Effectiveness of the Point of Care Test for Syphilis in Local Health Clinics

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Background

The Syphilis Health Check (SHC) (VEDALAB – France) is a rapid qualitative point of care (POC) test used for the screening of human *Treponema pallidum* (TP) antibodies in whole blood, serum or plasma. The test is Food and Drug Administration (FDA) cleared as a moderate complex test (non-waived). It is advertised to be used as an initial screening test or in conjunction with a non-treponemal laboratory test and clinical findings should aid in the diagnosis of syphilis infection. In addition, it is not FDA-cleared for screening blood or plasma donors.

The Texas Department of State Health Services (DSHS) staff decided the point of care test had potential to improve the diagnosis, treatment, and partner services for persons infected with (or at increased risk for) syphilis.

Methods

Four independent laboratories (Austin-Travis County Health and Human Services, Beaumont Public Health Department, Port Arthur Public Health Department and Corpus Christi-Nueces County Public Health Department) for a period of six months, were selected to participate in the study based on the following criteria:

- Associated with a Sexually Transmitted Disease Clinic
- Routinely performed stat Rapid Plasma Reagin (RPR) tests in the clinic while patients were receive care
- Experienced more than one day delays in receiving treponemal test results from either an in-house lab or other lab
- Expressed interest in participating in the pilot project

Sites were instructed to test persons with the POC test whose RPR test results were reactive and did not have prior syphilis history. Reactive RPR test results were then confirmed with the SHC As part of the pilot, sites were instructed to submit their specimens through the DSHS Austin laboratory or local lab (Corpus Christi-Nueces County HD) for traditional Treponemal Pallidum Particle Agglutination Assay (TPPA) testing confirmation testing processes to verify the reliability of the POC test.

If there was a discordant result between the SHC and the RPR, sites were allowed to make a clinical decision with their patient. Once the site received their treponemal test result, it was logged in and all results were submitted to DSHS for further evaluation. If there was a discordant result between the SHC and the TPPA, sites were instructed to inform DSHS staff and have the lab perform another treponemal test, such as the Florescent Treponemal Antibody Absorption (FTA-ABS).

Testing logs were submitted to DSHS staff where the data was entered into a spreadsheet to evaluate different benefits to implementing the SHC testing technology. The information collected in the logs was matched up to patient identification within the STD*MIS system for measuring the public health follow-up efficiency.

Results

		RPR	
		Positive	Negative
SHC	Positive	202 (TP)	4 (FP)
	Negative	34 (FN)	73 (TN)
Sensitivity		202/202+34 = 85.59 = 85.6%	
Specificity		73/73+4 = .94805 = 94.8%	
Positive Predictive Value (PPV)		202/202+4 = 98.05 = 98.1%	
Negative Predictive Value (NPV)		73/73+34 = .68224 = 68.2%	

Table 2: Comparison of RPR and SHC results

		TPPA	
		Positive	Negative
SHC	Positive	205 (TP)	1 (FP)
	Negative	4 (FN)	103 (TN)
Sensitivity		205/205+4 = .98086 = 98.1%	
Specificity		103/103+1 = .9903 = 99.1%	
Positive Predictive Value (PPV)		205/205+1 = 99.51 = 99.5%	
Negative Predictive Value (NPV)		103/103+4 = .96261 = 96.3%	

Table 3: Comparison of TPPA and SHC results

		RPR + TPPA	
		Positive	Negative
SHC	Positive	206 (TP)	0 (FP)
	Negative	36 (FN)	71 (TN)
Sensitivity		206/206 + 36 = .85123 = 85.1%	
Specificity		71/71 + 0 = 100 = 100%	
Positive Predictive Value (PPV)		206/206 + 0 = 100 = 100%	
Negative Predictive Value (NPV)		71/71 + 36 = .6635 = 66.4%	

Table 4: Comparison of RPR+TPPA and SHC results

(TP= True Positive, FP=False Positive, FN=False Negative, TN=True Negative)

Partner Services Outcomes

	N	Ix	Treated same day	Partners Initiated	Suspects Initiated	Partner C dispo	Partner A dispo	DII	Tx Index	Suspect C	Suspect A
Total	189	188 (98.9 %)	158 (83.2%)*	305 (1.62)	74 (.39)	38	136 (96,27, 13)	99 (.53)	217 (1.15)	5	38
Same Day Interview	153	152 (99.3%)	NA	253 (1.66)	62 (.41)	31	115 (75, 23, 11)	81 (.53)	191 (1.26)	5	29
Follow-up	15	14(87.5%)	NA	17 (1.06)	2 (.13)	1	8 (6, 1, 1)	7 (.5)	15 (1.07)	0	4

Ix = Number of Patients interviewed
Partners Initiated = Number of partners initiated at original interview
Suspects Initiated = Number of persons identified as benefiting from being offered a test
Partner C Dispo = all partners (from original interviews and re-interviews) who were identified as a new case and brought to treatment
Partner A Dispo = all partners (from original and re-interviews) who tested negative and were treated prophylactically for the onset of incubating disease
DII = Disease Intervention Index – the number of cases in which at least one partner was dispositioned as a "C" or an "A"
Tx Index = Treatment Index – the number of partners or suspects who were treated per case
Suspect C = the number of suspects who were identified as a new case and brought to treatment
Suspect A = the number of suspects who tested negative and were treated prophylactically for the onset of incubating disease

*87.3% when excluding persons treated prior to clinic visit

Table 1: Comparison of original interview outcomes (same-day vs. another day)

Conclusions

The data in Table One suggest that the SHC test **would not** be a suitable substitute to replace the RPR test. The sensitivity of the SHC is 85.6% which is low and not within the acceptable regulatory guidelines as outlined by the Centers for Medicare and Medicaid Services – Clinical Laboratory Improvement Amendments (CMS – CLIA) for the incorporation of a new test technology. The low sensitivity also results in a low negative predictive value (NPV) of 17.1%. In addition, the specificity of SHC is 63.6% with a positive predictive value (PPV) of 98.1%.

The data in Table Two suggests SHC **would be** a suitable substitute to replace the *Treponema pallidum* Particle Agglutination Test (TPPA). The sensitivity of SHC is 98.6% with a NPV of 92.7%, well within the limits of acceptable regulatory guidelines. In addition, the specificity of SHC is 97.4% with a PPV of 99.5%. This test would be a good choice to replace the TPPA in the current syphilis screening algorithm, i.e. screen with a non-treponemal test (RPR) followed by a treponemal confirmatory test (TPPA or SHC).

The data in Table Three suggest that SHC **would not** be a suitable substitute to replace the combination of the RPR and TPPA. The sensitivity is 85.5% with a NPV of 14.6%. In addition, the specificity of SHC is 100% with a PPV of 100%.

Recommendations

- New sites should run at least 20 SHC tests on known specimens prior to implementing.
- Persons with a confirmed syphilis history do not need a SHC test
- If the patient is named as a partner to an early syphilis case, and either the non-treponemal test or the treponemal test is non-reactive, the patient should be prophylactically treated
- If a patient presents with primary symptoms and the non-treponemal test is non-reactive, a SHC may be conducted. A darkfield on a specimen collected from a suspected primary lesion should be conducted and treatment decisions should be made based on symptom history and darkfield results
- Sites will not be required to conduct secondary treponemal test (e.g. TPPA or FTA-ABS) following a reactive SHC
- Sites may follow their current processes for ordering secondary treponemal tests, per the guidance of their local laboratory director

Special Thanks to…

The Austin/Travis County Health and Human Services Department, City of Beaumont Health Department, Corpus Christi/Nueces County Health Department, and Port Arthur Health Department, Jim Lee, Karen Arrowood, Ann Robbins, Dr. Ed Bannister and Tammy Foskey.