New sites should run at least 20 SHC tests on known specimens prior to start. Routinely performed stat Rapid Plasma Reagin (RPR) tests in the clinic while patients received care. Experienced more than one day delays in receiving treponemal test results from either lab, or if there was a discordant result between the SHC and the RPR, sites were allowed to receive care. SHC is 100% with a PPV of 100%. The data in Table One suggest that the SHC test would not be a suitable substitute to replace the RPR test. The specificity 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 the 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%.

Recommended:
- 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.

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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 traditional Treponemal Pallidum Particle Agglutination Assay (TPPA) testing confirmation testing processes to verify the reliability of the POCT test. If there was a discordant result between the SHC and the RPR, sites were allowed to initiate a clinical decision with their patient. Once the site received their treponemal test results, 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 darkfield 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.

Conclusions

- 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.
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