

Title

Performance of syphilis treponemal and nontreponemal serologic tests in specimens from pregnant women: A review.

Background

Congenital syphilis continues to surge in the US. Expedited screening in pregnancy, including research into effective rapid point of care tests (POCTs), has become priority. To guide evaluations of new POCTs for maternal syphilis screening, it is necessary to clarify the diagnostic evidence for current laboratory reference tests. We systematically reviewed literature to answer this question: In specimens from pregnant women, what is the sensitivity and specificity of currently approved treponemal/nontreponemal serologic tests?

Methods

We searched PubMed, Embase, and Cochrane Library from inception to February 15, 2022, combining controlled vocabulary, keywords, and synonyms for: (Syphilis OR Neurosyphilis OR *Treponema pallidum*) AND (Syphilis Serodiagnosis OR Serologic Tests OR Diagnostic test) AND (Pregnancy OR Pregnant Women OR Prenatal).

Applying no date or geographical restrictions, we followed PRISMA protocols for the selection, review, and analysis of non-animal studies written in English. We screened 5379 nonduplicate publications and selected 78 for full review. We excluded studies with unclear methods or results for pregnant cohorts, obsolete tests, or included few pregnancy specimens only as controls to evaluate potential serologic cross reactivity.

Results

The 10 studies most relevant to the research question evaluated 2 nontreponemal (N=9383) and 11 treponemal assays (N=4143). We report pooled treponemal sensitivity (93.5%, 8 immunoassays) and specificity (98.7%, 11 immunoassays); and nontreponemal sensitivity (90.9%, 1 assay) and specificity (99.8%, 2 assays) regardless of test brand. The *Treponema Pallidum* Particle Agglutination assay was the most commonly used treponemal reference.

Conclusion

While the total number of studies were few, the observed specificity was high and should give clinicians confidence in positive test results. The moderate sensitivity however supports current recommendations for repeat screening.

Overall, more studies are needed in pregnant women, particularly with newer assays and rapid point of care tests.