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Articles

Evaluating Diagnostic Tests for *Chlamydia trachomatis* in the Absence of a Gold Standard: A Comparison of Three Statistical Methods

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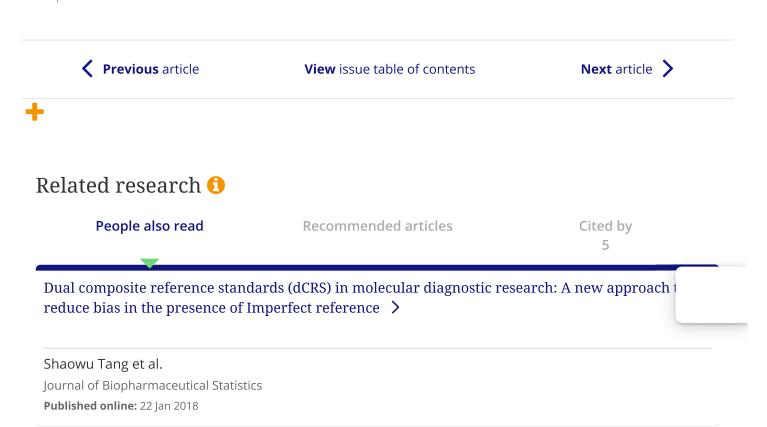❝ **Citations**   📊 **Metrics**   🖶 **Reprints & Permissions**   Get access

Abstract

Studies designed to evaluate diagnostic tests for *Chlamydia trachomatis* typically involve a panel of new and established tests. Statistical analysis of these studies has proven challenging as no gold standard reference test is available. We illustrate a novel multiple latent variable model (MLVM), which improves over earlier methods by recognizing that different diagnostic tests for *C. trachomatis* may be measuring different targets. For example, nucleic acid amplification tests (NAATs) are designed to measure *C. trachomatis* DNA, while cell culture is designed to measure the presence of

current *C. trachomatis* infection. The MLVM does not arbitrarily assume any test is perfect. Further, it provides separate sensitivity and specificity estimates with respect to each latent target. Using simulated and real data, we will contrast the performance of MLVM with two other methods for evaluating *C. trachomatis* tests: (i) the composite reference standard (CRS) approach, and (ii) the standard latent class model (TLCM). We show that the tests involved in the definition of the CRS are arbitrarily assumed to have perfect specificity, and that both the CRS and the TLCM assume that all tests are measuring the same latent variable, the "current infection." When these assumptions are not justified, as is frequently the case, the resulting estimates of sensitivity and specificity may be seriously biased. The MLVM attempts to address these problems.

Q **Keywords: :** Bayesian estimation   Biased estimator   Chlamydia trachomatis   Composite reference standard   Latent class models

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