experience administering the SHC test as identified by the Florida Department of Health STD program. The roles served by these field staff included syphilis testing, supervising staff who conduct syphilis testing, and those involved in follow-up partner services. Field staff participating in the survey were representative of the top 11 SHC-using Florida counties: Orange, Miami-Dade, Escambia, Lee, Alachua, Polk, Duval, Leon, Hillsborough, Palm Beach, and Brevard. For consistency, all surveys were conducted by one research team member via telephone interview.

Data Analysis

Statistical analyses were done using SAS 9.4 (Cary, NC) and [OpenEpi.com](https://openepi.com/) (Dean, Sullivan, & Soe, 2011). Chi Square tests were used to determine statistically significant differences between groups. Generalized Linear Models (GLM) were used to determine whether statistically significant differences existed between the means of programmatic outcomes for the SHC Testing Group and the Traditional Testing Group.

RESULTS

SHC Reactivity Rate Determination

For 08/01/2015 through 12/31/2016, there were 3630 SHC tests reported, 442 (12.0%) were positive, 3168 (87.0%) were negative, and 20 (1.0%) were inconclusive. Of the 442 positive SHC results, 92 (20.8%) had a prior diagnosis of syphilis (even though a screening tool was used to minimize SHC testing in this group), 7 (1.6%) had missing information regarding prior diagnosis of syphilis or had no further confirmatory testing, leaving 343 (77.6%) who had no prior diagnosis of syphilis and had further testing. Of these 343, 158 (46.0%) were

considered true positives based on non-treponemal reactive rapid plasma reagin (RPR) and treponemal (primarily treponemal enzyme immunoassays [EIA]) testing (157) or a negative RPR with a reactive treponemal test and a lesion consistent with primary syphilis (Figure 1). Treatment was documented for 157 (99.4%) of the 158 new cases. There were 168 (49.0%) false positives that were not reported as new cases and had negative results on the RPR (138), treponemal test, or both (29). Finally, 17 (5.0%) of the 343 with reactive SHC were considered inconclusive because they were not reported as a new case of syphilis but had reactive results on the RPR (7), treponemal test, or had the combination of reactive treponemal test /negative RPR (9). The prevalence of new syphilis in the population tested (after removing those with inconclusive SHC results, prior syphilis, or no further testing) was 4.5% (158/[3630–20–92–7]). Specificity was estimated to be 95% using the false positives (168) and all 3168 who tested negative on SHC (3168/[168+3168], x 100). The PPV was estimated from the true and false positives to be 48.5% (158/[158+168]) (Table 1).

The largest number of SHCs were done in Orange County, followed by Miami-Dade, Escambia, Lee, Alachua, Polk, Duval, Leon, Hillsborough, Palm Beach, and Brevard. These counties accounted for approximately 93.0% of all SHC testing conducted and approximately 90.0% of all new cases of syphilis that were identified using the SHC test in Florida during the time period. The statewide prevalence of newly identified syphilis (those cases found using the SHC test) in the populations tested was estimated to be 4.5% (range of 0.4% to 28.2% in all SHC using counties). Statewide, 48.5% of persons with a positive SHC had newly diagnosed syphilis (the positive predictive value). By county, this ranged from 8.0% to 100%, depending on the prevalence of syphilis among those tested, and was lowest in the two highest SHC volume counties. Per county, the specificity ranged from 90.1% to 100% among the 11 most SHC-using counties (Table 1).

Programmatic Outcomes Assessment Comparing SHC with Traditional Syphilis Testing

The sample size of syphilis cases used in the analyses of programmatic outcomes was $n=1644$ and included those who: (a) were tested for syphilis using SHC or traditional testing during the study period, (b) were from the top 11 SHC-using Florida counties, (c) had no prior diagnosis of syphilis, and (d) had public initial lab ordering providers. Of these 1644 cases, 93 were from the SHC testing group and 1551 were from the traditional testing group. In the SHC testing group, all 93 cases were treated. In the traditional testing group, 37 of the 1551 cases (2.4%) were not treated or were otherwise lost to follow-up.

Timeliness of treatment.—Persons tested with SHC were more likely to receive prompt treatment than persons from the traditional testing group [same day (RR = 1.88; 95% CI, 1.54–2.30), 7 days or less (RR = 1.63; 95% CI, 1.44–1.84), 14 days or less (RR = 1.19; 95% CI, 1.10–1.28), and 30 days or less (RR = 1.06; 95% CI, 1.03–1.10)]. The average time to treatment among those treated was 7.3 days for the SHC group versus 13.0 days for the traditional testing group ($F=3.55$, $p=0.06$) (Table 2).

Partner Elicitation, Testing, and Treatment.—Among new cases, patients tested with the SHC were more likely to name partners than patients who had traditional testing (RR = 1.44; 95% CI, 1.27–1.63) and they named a higher average number of partners (1.3

compared to 0.8 partners) ($F=16.79$, $p<.0001$) (Table 2). Patients who had SHC testing were more likely to have at least one named partner tested than patients from the traditional testing group (RR = 1.45; 95% CI, 1.23–1.72) and they had a higher average number of named partners tested (0.9 partners compared to 0.6 partners) ($F=20.35$, $p<.0001$) (Table 2). The SHC testing group was more likely to have named partners identified as infected than was the traditional testing group (RR = 2.34; 95% CI, 1.82–3.01) and had a higher average number of named partners identified as infected (0.5 compared to 0.2 partners infected) ($F=40.20$, $p<.0001$), even when controlling for those who named at least one partner (0.8 compared to 0.5) ($F=19.13$, $p<.0001$) (Table 2). The SHC testing group was more likely to have infected partners subsequently treated than was the traditional testing group (RR = 2.29; 95% CI, 1.77–2.96) and had a higher average number of named infected partners treated (0.5 compared to 0.2) ($F=37.58$, $p<.0001$) (Table 2).

Survey Interviews of Field Staff

A total of 20 field staff surveys were conducted. These field staff included one test administrator and one program manager from each of the high-volume SHC-using programs (with one of the test administrators and one of the program managers representing two of the high-volume counties that are adjacent to each other). The 20 survey participants reported that the training they received from the SHC distributor for using the SHC test prepared them to confidently administer the test. Most said the SHC test was easy to use (15/20), test results were easy to read (16/20), and that they had confidence in the accuracy of the results (12/20). Strengths of the SHC included: (a) highly appropriate to use in outreach settings (6/20, 30%), and (b) quick results were appreciated by staff and patients (8/20, 40%). Respondents described twenty-two examples in which the SHC test was particularly helpful to field staff and/or patients and are elucidated here: (a) confirming syphilis in the presence of symptoms (2/20), (b) quickly putting patients' minds at ease when SHC results were negative or making patients aware of the need for further testing when SHC results were positive (3/20), (c) testing people who preferred a finger-stick or were afraid of needles (16/20), and (d) quickly identifying an infected pregnant patient who was HIV positive (1/20).

Settings that survey respondents thought were most appropriate for using the SHC test were health department clinics, outreach sites, physician's offices, emergency rooms, community-based organizations, jails, STD clinics, and any sites that offer free services. Most respondents thought the SHC test was a beneficial addition to traditional syphilis testing (16/20). When asked about the percentage of clients who had a difficult time understanding what a positive SHC test result meant, the answers varied widely from 0.0% to 80.0%, with the majority being 10.0% or less. The respondents further stated that this was "about the same" amount as clients who also had difficulty understanding results from traditional syphilis testing.

The weaknesses reported for the SHC test were that test kits expired too quickly (2/20) and that the pipet included in the test kit was flimsy, making it difficult to get a blood sample (7/20). The most common complaint about the SHC test was field staff were concerned there may have been too many "false positive" results (14/20).

Most respondents said they did not notify named partners of clients with positive SHC test results until they have the confirmatory test results back (14/20). Replies from the 20 respondents about beginning treatment for syphilis, based on positive test results from the SHC alone, were mixed; five were “highly likely” to begin treatment, five were “likely” to begin treatment, one was “neutral,” three were “unlikely,” and six were “very unlikely.” Those who were “highly likely” or “likely” to begin treatment reserved this only for clients who also had symptoms of syphilis or had a confirmed syphilis exposure.

Most respondents said that positive SHC test results presented no more of a challenge for counseling or administering treatment than positive results from traditional syphilis testing (17/20). Most respondents also said that the quick results from the SHC test provided a better service than traditional testing for clients in settings other than the health clinics (17/20). For syphilis testing in settings other than the health clinic (such as outreach sites), most respondents said they prefer to use the SHC test because a larger volume of testing can be done, and it helps to mitigate the spread of syphilis, especially in jails, where there is a readily available audience for testing participation (13/20). Respondents’ opinions varied regarding the use of the SHC test in the health clinic settings; five preferred using the SHC test alone, four preferred using traditional testing alone, six preferred using both the SHC test and traditional testing together, three had no preference, and two were neutral.

DISCUSSION

Using data collected from testing in a wide variety of settings in Florida, we estimate the specificity of the SHC was 95.0%, as in many cases the SHC was compared against a non-treponemal result. Although the specificity was fairly consistent in the 11 different counties studied, the proportion of persons with positive tests who were diagnosed as having syphilis (predictive value of a positive test) varied, mostly due to differences in the prevalence of syphilis among those tested (0.4% to 28.2%). Compared to the traditional testing group, the SHC testing group had more timely treatment, more partners named, and more partners identified as infected. These enhanced outcomes may be due to quick SHC test results allowing for more accurate recall in naming partners, as well as enabling Disease Intervention Specialists (DIS) to promptly notify these named partners (Hoots et al., 2014; Rudy et al., 2012).

Additionally, a greater sense of urgency for both patient and practitioner may exist when SHC results are positive in the presence of signs and symptoms and/or a known syphilis exposure. This scenario might create expediency for an intervention conversation at this initial encounter to educate the patient and possibly administer treatment. Our findings suggest the SHC could improve syphilis control efforts, however the administration and selection for SHC testing was not randomly assigned and outcomes were assessed against a small sample size of newly detected cases. Going forward, a more rigorous evaluation could help determine if the SHC test truly does improve these outcomes.

Our estimated specificity is higher than the specificity estimated in a previous investigation in Florida (Matthias et al., 2016). A low specificity could be a serious deterrent to using the SHC in low prevalence settings. However, one study concluded that even in low prevalence

settings, screening with rapid syphilis testing remains cost-effective and less expensive than use of the RPR (Mallma et al., 2016). Before implementing the SHC, program administrators should discern the potential value of the test, based on the specific characteristics of their individual programs. Given the relatively stable specificity, but highly variable PPV, the benefits of the SHC will depend on the population tested.

Field staff liked the SHC test, with a majority citing practicality for use by non-laboratory health care workers, flexibility for use in non-traditional settings, and faster test results that allowed quicker identification and treatment of new syphilis cases. They also believed that use of the SHC test could help reduce the spread of syphilis. Field staff also reported concerns about test kits expiring too quickly, challenges in sample collection, and accuracy of results. This information helps to fill in previously recognized gaps in understanding of the performance, usefulness, and limitations of the SHC (Seña et al., 2010).

This study had several limitations. The sensitivity of the SHC test could not be determined because specimens with negative SHC results were not re-tested with other tests to see if any infections were missed. The estimated specificity and “false positives” compared results from a treponemal-based rapid test to, in many cases, only a non-treponemal test. Although these persons would be unlikely to have syphilis, some probably had treponemal antibody due to a previous infection. These issues may limit the confidence in the specificity estimate. Information from the survey interviews of field staff may be unique to Florida’s syphilis prevention program, and therefore may not be generalizable to other programs.

Appendix 1.: Variables of Interest Regarding Programmatic Outcomes

Variable Name	Variable Type	Definition
SHC ^a Testing Group	Categorical	New cases of syphilis identified with the SHC test
Traditional Testing Group	Categorical	New cases of syphilis identified with traditional syphilis tests
Timeliness of Treatment	Categorical and continuous	Categorical – mutually inclusive time interval cut points: Zero days to treatment 7 days or less to treatment 14 days or less to treatment 30 days or less to treatment Over 30 days to treatment or no treatment given Continuous – time to treatment in days
Number of Named Partners	Categorical and continuous	Categorical – stratified responses as “Yes” (partners were named) or “No” (zero partners were named) Continuous – numbers of partners named
Number of Named Partners Who Were Tested	Categorical and continuous	Categorical – stratified responses as “Yes” (named partners were tested) or “No” (zero named partners were tested) Continuous – numbers of named partners tested
Number of Named Partners	Categorical and continuous	Categorical – stratified

Variable Name	Variable Type	Definition
Who Were Infected		responses as “Yes” (named partners were infected) or “No” (zero named partners were infected) Continuous – numbers of named partners infected
Number of Named Partners Who Were Infected and Treated	Categorical and continuous	Categorical – stratified responses as “Yes” (named partners were infected and treated) or “No” (zero named partners were infected and treated) Continuous – numbers of named partners infected and treated

This table describes the variables of interest used to analyze programmatic outcomes.

^aSyphilis Health Check

Appendix 2.: Field Staff Questionnaire – Assessment of the Rapid Syphilis Health Check

Name of Staff Member _____

County Name _____

Instructions:

This survey is being done to obtain the perspectives of field staff about syphilis testing using the Rapid Syphilis Health Check (RSHC). We would like to know what you think about the implementation of syphilis testing using the RSHC in your field setting to help determine best practices and effectiveness of this test.

Section A.

Please complete the following questions.

1. What is your primary profession or role? (Check one response only)

- | | |
|----------------------------------------------------------|----------------------------------------------------|
| <input type="checkbox"/> Nurse | <input type="checkbox"/> Phlebotomist |
| <input type="checkbox"/> Disease Intervention Specialist | <input type="checkbox"/> Lab Technician |
| <input type="checkbox"/> Nurse Practitioner | <input type="checkbox"/> Health Support Technician |
| <input type="checkbox"/> Area Manager | <input type="checkbox"/> STD Supervisor |
| <input type="checkbox"/> Other _____ | |

2. What is your role in syphilis testing? (Check all that apply)

- ☐ Management or administrative role in syphilis testing
- ☐ Supervise staff conducting syphilis testing

- ☐ Conduct syphilis testing
- ☐ Provide health care services for patients who have received syphilis testing/screening
- ☐ Teach other providers or students about syphilis testing
- ☐ Follow-up partner services
- ☐ Other (Specify) _____

Section B.

When answering the following questions, think of the value of the RSHC as a screening test for syphilis.

1. Did the training you received for the RSHC test prepare you to confidently administer this test to those seeking syphilis testing?

☐ Yes ☐ No

☐ If you answered “no”, please explain:

2. Would you rate the RSHC test:

☐ Easy to use ☐ Difficult to use ☐ Neutral

If you answered “difficult”, please explain:

3. Did you experience any challenges in administering the RSHC test?

☐ Yes ☐ No

If you experienced any challenges, please list them here:

Please list any suggestions you may have to address these challenges:

4. Would you rate RSHC test results:

☐ Easy to read/interpret ☐ Difficult to read/interpret ☐ Neutral

If you answered “difficult”, please explain:

5. Do you have confidence in the accuracy of the RSHC test results?

☐ Yes ☐ No

Please explain your answer, for either “Yes” or “No”:

6. Were there any strengths of the RSHC test as a screening test? If so, please list them:

7. Were there any weaknesses of the RSHC test as a screening test? If so, please list them:

8. Was there a situation(s) in which you found the RSHC to be particularly helpful?

☐ Yes ☐ No ☐ Unsure/don't know

Please explain your answer:

9. What settings are most appropriate for use of the RSHC test? (Check all that apply)

- | | | |
|---------------------------------------------------|-------------------------------------------------------|---------------------------------------------|
| <input type="checkbox"/> Health Department Clinic | <input type="checkbox"/> Outreach site | <input type="checkbox"/> Physician's office |
| <input type="checkbox"/> Emergency Room | <input type="checkbox"/> Community-based Organization | |
| <input type="checkbox"/> Other: _____ | | |

10. Has the use of the RSHC test been a beneficial addition to traditional syphilis testing, or would the traditional testing alone suffice?

- ☐ The RSHC has been a beneficial addition
- ☐ The traditional syphilis testing alone would suffice

Please explain your answer:

11. In regard to syphilis testing, what is your opinion about patients' preferences regarding having a finger-stick versus having a tube of blood drawn?

- ☐ Patients prefer a finger-stick
- ☐ Patients prefer having a tube of blood drawn
- ☐ Patients have no preference
- ☐ Unsure/don't know

12. In communicating results of the RSHC test to the patient, what percentage of patients would you say had issues in understanding what a positive screening test means?

_____ %

13. Would you say this percentage is higher or lower than traditional syphilis testing?

- ☐ Higher than traditional testing
- ☐ Lower than traditional testing
- ☐ About the same as traditional testing

Section C.

When answering the following questions, think of the value of the RSHC as a tool in your arsenal against the spread of syphilis.

1. As part of the protocol for RSHC testing, a Rapid Syphilis Test Risk Assessment questionnaire is completed on all clients to determine whether they are at risk for syphilis. Would you say that this questionnaire adequately provides this information?

☐ Yes ☐ No ☐ Neutral ☐ Unsure/don't know

Please explain your answer:

2. As part of the protocol for RSHC testing, a Rapid Syphilis Test Risk Assessment questionnaire is completed on all clients to determine whether they have a history of syphilis. Would you say that this questionnaire adequately provides this information?

☐ Yes ☐ No ☐ Neutral ☐ Unsure/don't know

Please explain your answer:

3. Is the Rapid Syphilis Test Risk Assessment (described in questions 1 and 2 above) helpful, as it pertains to the effectiveness in identifying new syphilis cases?

☐ Yes ☐ No ☐ Neutral

Please explain your answer:

4. Were partners of patients with positive RSHC test results notified before the patient got confirmatory results from traditional syphilis testing?

☐ Yes ☐ No ☐ Unsure/don't know

If you answered "yes", did the RSHC test increase the timeliness of partner notification versus using traditional syphilis testing alone?

☐ Yes ☐ No ☐ Made no difference ☐ Unsure/don't know

5. How likely are you to begin treatment for syphilis based on a positive RSHC test result (before getting confirmatory test results)? (Check one response only)

☐ Highly likely ☐ Likely ☐ Neutral ☐ Unlikely ☐ Very unlikely

6. Did positive RSHC test results present more of a challenge to you in how to proceed with counseling/administering treatment compared to having a positive result from traditional testing?

- ☐ Yes, it presented more of a challenge
- ☐ No, it did not present more of a challenge
- ☐ Neutral, it made no difference either way

Please explain your answer:

7. Does the RSHC test, with same day results, (versus traditional syphilis testing, with a 3 – 7 day wait time for results) better serve the patient population that receives syphilis testing in settings other than the health clinic?

☐ Yes ☐ No ☐ Neutral ☐ Unsure/don't know

Please explain your answer:

8. For syphilis testing in the health clinic, would you prefer to use the RSHC test or traditional syphilis testing alone?

☐ RSHC testing alone ☐ traditional syphilis preference ☐ No know ☐ Unsure/don't

Please explain your answer:

9. For syphilis testing in settings other than the health clinic (such as jail or outreach sites), would you prefer to use the RSHC test or traditional syphilis testing alone?

☐ RSHC testing alone ☐ traditional syphilis preference ☐ No know ☐ Unsure/don't

Please explain your answer:

Section D.

1. List any benefits or positive outcomes that have resulted from the implementation of the RSHC test in your work setting.

2. List any problems or negative outcomes that have resulted from the implementation of the RSHC test in your work setting.

3. Share any other comments about the RSHC test.

Thanks for your help!

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Implications for Public Health Practice

The SHC test appears to be an effective screening tool that provides rapid and reliable test results, especially in the presence of symptoms, that may facilitate same-day treatment or shorter overall time to treatment. The rapid results may enhance timely partner notification by reducing delays in new case identification and reporting, as well as facilitate successful partner services interactions. In addition, it was highly acceptable to both healthcare workers and patients. Our findings about the impact of the SHC on these important outcomes are promising. Further research is needed to continue to define the benefits and limitations of this new test.

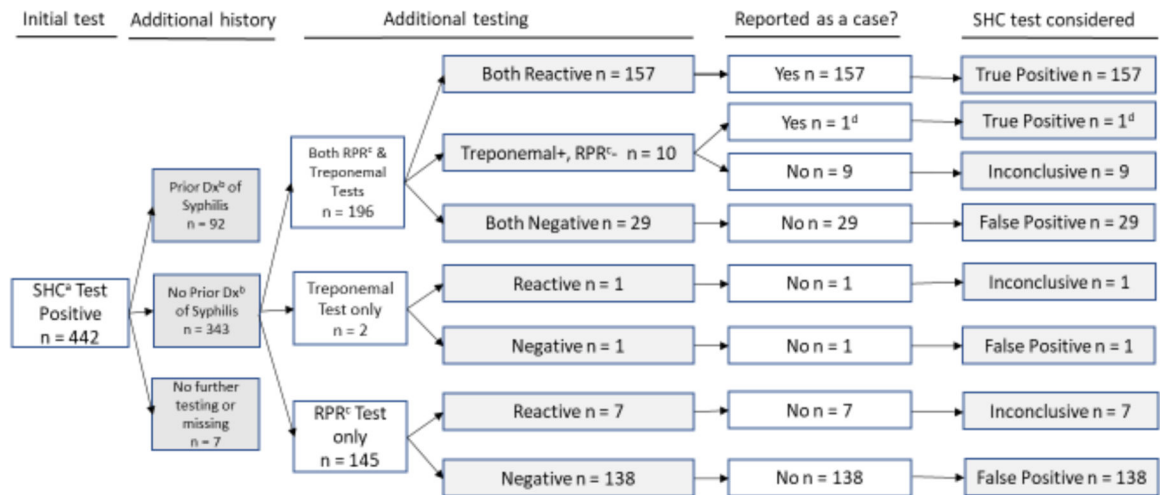


Figure 1. Flow Chart for Syphilis Health Check Positive Results Leading to New Syphilis Cases

A flow chart showing SHC^a positive test results leading to new syphilis cases from 08/01/2015 through 12/31/2016.

^aSyphilis Health Check, ^bDiagnosis, ^cRapid Plasma Reagin, ^dOutlier case conclusively identified as primary syphilis

Syphilis Health Check (SHC) Tests Conducted, those Leading to New Syphilis Cases^a, and Estimated Specificity by County

Table 1.

County	Total SHC ^b Tests Conducted	Total Negative SHC ^b	Total Reactive SHC ^b			Positive Predictive Value (PPV)	Estimated Specificity ^e
			Total Positives ^{ac} SHC ^b	New Syphilis Cases ^a	False Positives ^d		
1 - Orange	1042	936	72	20	52	27.8%	94.7%
2 - Miami-Dade	568	530	28	2	23	8.0%	95.8%
3 - Escambia	471	401	60	32	26	55.2%	93.9%
4 - Lee	450	426	22	5	17	22.7%	96.2%
5 - Alachua	202	179	17	4	13	23.5%	93.2%
6 - Polk	162	150	8	6	1	85.7%	99.3%
7 - Duval	130	78	39	33	2	94.3%	97.5%
8 - Leon	100	90	9	1	8	11.1%	91.8%
9 - Hillsborough	95	64	29	22	7	75.9%	90.1%
10 - Palm Beach	87	73	12	3	7	30.0%	91.3%
11 - Brevard	75	41	15	14	0	100%	100%
All other testing counties (n=24)	248	200	32	16	12	57.1%	94.3%
Total for entire state of Florida	3630	3168	343	158	168	48.5%	95.0%

^aFor those who had no prior diagnosis of syphilis

^bSyphilis Health Check

^cExcludes those with inconclusive SHC (20), prior syphilis (92), or no further testing after a positive test (7)

^dExcludes those with inconclusive test results (17)

^eEstimated Specificity = True Negatives/(True Negatives + False Positives)

Table 2.

Comparison of Group Averages for Programmatic Outcomes Between the SHC^a Testing Group and the Traditional Testing Group

Programmatic Outcome	SHC ^a Testing Group n=93 ^b	Traditional Testing Group n=1551 ^b	p-value
Time to Treatment Among Those Who Were Treated, (days, mean)	7.3	13.0 (n=1514)	0.0597
Named Partners, (mean)	1.3	0.8	<0.0001
Partners Tested, (mean)	0.9	0.6	<0.0001
Named Partners Tested Among Those Who Named Partners, (mean)	1.3 (n=70)	1.1 (n=811)	0.0632
Partners Infected, (mean)	0.5	0.2	<0.0001
Partners Infected Among Those Who Named Partners, (mean)	0.8 (n=58)	0.5 (n=665)	<0.0001
Infected Partners Treated, (mean)	0.5	0.2	<0.0001

^a Syphilis Health Check

^b This sub-group includes only the top 11 SHC using counties, subjects with no prior diagnosis of syphilis, and only those subjects who had a public initial lab ordering provider