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[Diagnostic Test Accuracy Review]

Rapid point of care test for detecting urogenital *Chlamydia trachomatis* infection in nonpregnant women and men at reproductive age

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ABSTRACT

Background

Chlamydia trachomatis (*C trachomatis*) is one of the most frequent sexually transmitted infections and a source of deleterious effects on the reproductive health of men and women. Because this infection is likely asymptomatic and is associated with subfertility, ectopic pregnancy, and chronic pain, its presence needs to be confirmed. Technologies available for the diagnosis of *C trachomatis* infection can be classified into tests performed in a laboratory and rapid tests at the point of care (POC tests). Laboratory-based tests include culture, nucleic acid amplification tests, enzyme immunoassays (EIA), direct fluorescent antibody, nucleic acid hybridization, and transformation tests. Rapid tests include solid-phase EIA and solid-phase optical immunoassay. POC tests can be performed within 30 minutes without the need for expensive or sophisticated equipment. The principal advantage of this technology is the immediate presentation of results with the subsequent possibility to start the treatment of infected patients immediately.

Objectives

To determine the diagnostic accuracy of rapid point-of-care (POC) testing for detecting urogenital *C trachomatis* infection in nonpregnant women and men of reproductive age, as verified with nucleic acid amplification tests (NAATs) as the reference standard.

Search methods

In November 2019 we searched CENTRAL, MEDLINE, Embase and LILACS. We also searched Web of Science, two trials registries and an abstract database. We screened reference lists of included studies for additional references.

Selection criteria

We included diagnostic accuracy studies of symptomatic or asymptomatic nonpregnant women and men reproductive age. Included trials should have prospectively enrolled participants without previous diagnostic testing, co-infections or complications and consecutively or through random sampling at primary or secondary care facilities. Only studies reporting that all participants received the index test and the reference standard and presenting 2 x 2 data were eligible for inclusion. We excluded diagnostic case-control studies.

Data collection and analysis

Two review authors independently screened titles and abstracts for relevance. Two review authors independently, and in duplicate, assessed eligibility, extracted data, and carried out quality assessment. We resolved differences through consensus or by involving a third review author. We assessed studies for methodological quality using QUADAS-2 and used meta-analysis to combine the results of studies

using the bivariate approach to estimate the expected sensitivity and specificity values. We assessed the quality of the evidence using GRADE criteria and explored sources of heterogeneity.

Main results

We included a total of 19 studies, with 13,676 participants, that assessed the diagnostic accuracy of POC tests for *C trachomatis* infection in nonpregnant women and men of reproductive age, as verified with NAATs as the reference standard. Rapid tests were provided by the distributors in nine studies. Seven studies recruited a predominantly high risk or symptomatic population; the studies were conducted in America, Asia, Africa, Europe and Oceania, with a median prevalence of 10% (range 8% to 28%); nine different brands were assessed. The mean sensitivity for rapid tests for detecting urogenital infection was 0.48 (95% confidence interval (CI) 0.39 to 0.58; low-quality evidence) with a mean specificity of 0.98 (95% CI 0.97 to 0.99; moderate-quality evidence). We explored sources of heterogeneity by looking into differences in diagnostic accuracy according to the specimen (endocervical versus urine or vaginal), symptoms among participants (symptomatic versus asymptomatic), and setting (low/middle-income versus high-income countries). Likelihood ratio tests were not significantly different in terms of sensitivity or specificity by specimen ($P = 0.27$) or setting ($P = 0.28$); for this reason, these covariates do not appear to explain the observed variability. Included studies did not provide enough information to assess the 'presence of symptoms' covariate. We downgraded the quality of evidence because of some limitations in applicability and heterogeneity.

Authors' conclusions

Based on the results of this systematic review, the POC test based on antigen detection has suboptimal sensitivity but good specificity. Performance of this test translates, on average, to a 52% chance of mistakenly indicating absence of infection and a 2% chance of mistakenly pointing to the presence of this condition. Because of its deleterious consequences for reproductive health, and considering the current availability of safe and effective interventions to treat *C trachomatis* infection, the POC screening strategy should not be based on a rapid diagnostic test for antigen detection. Research in this topic should focus on different technologies.

PLAIN LANGUAGE SUMMARY

What are the most accurate rapid point-of-care tests for the detection of Chlamydia?

Review question

Chlamydia trachomatis (*C trachomatis*) is a common, sexually transmitted infection. It can cause serious health problems if not treated early, but many people with *C trachomatis* do not notice any symptoms and need to have a urine or swab test to confirm infection. This review aimed to find out how accurate new test methods, such as rapid point-of-care (tests at the time and place of patient care) tests are for diagnosing *C trachomatis* infection.

Background

There are about 90 million cases of *C trachomatis* infection worldwide and 3 million cases annually among young and sexually active people. Rapid point-of-care tests can be performed in less than 30 minutes without the need for expensive or sophisticated equipment. The main advantage of this technology is the immediate display of results so that treatment can start straight away.

Study characteristics

We searched for evidence in November 2019 and found 19 relevant studies with 13,676 participants, published between 1999 and 2016. The studies compared the accuracy of the current 'gold standard' test (nucleic acid amplification tests (NAAT)) with a total of nine different brands of rapid point-of-care tests.

Key Results

This review looked at the accuracy of rapid point-of-care tests for diagnosing *C trachomatis* infection in nonpregnant women and men. Our results show that there is a 42% to 62% chance of the test result incorrectly indicating no *C trachomatis* infection, and close to a 2% chance of the test incorrectly indicating a *C trachomatis* infection. This means that for every 1000 patients tested, the point-of-care test could fail to diagnose between 420 to 620 people, who could go on to develop serious health problems as a result of the incorrect diagnosis.

Quality of the evidence

All the included studies used reliable methods to look at the tests, so we thought that they were high quality. However, in some studies, most of the participants were at high risk of *C trachomatis* infection or already showed symptoms, so we are not sure how useful their results would be for low-risk people not showing symptoms. Also, some studies reported very different results from others, and we could not explain the difference.

Conclusion

C trachomatis infection is potentially very serious so we think that health providers should not rely on rapid point-of-care tests to diagnose *C trachomatis* infection. In future, research should investigate different technologies.

SUMMARY OF FINDINGS

Summary of findings 1. Point-of-care test to diagnose urogenital *Chlamydia trachomatis* infection

Review question	What is the diagnostic accuracy of POC test for detecting urogenital <i>Chlamydia trachomatis</i> infection?		
Importance	POC tests could offer the advantages of test performance while the patient awaits their results and applicability in different settings without a technically demanding procedure		
Patients/population	Nonpregnant women and men at reproductive age		
Settings	Ambulatory services of hospitals and clinics (public or private of general gynaecology, STD clinic, and reproductive health)		
Index test	Chlamydia Rapid Test; Rapid Optical Immunoassay; Acon; Clearview; QuickVue; Handilab-C; Biorapid; BioVei and Chlamydia Test Card.		
Reference standard	Nucleic acid amplification tests (NAATs)		
Study design	Cross-sectional or a single-gate design; prospective enrolment; a single study could assess more than one test		
Risk of bias	High quality for retrieved studies		
	High risk: 0 studies; unclear risk: 0 studies; low risk: 19 studies		
	High risk: 0 studies; unclear risk: 7 studies; low risk: 12 studies		
	High risk: 0 studies; unclear risk: 5 studies; low risk: 14 studies		
	High risk: 0 studies; unclear risk: 8 studies; low risk: 11 studies		
Applicability concerns	High concern: 7 studies; unclear concern: 5 studies; low concern: 7 studies		
	High concern: 1 study; unclear concern: 5 studies; low concern: 13 studies		
	High concern: 0 studies; unclear concern: 2 studies; low concern: 17 studies		
No. of participants 13,676 (19 studies)	Number of results per 1000 participants tested (prevalence 10%)	Diagnostic estimates (95% CI)	Implications
	False negatives True negatives False positives		

	(95% CI)	(95% CI)	(95% CI)		
POC accuracy	52 (42 to 61)	882 (873 to 891)	18 (9 to 27)	Sensitivity 0.48 (0.39 to 0.58) Specificity 0.98 (0.97 to 0.99)	Very low sensitivity. Estimates did not meet the criteria for a replacement or a triage test.
Quality of the evidence (GRADE)	⊕⊕○○ ^{a,b} Low	⊕⊕⊕○ ^a Moderate			

CI: confidence interval; **POC:** point-of-care; **STD:** sexually transmitted disease

^aDowngraded by 1 level for applicability. Some limitations regarding participant selection.

^bDowngraded by 1 level for inconsistency. Wide range for the prediction region.

BACKGROUND

Target condition being diagnosed

Chlamydia trachomatis (*C trachomatis*) is an obligate intracellular gram-negative bacterium that infects the columnar epithelium of the cervix, urethra, and rectum (Chernesky 2005). *C trachomatis* has various serovars, such as: D, Da, E, F, G, Ga, H, I, Ia, J, and K (Morre 2000). *C trachomatis* is one of the most frequent sexually transmitted infections; the estimated prevalence is 90 million cases worldwide and 3 million cases annually among the young and sexually active population (Chernesky 2005). The prevalence of *C trachomatis* varies according to the clinical scenario: 20% in sex workers (Cárcamo 2012; Soto 2007), and from 5% to 9% in women with vaginal discharge (Angel-Müller 2012; Sánchez 2006). The prevalence of *C trachomatis* is highest among people aged 25 years or younger (De Codes 2006; Geisler 2011). *C trachomatis* infection is associated with cervicitis, vaginal discharge, and urethritis syndromes in women; and with urethritis and prostatitis in men (PHAC 2010). However, *C trachomatis* infection is asymptomatic in 70% to 80% of cases (Coppus 2008).

As a result of ascending infection from the cervix, *C trachomatis* infection in women can cause serious complications such as pelvic inflammatory disease (PID) including endometritis, salpingitis, tubo-ovarian abscess, or pelvic peritonitis (Kimani 1996). Often PID associated with *C trachomatis* is asymptomatic (Workowski 2010). Sequellae of women with PID may include infertility, ectopic pregnancy, and chronic pelvic pain (Workowski 2010). *C trachomatis* re-infection is associated with a higher risk of PID (Kimani 1996), probably as the result of inflammatory host response (López-Castro 2012). Early diagnosis of *C trachomatis* infection is essential for reducing its prevalence and for preventing PID (Low 2016; RCOG 2008). As many infections are asymptomatic, it has been found that screening programmes should be directed especially towards young women (Gottlieb 2013), and that identification and treatment of sexual partners are important for reducing the risk of re-infection (Althaus 2012; Romero 2017).

Traditionally, culture testing had been the reference standard. However, few laboratories offer this service (Chernesky 2005). Culture is a technically demanding procedure that requires collecting of the sample from the endocervix or urethra in women and from the urethra in men by using swabs and transporting the specimen carefully to maintain the viability of organisms. This procedure is uncomfortable and usually is not acceptable to patients (CDC 2009), because it requires insertion of a 2- to 3-cm swab into the male urethra or a 1- to 2-cm swab into the endocervical canal, followed by two or three rotations to collect sufficient columnar or cuboidal epithelial cells (Papp 2014). The sample is inoculated in a monolayer of susceptible cells, and after 72 hours, infected cells exhibit the characteristic intracytoplasmic inclusion containing a significant number of *C trachomatis* elementary and reticulate bodies (CDC 2002). Culture accuracy varies substantially among laboratories according to the method used to detect intracytoplasmic inclusions, but even under ideal conditions, sensitivity is less than 75%, although specificity could reach 100% (Carder 2006). The principal disadvantages of the culture are lack of sensitivity, the fact that the process is time-consuming, the requirement for highly qualified personnel, the need for stringent transport, and it is more expensive than other diagnostic methods; culture is technically demanding, and patients must make a second appointment with their healthcare provider

if they are to obtain treatment. This can lead to loss to follow-up (CDC 2002; Workowski 2010). The principal advantages of culture testing are its high specificity and its ability to retain the isolated micro-organism should it be needed for legal investigation or for evaluation of antimicrobial susceptibility or resistance (CDC 2002).

Diagnosis of *C trachomatis* has changed over time. Molecular diagnostic testing overcomes the inherent difficulties of the culture (CDC 2009). Nowadays a new generation of nucleic acid amplification tests (NAATs) based on detection of DNA or RNA sequences has been developed. A systematic review of NAATs found a sensitivity of 85.5% and specificity of 99.6% (Cook 2005). This new-generation test amplifies specific *C trachomatis* nucleic acid sequences without requiring the presence of viable organisms in the sample (CDC 2009). NAATs are not known to cross-react with nucleic acid from other bacteria found in humans (Chernesky 2005). NAATs can be performed on samples from different sources, such as endocervix, vagina, urethra, and urine, which are easier to take and are better accepted by patients compared with culture (CDC 2009). Rectal and oropharyngeal specimens undergo limited evaluation, which is not recommended by the Food and Drug Administration (FDA) (CDC 2002; Papp 2014). The principal disadvantage is that specimens could contain amplification inhibitors that cause false-negative results. On the other hand, test results are not immediately available, requiring the patient to schedule a second appointment with the healthcare provider, which may lead to losses to follow-up (Workowski 2010).

The superior diagnostic accuracy of NAATs over culture and the advantages previously mentioned show why NAATs are currently the tests of choice for confirming the diagnosis of *C trachomatis* infection in sexually active men and women (Geisler 2011).

Index test(s)

Technologies available for the diagnosis of *C trachomatis* infection can be classified into tests performed in a laboratory and rapid tests at the point of care (POC tests), which are performed while patients await results in the same place that they are seen; laboratory facilities may or may not be used (Chernesky 2005). Laboratory-based tests include culture, NAATs, enzyme immunoassays (EIAs), direct fluorescent antibody (DFA), nucleic acid hybridization, and transformation tests. Rapid tests at POC include solid-phase EIA and solid-phase optical immunoassay (CDC 2002). These dipstick tests are applied to urine, and urethral and endocervical specimens to detect infection (CDC 2002); they use monoclonal or polyclonal antibodies against *C trachomatis* lipopolysaccharides (LPS) that have been labelled with an enzyme (CDC 2009). The enzyme converts a colorless substrate into a colored product (CDC 2002), and results are expressed in a qualitative way: antigen-specific for *C trachomatis* detected or not detected (Domeika 2009).

Point-of-care tests can be performed within 30 minutes without the need for expensive or sophisticated equipment (CDC 2002). The principal advantage of this technology is the immediate presentation of results with the subsequent possibility to start treatment of infected patients immediately. Delayed diagnoses affect the effectiveness of treatment because 20% to 40% of patients with sexually transmitted infection will not come back to get the results (Schwebke 1997), and new infections could take place at this time (Vickerman 2003). Thus, small clinics, hospitals, detection centers, and clinical settings such as physicians' offices consider it a priority to perform rapid tests, which allow faster

diagnosis and treatment at the point of care (Peeling 2006). These tests are usually less sensitive than laboratory-based tests and have some potential for false-positive results caused by cross-reaction with other bacterial micro-organisms; however, in contrast to NAATs and culture (CDC 2002), the POC test does not require extensive clinical expertise; periodic reinforcement of staff training; sample storage and transport; use of complex work areas, amplification controls to identify inhibitors, or a specialized data system; and implementation of high-quality protocols (CDC 2009). Use of POC tests can facilitate identification of symptomatic or asymptomatic patients with *C trachomatis* infection, avoiding the cost of sophisticated laboratory equipment and making possible early administration of treatment during first contact with the care provider.

Clinical pathway

Typically, two clinical pathways can be followed when a clinician wishes to confirm or discard the presence of *C trachomatis* (Figure 1). The first pathway involves the care of an asymptomatic patient. The practitioner, during the consultation, explores sexual behavior and asks about the presence of risk factors for *C trachomatis* infection: number of sexual partners, contraceptive use, types of partners, and unsafe sexual practices, among others (Navarro 2002). If the patient presents two or more risk factors for *C trachomatis* infection, the diagnostic test should be offered even in the absence of symptoms (Gaitán-Duarte 2013).

Figure 1. Clinical pathway

The second pathway is followed by the clinician who finds a symptomatic patient, such as a woman who describes abnormal vaginal discharge with signs of cervicitis, or who complains of acute pelvic pain, presents with adnexal tenderness and pain during cervical mobilization, or reports purulent vaginal discharge with or without signs of a systemic inflammatory response. In this case, *C trachomatis* infection should be suspected or confirmed. When a male patient consults for signs or symptoms related to urethritis or epididymo-orchitis, a diagnostic test for *C trachomatis* is indicated (Gaitán-Duarte 2013).

Rationale

Currently, the performance of rapid tests at the point of care for the diagnosis of *C trachomatis* infection in nonpregnant women and men of reproductive age is controversial. Point-of-care testing could be advantageous in that it may be performed while the patient awaits the results and may be applied in different settings

without a technically demanding procedure; these tests allow rapid identification and treatment of infected patients and overcome the limitations of culture and NAATs. We conducted this review to assess the diagnostic accuracy of POC tests for the diagnosis of *C trachomatis* infection in nonpregnant women and men of reproductive age.

OBJECTIVES

To determine the diagnostic accuracy of rapid POC testing for detecting urogenital *C trachomatis* infection in nonpregnant women and men of reproductive age, as verified with NAATs as the reference standard.

Secondary objectives

To assess the accuracy of rapid POC testing according to POC brand: Chlamydia Rapid Test; Rapid Optical Immunoassay; Acon;

Clearview; QuickVue; Handilab-C; Biorapid; BioVei and Chlamydia Test Card.

METHODS

Criteria for considering studies for this review

Types of studies

We included diagnostic accuracy studies. Participants in included studies should have been enrolled prospectively and consecutively or through random sampling. Only studies reporting that all participants received the index test and the reference standard and presenting 2 x 2 data were eligible for inclusion. We excluded diagnostic case-control studies.

Participants

We included symptomatic or asymptomatic nonpregnant women and men of reproductive age, recruited at primary or secondary care facilities, without previous diagnostic testing, co-infections or complications. Co-infection with both *C. trachomatis* and *Neisseria gonorrhoeae* or any other bacteria, may affect assay performance.

Index tests

Rapid tests at point of care from urine, urethral, or endocervical specimens, regardless of the type: solid-phase EIA, solid-phase optical immunoassay, or any other technology.

Target conditions

Urogenital *C. trachomatis* (serovars D, Da, E, F, G, Ga, H, I, Ia, J, and K) infection.

Reference standards

NAATs of endocervical, vaginal, urethral, or urine samples. NAAT is considered the gold standard over culture for confirming the diagnosis of *C. trachomatis* infection because of its superior diagnostic accuracy and the advantages described previously (Geisler 2011).

Search methods for identification of studies

Electronic searches

We contacted the Cochrane Sexually Transmitted Infections' Information Specialist in order to implement a comprehensive search strategy to identify as many relevant diagnostic accuracy studies as possible in electronic databases. We used a combination of controlled vocabulary (Medical Subject Headings (MeSH), Emtree terms, DeCS, including exploded terms) and free-text terms (considering spelling variants, synonyms, acronyms and truncation) and performed the search in the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, Embase, and Latin American Caribbean Health Sciences Literature (LILACS) from inception up to November 2019, using search terminology for the index tests (point-of-care test, point of care, point of care testing, point of care devices, point of care diagnostic, point of care laboratory, POC, POCT, rapid test, rapid test device, self testing, self test, patient self testing) and the target condition (*Chlamydia* Infection, *Chlamydia* infections, *Chlamydia trachomatis*, sexually transmitted disease, pelvic infection, reproductive tract infection, urogenital infection, PID). In addition, we searched Web of Science (2001 to current) for conference proceedings, dissertations, and theses and the database of the World Health Organization

International Clinical Trials Registry Platform (ICTRP), Health Services Research Projects in Progress (HSRProj), and the Database of Abstracts of Reviews of Effect (DARE) for additional articles. Detailed search strategies can be found in [Appendix 1](#), [Appendix 2](#), [Appendix 3](#), [Appendix 4](#), [Appendix 5](#), [Appendix 6](#), [Appendix 7](#), and [Appendix 8](#). We did not apply any language restrictions (Lefebvre 2019).

Searching other resources

We conducted handsearching of conference proceeding abstracts of the following events.

- International Society for Sexually Transmitted Diseases Research (ISSTD; www.isstdr.org): 2007, 2009, 2011, 2013 and 2015
- British Association for Sexual Health and HIV (BASHH; www.bashh.org): from 2004 to 2018
- International Congress on Infectious Diseases (ICID; isid.org): 2010 and 2012
- International Union Against Sexually Transmitted Infections (IUSTI; www.iusti.org): 2011, 2012 and 2019
- International Society for Infectious Diseases (ISID; isid.org): 2011
- International Meeting on Emerging Diseases and Surveillance (IMED; www.isid.org): 2007, 2009, and 2011
- International Federation of Gynecology and Obstetrics (FIGO; www.figo.org): 2009, 2012 and 2015

Finally, we searched the citation lists from reviewed articles.

Data collection and analysis

Selection of studies

Two review authors (CFG-A, MT) independently applied inclusion and exclusion criteria in selecting potential titles and abstracts of studies retrieved as a result of the search. We resolved disagreements through consensus or, if required, by consultation with a third review author (HG). We retrieved the full text of a study if we had doubts about whether the study should be included or excluded.

Data extraction and management

We designed a data extraction form, which we pilot tested, to extract data from the included studies. For eligible studies, two review authors (CFG-A, MT) extracted data independently using the form. We resolved discrepancies through consensus or, if required, by consultation with a third review author (HG). The data extraction form included the following.

- Methods
 - * Country of the study. Setting
 - * Basic study design
 - * Power calculation
 - * Number of participants and sampling of patients
 - * Ethical issues
- Participants
 - * Inclusion and exclusion criteria
 - * Baseline information on participants: presentation at recruitment and characteristics (e.g. symptoms, presence of risk factors, sociodemographic characteristics)

- Index test
 - * Point-of-care test specimen: urine, urethral, or endocervical
 - * Point-of-care test technology: solid-phase EIA, solid-phase optical immunoassay, or any other technology.
- Outcomes
 - * True positives, false positives, false negatives, true negatives

We collated and presented this information in 'Characteristics of included studies' tables. We added the data to Review Manager 5.3 (Review Manager 2014), and two review authors (CFG-A, MT) independently assessed the accuracy of the data. We resolved differences through consensus or by evaluation by a third review author (HG). When information regarding any of the above was unclear, we contacted authors of the original reports to request further details.

Assessment of methodological quality

We assessed the quality of included articles by using the Quality Assessment of Diagnostic Accuracy Studies-2 (QUADAS-2) tool (Whiting 2011). Two review authors (CFG-A, MT) independently performed the quality assessment using the four key domains to assess the risk of bias and concerns regarding applicability to the research question (participant selection, index test, reference standard, and flow and timing domains; Appendix 11). In case of disagreement, we resolved differences through consensus or by consultation with a third review author (HG).

To summarize the quality of the evidence, we defined low-quality studies as those ranked with high risk of bias for the domains of patient sampling, index test, reference standard or flow and timing. We explored the impact of the level of bias by means of sensitivity analyses (see Sensitivity analyses).

Statistical analysis and data synthesis

We summarized diagnostic test accuracy by creating a 2 × 2 table for each study based on information retrieved directly from the papers. When there were two or more tests evaluated in the same cohort, we included them as separate data sets, since the unit of analysis was the test result, not the participant. Each table contained false-positive, false-negative, true-positive, and true-negative rates. Two review authors (CFG-A, MT) independently entered the data into Review Manager 2014. We resolved discrepancies by consensus or, if required, by consultation with a third review author (HG).

In the first instance, we analysed in a descriptive way all data retrieved from the included studies. For this purpose and given that results of the rapid POC tests are reported qualitatively (positive or negative), we presented the results by plotting their sensitivity and specificity (and their 95% confidence intervals) both in forest plots and in a scatter plot in receiver operating characteristic (ROC) space. For the meta-analysis of diagnostic accuracy measures, we used the bivariate model (Reitsma 2005). For studies with a common threshold, this model takes into account within-study variation and between-study variation and focuses on estimating a summary operating point (i.e. a summary value for sensitivity and specificity). In addition, we estimated the 95% confidence region and the 95% prediction region around the summary operating point. We performed these analyses using STATA (Stata 2017), according to the licenses available.

Investigations of heterogeneity

We explored heterogeneity initially by performing visual inspection of forest plots of sensitivities and specificities and visual examination of the prediction region. We formally assessed the source of heterogeneity by examining differences in diagnostic accuracy between subgroups of studies. Again we used the bivariate method to analyse how the summary estimate of sensitivity and specificity varies according to study-level covariates. For this purpose, we created a factor variable with N categories and will generate an N-1 dummy that was entered into the bivariate model to test the effects of covariates on both sensitivity and specificity (Macaskill 2010).

We defined sources of heterogeneity a priori and we included the following factors: POC specimen (endocervical versus urine or vaginal), reports of urogenital symptoms among participants (symptomatic versus asymptomatic participants), and study setting (low/middle-income versus high-income countries).

Sensitivity analyses

We performed sensitivity analyses taking into account the risk of bias associated with the quality of included studies based on overall 'Risk of bias' assessment according to QUADAS-2 domains (participant sampling, index test, reference standard, and flow and timing).

Assessment of reporting bias

We assessed publication bias because we included more than ten studies in this systematic review. We initially assessed reporting bias using funnel plot visual asymmetry, plotting a measure of effect size against a measure of study precision. We then performed a formal assessment using Deeks' test and diagnostic odds ratio (DOR) as a measure of test accuracy (Van Enst 2014).

'Summary of findings' table

We prepared 'Summary of findings 1' using the GRADE approach to diagnostic test accuracy (Hsu 2011), using the template provided in the *Cochrane Handbook for Systematic Reviews of Diagnostic Test Accuracy (DTA)* (Bossuyt 2013). These tables evaluate the overall quality of the body of evidence for the review outcomes (true positives, false positives, false negatives, true negatives). We assessed the quality of the evidence using GRADE criteria: risk of bias, consistency of effect, imprecision, indirectness and publication bias. All review authors (CFG-A, MT and HG) independently made judgments about evidence quality (high, moderate, low or very low), with disagreements resolved by discussion. We justified, documented and incorporated judgments into reporting of results for each outcome. We presented a summary table in order to provide a more accessible perspective of diagnostic information to healthcare providers and other users.

RESULTS

Results of the search

We searched the available literature up to 21 November 2019 and retrieved a total of 3434 references, of which we screened 2758 after removing duplicates. Of these, we initially screened the full-text articles of 25 references. Overall, 19 published studies met our inclusion criteria, with four of these 19 studies evaluating more than one POC test, resulting in a total of 25 cohorts (i.e. 25 study arms).

that contributed to this meta-analysis (Abbai-Shaik 2016; Bandea 2009; Hesse 2011; Huang 2013; Hurly 2014 Acon; Hurly 2014 CRT; Lauderdale 1999; Mahilum-Tapay 2007; Michel 2009; Nadala 2009; Nuñez-Forero 2016 Acon; Nuñez-Forero 2016 Acon Duo; Nuñez-Forero 2016 QuickVue; Pate 1998; Rani 2002; Sabidó 2009; Saison 2007 Clearview; Saison 2007 CRT; Swain 2004; Van der Helm 2012; Van Dommelen 2010 Biorapid; Van Dommelen 2010 Handilab-C; Van Dommelen 2010 QuickVue; Widjaja 1999; Yin 2006). The studies with more than one arm in analyses are by Hurly (Hurly 2014 Acon; Hurly 2014 CRT (2 arms); Nuñez-Forero (Nuñez-Forero 2016 Acon; Nuñez-Forero 2016 Acon Duo; Nuñez-Forero 2016 QuickVue (3 arms); Saison (Saison 2007 Clearview; Saison 2007 CRT;(2 arms); and Van Dommelen (Van Dommelen 2010 Biorapid; Van Dommelen 2010 Handilab-C; Van Dommelen 2010 QuickVue).

Seven studies, with 10 study arms, were sponsored by academic institutions (Huang 2013; Michel 2009; Nuñez-Forero 2016 Acon; Nuñez-Forero 2016 Acon Duo; Nuñez-Forero 2016 QuickVue; Sabidó 2009; Saison 2007 Clearview; Saison 2007 CRT; Van der Helm 2012; Widjaja 1999), nine (11 study arms) received industry support (Abbai-Shaik 2016; Bandea 2009; Hesse 2011; Lauderdale 1999; Mahilum-Tapay 2007; Nadala 2009; Rani 2002; Swain 2004; Van Dommelen 2010 Biorapid; Van Dommelen 2010 Handilab-C; Van Dommelen 2010 QuickVue), and three (four study arms) did not show a clear statement in this regard (Hurly 2014 Acon; Hurly 2014 CRT; Pate 1998; Yin 2006). A PRISMA diagram is shown in Figure 2 to illustrate the study selection process.

Figure 2. Study flow diagram

Methodological quality of included studies

The quality of the included studies is illustrated in the QUADAS-2 results summary figure ([Figure 3](#)). Overall, the studies were of good

methodological quality, but almost all of them had an unclear risk of bias in at least one domain.

Figure 3. Summary of risk of bias and applicability concerns: review authors' judgements about each domain for each included study

	Risk of Bias				Applicability Concerns		
	Patient Selection	Index Test	Reference Standard	Flow and Timing	Patient Selection	Index Test	Reference Standard
Abbai-Shaik 2016	+	?	?	+	+	?	?
Bandea 2009	+	?	?	?	+	?	+
Hesse 2011	+	+	+	+	?	-	+
Huang 2013	+	?	?	+	-	+	+
Hurly 2014 Acon	+	?	+	+	+	+	+
Hurly 2014 CRT	+	?	+	+	+	+	+
Lauderdale 1999	+	+	?	?	+	+	+
Mahilum-Tapay 2007	+	+	+	?	+	+	+
Michel 2009	+	+	+	?	-	+	+
Nadala 2009	+	+	+	+	-	+	+
Núñez-Forero 2016 Acon	+	+	+	+	-	?	+
Núñez-Forero 2016 Acon Duo	+	+	+	+	-	?	+
Núñez-Forero 2016 QuickVue	+	+	+	+	-	?	+
Pate 1998	+	+	+	?	-	+	+
Rani 2002	+	?	?	?	?	?	?
Sabidó 2009	+	+	+	+	+	+	+
Saison 2007 Clearview	+	+	+	+	-	+	+
Saison 2007 CRT	+	+	+	+	-	+	+
Swain 2004	+	+	+	+	?	+	+
Van der Helm 2012	+	+	+	+	+	+	+
Van Dommelen 2010 Biorapid	+	+	+	?	?	+	+
Van Dommelen 2010 Handilab-C	+	+	+	?	?	+	+
Van Dommelen 2010 QuickVue	+	+	+	?	?	+	+
Widjaja 1999	+	?	+	?	?	?	+
Yin 2006	+	?	+	+	-	+	+

Figure 3. (Continued)

Participant selection

We assessed all studies as low risk of bias for this domain. Retrieved studies reported a consecutive sampling of participants in primary or secondary care without previous test results, making this bias unlikely.

Index test

We rated seven studies (eight study arms) as unclear risk of bias (Abbai-Shaik 2016; Bandea 2009; Huang 2013; Hurly 2014 Acon; Hurly 2014 CRT; Rani 2002; Widjaja 1999; Yin 2006), because they did not report whether they had conducted the index test without knowledge of the results of the reference standard, or whether they had completed the index test before the reference standard was known. The other included studies described the index test appropriately, and how they conducted and interpreted it, making risk of bias unlikely.

Target condition and reference standard

Five studies did not report appropriately how they had conducted and interpreted the reference standard (Abbai-Shaik 2016; Bandea 2009; Huang 2013; Lauderdale 1999; Rani 2002), making the risk of bias unclear for this domain. Trained operators conducted the reference standard in the remaining studies, and it was interpreted in a blind manner without knowledge of the index test results. We appraised these studies as low risk of bias, because NAAT is considered the current gold standard for the diagnosis of *C trachomatis* infection. For this reason, we assessed the included studies as being at unlikely risk for misclassification bias.

Flow and timing

All the included studies collected the index test and reference standard on the same participants at the same time, the whole study group received confirmation of the diagnosis by the reference standard and the study group received the reference standard irrespective of the index test results. However, we considered risk of bias to be unclear in eight studies (10 study arms), which did not provide a flow diagram of participants, did not explain withdrawals or exclusions, and were unclear as to whether the numbers recruited matched those in the analysis (Bandea 2009; Lauderdale 1999; Mahilum-Tapay 2007; Michel 2009; Pate 1998; Rani 2002; Van Dommelen 2010 Biorapid; Van Dommelen 2010 Handilab-C; Van Dommelen 2010 QuickVue; Widjaja 1999). For the remaining studies, it was clear what happened to all participants who entered the study and, therefore, we assessed them as low risk of bias.

Applicability

We assigned high concern in participant selection applicability to seven studies (10 study arms) because they recruited predominantly high-risk populations (e.g. female sex workers; Michel 2009; Saison 2007 Clearview; Saison 2007 CRT), or symptomatic populations (e.g. discharge, dysuria, or abdominal

pain; Huang 2013; Nadala 2009; Nuñez-Forero 2016 Acon; Nuñez-Forero 2016 Acon Duo; Nuñez-Forero 2016 QuickVue; Pate 1998; Yin 2006). Five studies (seven study arms) demonstrated unclear concern inasmuch as they did not provide enough information to judge whether the participants included matched the review question in terms of severity, demographic features, presence of differential diagnosis or comorbidity, or study setting (Hesse 2011; Rani 2002; Swain 2004; Van Dommelen 2010 Biorapid; Van Dommelen 2010 Handilab-C; Van Dommelen 2010 QuickVue; Widjaja 1999). The remaining studies posed low concern for participant selection applicability.

Regarding index test applicability, we considered five studies (seven study arms) as unclear concern because their reports had insufficient information to allow us to judge if the index test, its performance, or its interpretation differed from the review question (Abbai-Shaik 2016; Bandea 2009; Nuñez-Forero 2016 Acon; Nuñez-Forero 2016 Acon Duo; Nuñez-Forero 2016 QuickVue; Rani 2002; Widjaja 1999). We assessed one study as high concern given that, during the recruiting phase, there were multiple variations in terms of test technology (Hesse 2011). Consequently, we considered that variations in the test technology, its performance and interpretation may affect the index test's applicability. We rated the other included studies as low concern in terms of index test applicability.

Regarding the gold standard test applicability, we judged two studies as unclear concern, given that their reports did not provide enough information to allow us to make a judgment (Abbai-Shaik 2016; Rani 2002). We considered the other studies low concern, because the target condition (defined by the reference standard) matched the review question.

Findings

For each comparison of index test with the reference test, we extracted data on the number of true positives, true negatives, false positives and false negatives in the form of a 2 x 2 table. When studies evaluated two or more tests in the same cohort, we included them as separate data sets, since the unit of analysis was the test result and not the participant. See: [Summary of findings 1](#) for the overall POC accuracy for detecting urogenital *C trachomatis* infection.

1.0 Primary objective

1.1 Overall point-of-care test accuracy for detecting *Chlamydia trachomatis* infection

Nineteen articles, which included a total of 13,676 participants (based on data from 25 cohorts), conducted between 1998 and 2016, assessed the diagnostic accuracy of POC tests for detecting urogenital *C trachomatis* infection in nonpregnant women and men of reproductive age, which was verified using NAATs as the reference standard. Of these studies, six were conducted in North America (Bandea 2009; Hesse 2011; Huang 2013; Lauderdale 1999;

Pate 1998; Swain 2004), four (five study arms) in Asia (Michel 2009; Saison 2007 Clearview; Saison 2007 CRT; Widjaja 1999; Yin 2006), four (six study arms) in Europe (Mahilum-Tapay 2007; Nadala 2009; Rani 2002; Van Dommelen 2010 Biorapid; Van Dommelen 2010 Handilab-C; Van Dommelen 2010 QuickVue), two (four study arms) in South America (Nuñez-Forero 2016 Acon; Nuñez-Forero 2016 Acon Duo; Nuñez-Forero 2016 QuickVue; Van der Helm 2012), and one each in Africa (Abbai-Shaik 2016), Central America (Sabido 2009), and Oceania (two study arms; Hurly 2014 Acon; Hurly 2014 CRT).

The median sample size was 565 (range 65 to 1497), and the median prevalence of *C trachomatis* infection was 10% (range 8% to 28%).

The studies evaluated nine different POC brands: Chlamydia Rapid Test (n = 6), Rapid Optical Immunoassay (n = 4), Acon (n = 3),

Clearview (n = 3), QuickVue (n = 3), Handilab-C (n = 2), Biorapid (n = 1), BioVei (n = 1) and Chlamydia Test Card (n = 1). One study did not mention the brand of the POC test (Huang 2013).

Sensitivities of the tests ranged from 0.17 to 0.93, and specificities from 0.51 to 1.00. The mean sensitivity and specificity of all included studies were 0.48 (95% CI 0.39 to 0.58) and 0.98 (95% CI 0.97 to 0.99), respectively. Forest plots (Figure 4), and the ROC plot (Figure 5), demonstrated a high degree of heterogeneity between studies, which was greater for estimates of sensitivity than of specificity. The quality of the evidence was low for sensitivity due to limitations on applicability and consistency; and moderate for specificity due to limitation on applicability (See Summary of findings 1).

Figure 4. Forest plot of tests: assessment of point-of-care diagnostic test accuracy

Symptomatic participants

Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)	Sensitivity (95% CI)	Specificity (95% CI)
Nuñez-Forero 2016 Acon	5	0	17	207	0.23 [0.08, 0.45]	1.00 [0.98, 1.00]		
Nuñez-Forero 2016 Acon Duo	18	1	41	431	0.31 [0.19, 0.44]	1.00 [0.99, 1.00]		
Nuñez-Forero 2016 QuickVue	20	4	33	607	0.38 [0.25, 0.52]	0.99 [0.98, 1.00]		

Asymptomatic participants

Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)	Sensitivity (95% CI)	Specificity (95% CI)
Abbai-Shaik 2016	2	0	8	90	0.20 [0.03, 0.56]	1.00 [0.96, 1.00]		
Bandea 2009	44	3	30	184	0.59 [0.47, 0.71]	0.98 [0.95, 1.00]		
Sabidó 2009	17	1	10	248	0.63 [0.42, 0.81]	1.00 [0.98, 1.00]		

Mixed participants

Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)	Sensitivity (95% CI)	Specificity (95% CI)
Hesse 2011	7	31	6	32	0.54 [0.25, 0.81]	0.51 [0.38, 0.64]		
Lauderdale 1999	5	0	5	55	0.50 [0.19, 0.81]	1.00 [0.94, 1.00]		
Michel 2009	6	12	25	88	0.19 [0.07, 0.37]	0.88 [0.80, 0.94]		
Huang 2013	13	2	1	133	0.93 [0.66, 1.00]	0.99 [0.95, 1.00]		
Hurly 2014 Acon	11	8	11	177	0.50 [0.28, 0.72]	0.96 [0.92, 0.98]		
Rani 2002	11	0	9	180	0.55 [0.32, 0.77]	1.00 [0.98, 1.00]		
Saison 2007 CRT	66	2	27	196	0.71 [0.61, 0.80]	0.99 [0.96, 1.00]		
Pate 1998	28	3	21	254	0.57 [0.42, 0.71]	0.99 [0.97, 1.00]		
Hurly 2014 CRT	58	21	33	267	0.64 [0.53, 0.74]	0.93 [0.89, 0.95]		
Widjaja 1999	12	4	26	373	0.32 [0.18, 0.49]	0.99 [0.97, 1.00]		
Van Dommelen 2010 Handilab-C	18	73	63	581	0.22 [0.14, 0.33]	0.89 [0.86, 0.91]		
Van Dommelen 2010 Biorapid	14	44	70	635	0.17 [0.09, 0.26]	0.94 [0.91, 0.95]		
Saison 2007 Clearview	85	6	74	657	0.53 [0.45, 0.61]	0.99 [0.98, 1.00]		
Van Dommelen 2010 QuickVue	21	2	63	677	0.25 [0.16, 0.36]	1.00 [0.99, 1.00]		
Van der Helm 2012	42	29	60	781	0.41 [0.32, 0.51]	0.96 [0.95, 0.98]		
Nadala 2009	90	17	20	1084	0.82 [0.73, 0.89]	0.98 [0.98, 0.99]		
Mahilum-Tapay 2007	91	15	19	1224	0.83 [0.74, 0.89]	0.99 [0.98, 0.99]		
Swain 2004	92	14	51	1227	0.64 [0.56, 0.72]	0.99 [0.98, 0.99]		
Yin 2006	98	27	99	1273	0.50 [0.43, 0.57]	0.98 [0.97, 0.99]		

Figure 5. Summary ROC plot of tests: assessment of point-of-care diagnostic test accuracy

1.2 Secondary objectives

1.2.1 Accuracy according to point-of-care test brand

Table 1 summarizes the accuracy of rapid POC testing for Chlamydia Rapid Test; Rapid Optical Immunoassay; Acon; Clearview; QuickVue; Handilab-C; Biorapid; BioVei and Chlamydia Test Card.

1.2.1.1 Chlamydia Rapid Test

The results correspond to the meta-analysis of six study arms, which included a total of 4142 participants that assessed the diagnostic accuracy of the CRT (Abbai-Shaik 2016; Hurly 2014 CRT; Mahilum-Tapay 2007; Nadala 2009; Saison 2007 CRT; Van der Helm 2012). The median sample size was 708 (range 100 to 1349), and the median prevalence of Chlamydia trachomatis infection was 15% (range 8% to 31%).

Sensitivities of the tests ranged from 0.20 to 0.83, and specificities from 0.93 to 0.99. The mean sensitivity and specificity of all included studies were 0.64 (95% CI 0.47 to 0.78) and 0.97 (95% CI 0.95 to 0.98), respectively. Forest plots and the ROC plot demonstrated a high degree of heterogeneity between studies for estimates of sensitivity. In spite of the number of included studies and the number of recruited participants, visual inspection of sensitivity forest plots and the wide range for the prediction region, lead to the conclusion that estimates did not meet the criteria for a replacement or a triage test.

1.2.1.2 Rapid Optical Immunoassay

The results correspond to the meta-analysis of four studies including a total of 2366 participants that assessed the diagnostic accuracy of this test (Bandeia 2009; Pate 1998; Swain 2004; Widjaja 1999). The median sample size was 591 (range 261 to 1384), and the median prevalence of *C trachomatis* infection was 15% (range 9% to 28%).

Sensitivities of the tests ranged from 0.32 to 0.64, and specificities from 0.98 to 0.99. The mean sensitivity and specificity of all included studies were 0.54 (95% CI 0.42 to 0.66) and 0.98 (95% CI 0.98 to 0.99), respectively. Forest plots and the ROC plot demonstrated a high degree of heterogeneity between studies for estimates of sensitivity. In spite of the number of included studies and the number of recruited participants, visual inspection of sensitivity forest plots and the wide range for the prediction region, lead to the conclusion that estimates did not meet the criteria for a replacement or a triage test.

1.2.1.3 Acon

Two studies (three study arms), which included a total of 927 participants, assessed the diagnostic accuracy of Acon and Acon Duo for detecting urogenital *C trachomatis* infection (Hurly 2014 Acon; Nuñez-Forero 2016 Acon; Nuñez-Forero 2016 Acon Duo). The median sample size was 309 (range 207 to 491), and the median prevalence was 10% (range 9% to 12%). Sensitivities of the tests ranged from 0.23 to 1.00, and specificities from 0.91 to 0.94. Due to the limited number of studies available for this test type, we were unable to estimate the mean sensitivity and specificity for this POC test. Forest plots and the ROC plot demonstrated some degree of heterogeneity between studies for estimates of sensitivity.

1.2.1.4 Clearview

Three studies, which included a total of 2384 participants, assessed the diagnostic accuracy of Clearview for detecting urogenital *C trachomatis* infection (Lauderdale 1999; Saison 2007 Clearview; Yin 2006). The median sample size was 794 (range 65 to 1497), and the median prevalence was 15% (range 13% to 19%). Sensitivities of the tests ranged from 0.50 to 0.53, and specificities from 0.98 to 1.00. Due to the limited number of studies available for this test type, we were unable to estimate the mean sensitivity and specificity for this POC test. Forest plots and the ROC plot did not show heterogeneity between studies for estimates of sensitivity or specificity.

1.2.1.5 QuickVue

Three studies, which included a total of 1627 participants assessed the diagnostic accuracy of QuickVue for detecting urogenital *C trachomatis* infection (Nuñez-Forero 2016 QuickVue; Rani 2002; Van Dommelen 2010 QuickVue). The median sample size was 542 (range 200 to 763), and the median prevalence was 9% (range 7% to 11%).

Sensitivities of the tests ranged from 0.25 to 0.55, and specificities from 0.99 to 1.00. Due to the limited number of studies available for this test type, we were unable to estimate the mean sensitivity and specificity for this POC test. Forest plots and the ROC plot demonstrated some degree of heterogeneity between papers for estimates of sensitivity.

1.2.1.6 Handilab-C

Two studies, which included a total of 866 participants assessed the diagnostic accuracy of Handilab-C for detecting *C trachomatis* infection (Michel 2009; Van Dommelen 2010 Handilab-C). The median sample size was 433 (range 200 to 763), and the median prevalence was 17% (range 11% to 23%). Sensitivities of the tests ranged from 0.19 to 0.22, and specificities from 0.88 to 0.89. Due to the limited number of studies available for this test type, we were unable to estimate the mean sensitivity and specificity for this POC test. Forest plots and the ROC plot did not show heterogeneity between papers for estimates of sensitivity or specificity.

1.2.1.7 Biorapid

One study recruited 763 participants and, with a prevalence of 11%, assessed the diagnostic accuracy of Biorapid for detecting *C trachomatis* infection (Van Dommelen 2010 Biorapid). Test sensitivity and specificity were 0.17 (95% CI 0.09 to 0.26) and 0.94 (95% CI 0.91 to 0.95), respectively.

1.2.1.8 BioVei

One study recruited 76 participants and, with a prevalence of 17%, assessed the diagnostic accuracy of Biovei to identify *C trachomatis* infection (Hesse 2011). Test sensitivity and specificity were 0.54 (95% CI 0.25 to 0.81) and 0.51 (95% CI 0.38 to 0.64), respectively.

1.2.1.9 Chlamydia Test Card

One study recruited 276 participants and, with a prevalence of 9%, assessed the diagnostic accuracy of Chlamydia Test Card to identify *C trachomatis* infection (Sabidó 2009). Test sensitivity and specificity were 0.62 (95% CI 0.42 to 0.81) and 1.00 (95% CI 0.98 to 1.00), respectively.

1.2.2.0 Unknown brand of the POC test

One study recruited 149 participants and, with a prevalence of 9%, assessed the diagnostic accuracy of a POC test (unknown brand) to identify *C trachomatis* infection (Huang 2013). Test sensitivity and specificity were 0.93 (95% CI 0.66 to 1.00) and 0.99 (95% CI 0.95 to 1.00), respectively.

Heterogeneity assessment

Initially we explored heterogeneity by visual inspection of sensitivity and specificity forest plots as well as of the prediction region. Later, we formally assessed the source of heterogeneity by examining differences in diagnostic accuracy between subgroups, using the bivariate method to analyze how the summary estimate of sensitivity and specificity varied according to specimen (endocervical versus urine or vaginal), reported urogenital symptoms among participants (symptomatic versus asymptomatic participants), and study setting (low/middle-income versus high-income countries). The results observed as a consequence of the formal evaluation of heterogeneity sources are shown below (Table 2).

According to specimen source (endocervical or urine and vaginal)

Eleven studies (14 study arms) assessed the accuracy of POC testing of endocervical samples (Bandeja 2009; Hesse 2011; Lauderdale 1999; Nuñez-Forero 2016 Acon; Nuñez-Forero 2016 Acon Duo; Nuñez-Forero 2016 QuickVue; Pate 1998; Rani 2002; Sabido 2009; Saison 2007 Clearview; Saison 2007 CRT; Swain 2004; Widjaja 1999; Yin 2006) and eight studies (13 study arms) assessed other specimen types (Abbai-Shaik 2016; Huang 2013; Hurly 2014 Acon; Hurly 2014 CRT; Mahilum-Tapay 2007; Michel 2009; Nadala 2009; Saison 2007 Clearview; Saison 2007 CRT; Van der Helm 2012; Van Dommelen 2010 Biorapid; Van Dommelen 2010 Handilab-C; Nuñez-Forero 2016 QuickVue).

Sensitivity for endocervical specimens ranged from 0.23 to 0.64 while specificity ranged from 0.51 to 1.00. The mean sensitivity and specificity of included studies were 0.48 (95% CI 0.41 to 0.56) and 0.99 (95% CI 0.97 to 0.99), respectively. Findings were quite similar to those that were documented for POC testing performed in other specimen types (urine or vaginal). Sensitivities ranged from 0.17 to 0.93 and specificities from 0.88 to 1.00. The mean sensitivity and specificity were 0.49 (95% CI 0.32 to 0.67) and 0.97 (95% CI 0.94 to 0.98), respectively. Regardless of the specimen type, the visual inspection of forest plots for sensitivities, demonstrated a substantial degree of heterogeneity between studies and visual inspection suggested similar performance for both samples. The likelihood ratio test was not significantly different in terms of sensitivity or specificity when heterogeneity source was explored by specimen ($P = 0.27$; endocervical versus urine or vaginal). For this reason, this covariate did not appear to explain the variability in diagnostic accuracy.

According to the presence of symptoms of the participant (symptomatic versus asymptomatic participants)

The included studies did not provide enough information to carry out this analysis.

According to study setting (low/middle-income versus high-income countries)

Eight studies (12 study arms) assessed the accuracy of POC testing in low/middle income countries (Abbai-Shaik 2016; Hurly 2014 Acon; Hurly 2014 CRT; Michel 2009; Nuñez-Forero 2016 Acon; Nuñez-Forero 2016 Acon Duo; Nuñez-Forero 2016 QuickVue; Sabido 2009; Saison 2007 Clearview; Saison 2007 CRT; Van der Helm

2012; Widjaja 1999) and 11 studies (13 study arms) in high-income countries (Bandeja 2009; Hesse 2011; Huang 2013; Lauderdale 1999; Mahilum-Tapay 2007; Nadala 2009; Pate 1998; Rani 2002; Swain 2004; Van Dommelen 2010 Biorapid; Van Dommelen 2010 Handilab-C; Van Dommelen 2010 QuickVue; Yin 2006).

Sensitivities for POC testing in low/middle-income countries ranged between 0.19 and 0.71 while specificities ranged between 0.88 and 1.00. The mean sensitivity and specificity were 0.42 (95% CI 0.32 to 0.53) and 0.98 (95% CI 0.97 to 0.99), respectively. Findings, again, quite similar to those that were documented for high-income countries. Sensitivities ranged between 0.17 and 0.93 and specificities between 0.51 to 1.00. The mean sensitivity and specificity were 0.54 (95% CI 0.40 to 0.68) and 0.98 (95% CI 0.95 to 0.99), respectively. Regardless of the specimen type, the visual inspection of forest plots for sensitivities and specificities revealed a substantial degree of heterogeneity between studies, and visual inspection suggested similar performance for both settings. The likelihood ratio test was not significantly different in terms of sensitivity or specificity when heterogeneity source was explored by study setting ($P = 0.28$ low/middle versus high-income countries). For this reason, this covariate did not appear to explain the variability in diagnostic accuracy.

Sensitivity analyses

We planned to conduct sensitivity analyses to assess the impact of the methodological quality of included studies on the results of the meta-analysis. We defined low-quality studies as those with high risk of bias for the domains of participant sampling, index test, reference standard, or flow and timing. However, we could not carry out these analyses because we did not rate any of the included studies as high risk of bias.

Publication bias

We assessed publication bias because this review included more than 10 studies. Initially we assessed reporting bias using funnel plot visual asymmetry, plotting a measure of effect size against a measure of study precision. This inspection did not suggest an asymmetrical distribution of the studies around the regression line. We performed a formal evaluation using Deeks' test to investigate the asymmetry (Van Enst 2014; Figure 6). The statistically nonsignificant P value (0.74) for the slope coefficient suggests symmetry in the data and a low likelihood of publication bias. However, the test is known to have low power (Deeks 2005).

Figure 6. Publication bias

DISCUSSION

Summary of main results

This review included a total of 19 studies, with 13,676 participants, that assessed the diagnostic accuracy of POC tests for *C trachomatis* infection in nonpregnant women and men of reproductive age, as verified with NAATs as the reference standard. The distributors provided the rapid tests in nine studies. Seven studies recruited predominantly high-risk or symptomatic participants. The included studies were conducted in America, Asia, Africa, Europe and Oceania, with a median prevalence of 10% (range 8% to 28%). The studies assessed nine different brands of POC tests. The mean sensitivity of rapid POC tests for detecting urogenital *C trachomatis* infection was 0.48 (95% CI 0.39 to 0.58; low-quality evidence) and the mean specificity was 0.98 (95% CI 0.97 to 0.99; moderate-quality evidence). We explored sources of heterogeneity by examining differences in diagnostic accuracy according to specimen (endocervical versus urine or vaginal), symptoms among participants (symptomatic versus asymptomatic), and setting (low/middle-income versus high-income countries). Likelihood ratio tests were not significantly different in terms of sensitivity or specificity by specimen ($P = 0.27$) or setting ($P = 0.28$); for this reason, these covariates do not appear to explain the observed variability. Included studies did not provide enough information to assess the 'presence of symptoms' covariate. We downgraded the

quality of evidence because of some limitations in applicability and heterogeneity.

Strengths and weaknesses of the review

Completeness of evidence

We conducted a comprehensive search of the literature, including full-text publications, without language restrictions or use of filters in the search strategy. Although we included studies between 2001 and November 2019, it is unlikely that any may have been missed, given that publications of POC test studies in sexually transmitted infections began to appear in 2001, and considering that a 'snowball' search was conducted as well. However, we may have missed some studies as a result of the lack of a totally reliable search strategy for finding diagnostic test accuracy studies (Beynon 2013); moreover, we were unable to find some unpublished studies through our search strategy.

Accuracy of the reference standard used

Currently, the NAAT test is considered the gold standard for *C trachomatis* infections. The NAAT test has a better performance than culture because it is easier to handle and has a higher sensitivity. NAAT sensitivity is 92% to 95% and specificity is 99% (Black 1997), while culture has a sensitivity of 35% to 85% and a specificity of 100% (Olshen 2005). On the other hand, we did not detect any performance bias because the NAAT samples were

taken without knowledge of the POC results, and the tests were performed using trained staff and standardized procedures. It was clear that 12 studies carried out the POC tests before the results of the standard test were known; it is unlikely that the POC tests were done after the NAAT tests, and the result of the POC tests should have been obtained within the next hour after the sample was taken.

Quality of evidence of the included studies

This systematic review follows the standard methodology suggested by Cochrane, with two independent review authors assessing the inclusion criteria for the studies, extracting data and assessing the risk of bias of the included studies, thus reducing the risk of performance bias in the review and data extraction errors. Through the quality assessment, we classified all the included studies as having low risk of bias for the QUADAS-2 domains of participant sampling, and flow and timing. The participant selection domain was the major concern; three studies recruited predominantly high-risk or symptomatic participants. On the other hand, we found high heterogeneity among study results, which could not be explained by the differences in sample source or the setting where the tests were done (low/middle-income countries versus high-income countries).

The few published studies on seven of the nine brands did not allow us to estimate the median sensitivity and specificity or to build the summary ROC curves for comparison. Regarding the other subgroup analyses, we were able to compare the source of the sample, the performance of the tests and the setting where the POC tests were evaluated.

Comparison with other systematic reviews

We found three systematic reviews on POC testing in *C trachomatis* infections. Our results show a lower performance for POC tests than the systematic review by [Hislop 2010](#), which included 13 studies. They found a higher sensitivity of 89% (95% CI 73% to 85%) for vaginal specimens and 77% (95% CI 59% to 89%) for urine specimens, with similar specificity, and only included the CRT, with the comparator reference tests being different NAATs. They provided the pooled sensitivity and specificity and assessed heterogeneity using the I^2 statistic.

[Herbst de Cortina 2016](#) found eight studies that assessed the accuracy of POC testing for *C trachomatis*. They evaluated 10 rapid tests ranging from Gram stain to rapid NAATs, and all tests were compared against NAATs. They did not provide any grouped estimator of the assessed tests but the authors said that POC tests based on antigen detection showed a sensitivity and specificity lower than 75% or 50%.

Finally, in 2017, a systematic review ([Kelly 2017](#)) included 11 studies, nine of which assessed antigen detection rapid tests and two assessed rapid NAATs. [Kelly 2017](#) obtained similar results to our review, with a pooled sensitivity of 53% for endocervical swabs, 37% for vaginal sample and 63% for male urine, and a specificity higher than 97%. Our review included a higher number of studies, without language restriction, and took into account the studies included by those systematic reviews. Two of those systematic reviews report that rapid NAATs for POC use have a sensitivity higher than 90% and a specificity of more than 95%. However, costs could restrict their use in settings with constrained resources.

Applicability of findings to the review question

Most of the studies were done in women ([Hesse 2011](#); [Huang 2013](#); [Lauderdale 1999](#); [Mahilum-Tapay 2007](#); [Michel 2009](#); [Nuñez-Forero 2016 Acon](#); [Nuñez-Forero 2016 Acon Duo](#); [Nuñez-Forero 2016 QuickVue](#); [Rani 2002](#); [Sabido 2009](#); [Saison 2007 Clearview](#); [Saison 2007 CRT](#); [Swain 2004](#); [Van der Helm 2012](#); [Van Dommelen 2010 Biorapid](#); [Van Dommelen 2010 Handilab-C](#); [Van Dommelen 2010 QuickVue](#); [Widjaja 1999](#); [Yin 2006](#)), two in men ([Abbai-Shaik 2016](#); [Nadala 2009](#)), and two (one study with two cohorts) in both men and women ([Bandeia 2009](#); [Hurly 2014 Acon](#); [Hurly 2014 CRT](#)). Therefore, the results are applicable in certain ways to women and men.

On the other hand, we assigned high concern to participant selection applicability. Seven studies (10 study arms) recruited predominantly a high-risk population (e.g. female sex workers; [Michel 2009](#); [Saison 2007 Clearview](#); [Saison 2007 CRT](#)), or a symptomatic population (e.g. with discharge, dysuria, or abdominal pain; [Huang 2013](#); [Nadala 2009](#); [Nuñez-Forero 2016 Acon](#); [Nuñez-Forero 2016 Acon Duo](#); [Nuñez-Forero 2016 QuickVue](#); [Pate 1998](#); [Yin 2006](#)). Five studies (seven study arms) demonstrated unclear concern ([Hesse 2011](#); [Rani 2002](#); [Swain 2004](#); [Van Dommelen 2010 Biorapid](#); [Van Dommelen 2010 Handilab-C](#); [Van Dommelen 2010 QuickVue](#); [Widjaja 1999](#)), inasmuch as they did not provide enough information to judge whether the included participants matched the review question in terms of severity, demographic features, presence of differential diagnosis or comorbidity, or study setting. The remaining studies showed low concern for participant selection applicability.

Regarding index test applicability, we considered five studies (seven study arms) as unclear concern ([Abbai-Shaik 2016](#); [Bandeia 2009](#); [Nuñez-Forero 2016 Acon](#); [Nuñez-Forero 2016 Acon Duo](#); [Nuñez-Forero 2016 QuickVue](#); [Rani 2002](#); [Widjaja 1999](#)), given that the report had insufficient information for us to judge whether the index test, its performance, or its interpretation could differ from the review question. We assessed one study as high concern given that, during the recruiting phase, there were multiple variations in test technology ([Hesse 2011](#)). Consequently, we considered that variations in test technology, test performance and interpretation may affect index test applicability. We rated the other included studies as low concern in terms of index test applicability. With respect to gold standard test applicability, we judged two studies as unclear concern ([Abbai-Shaik 2016](#); [Rani 2002](#)), given that the report did not provide enough information to make a judgment. We considered the other studies as low concern, because the target condition, as defined by the reference standard, matched the review question.

Based on the diagnostic performance of the rapid test at POC, the precision and the prediction region, none of the assessed tests could be recommended as triage tests for *C trachomatis* urogenital tract infection. Given that we included eight studies carried out in low- and middle-income countries, our results could be applied to populations in those settings.

AUTHORS' CONCLUSIONS

Implications for practice

Based on the results of this systematic review, the point-of-care (POC) test based on antigen detection has suboptimal sensitivity

but good specificity. Performance of this test translates, on average, to a 52% chance of mistakenly indicating absence of infection and a 2% chance of mistakenly pointing to the presence of this condition. Because of its deleterious consequences for reproductive health, and considering the current availability of safe and effective interventions to treat *Chlamydia trachomatis* (*C trachomatis*) infection, the POC screening strategy should not be based on a rapid diagnostic test for antigen detection. Different technologies should be addressed in future research on this topic.

Implications for research

There is a need for well-conducted diagnostic accuracy studies of rapid POC tests performed in a general patient population. Given that some of the included studies recruited high-risk or symptomatic participants, future studies that evaluate the performance of the same tests could change our conclusions.

There are uncertainties that need to be addressed as part of research in this area, including the development of tests with higher sensitivity. Given the consequences of the disease, and considering the availability of safe and effective therapeutic interventions, it is imperative to have tests that detect this infection, especially in asymptomatic populations, in order to be able to provide timely treatment. Future evaluations should include the use of different technologies (e.g. rapid NAAT tests) in different contexts including general, male and asymptomatic populations.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Abbai-Shaik 2016
Study characteristics

Patient sampling	<p>Study design: prospective cross-sectional; consecutive enrolment</p> <p>Recruitment period: June-July 2015</p> <p>Country: South Africa</p> <p>Clinical setting: general population in Durban, KwaZulu-Natal, by staff from the South African Medical Research Council's (SAMRC) HIV Prevention Research Unit (HPRU)</p> <p>Sample size: 100</p>
Patient characteristics and setting	<p>Population: asymptomatic men who are not experiencing discharge from the penis, pain during coitus, pain during urination, genital itching or testicular pain</p> <p>Age: median age 31 years</p> <p>Sex: men</p> <p>Inclusion criteria: men > 18 years, asymptomatic</p> <p>Exclusion criteria: allergic to any medication because the study included a treatment phase</p>
Index tests	<p>Index test: Chlamydia Rapid Test</p> <p>Specimen: urine</p>
Target condition and reference standard(s)	<p>Reference standard: BD ProbeTec ET PCR Assay (Becton Dickinson Microbiology Systems, USA)</p> <p>Specimen: urine</p> <p>The prevalence for <i>C trachomatis</i> was: 10%</p>
Flow and timing	<p>Time interval between index test and reference standard: at the same time</p>
Comparative	<p>Source of funding: South African Medical Research Council and sponsorship of the rapid test kits from Alere Diagnostics (South Africa).</p>
Notes	<p>Source of funding: South African Medical Research Council and sponsorship of the rapid test kits from Alere Diagnostics (South Africa)</p>

Methodological quality

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		

Abbai-Shaik 2016 (Continued)

	Low	Low
DOMAIN 2: Index Test All tests		
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear	
	Unclear	Unclear
DOMAIN 3: Reference Standard		
Is the reference standards likely to correctly classify the target condition?	Unclear	
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear	
	Unclear	Unclear
DOMAIN 4: Flow and Timing		
Was there an appropriate interval between index test and reference standard?	Yes	
Did all patients receive the same reference standard?	Yes	
Were all patients included in the analysis?	Yes	
Did patients receive the reference standard irrespective of the index test results ?	Yes	
Were withdrawals from the study explained?	Yes	
Were uninterpretable/intermediate test results reported?	Yes	
	Low	

Bandea 2009

Study characteristics	
Patient sampling	Study design: prospective cross-sectional; consecutive enrolment Recruitment period: not mentioned Country: USA Clinical setting: public paediatric clinic in Atlanta, GA Sample size: 261
Patient characteristics and setting	Population: asymptomatic participants Age: 13-19 years Sex: male and female

Bandea 2009 (Continued)

Inclusion criteria: sexually active, HIV-negative, nonpregnant adolescent females aged 13-19 years and had a clinical indication for a pelvic examination

Exclusion criteria: had received antibiotics within the previous 30 days

Index tests	Index test: BioStar Chlamydia Specimen: endocervical
Target condition and reference standard(s)	Reference standard: not mentioned Specimen: endocervical The prevalence for <i>C trachomatis</i> was: 28.3%
Flow and timing	Time interval between index test and reference standard: at the same time
Comparative	Source of funding: BioStar, Inc., provided the BioStar Chlamydia OIAs used in this study.
Notes	Source of funding: BioStar, Inc., provided the BioStar Chlamydia used in this study

Methodological quality

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
		Low	Low
DOMAIN 2: Index Test All tests			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
		Unclear	Unclear
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Unclear		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		Unclear	Low
DOMAIN 4: Flow and Timing			

Bandea 2009 (Continued)

Was there an appropriate interval between index test and reference standard?	Yes
Did all patients receive the same reference standard?	Yes
Were all patients included in the analysis?	Yes
Did patients receive the reference standard irrespective of the index test results?	Yes
Were withdrawals from the study explained?	Unclear
Were uninterpretable/intermediate test results reported?	Unclear
Unclear	

Hesse 2011
Study characteristics

Patient sampling	Study design: prospective cross-sectional; consecutive enrolment Recruitment period: not mentioned Country: USA Clinical setting: City of Cincinnati's Health Department STI Clinic, and Cincinnati Children's Hospital Medical Center's Teen Health Center and Emergency Department Sample size: 83
Patient characteristics and setting	Population: not mentioned Age: mean age 18 years Sex: women Inclusion criteria: women were eligible for participation if they were between the ages of 14-30, reported a history of vaginal sex within the past 3 months, were getting a pelvic exam with <i>C trachomatis</i> testing on the day of their visit, and were willing to self-collect vaginal swabs Exclusion criteria: potential participants were ineligible if they had used oral antibiotics or topical vaginal medications within 2 weeks prior to recruitment.
Index tests	Index test: Biovei Specimen: cervical
Target condition and reference standard(s)	Reference standard: Strand Displacement Assay (SDA), BD Probetek ET, Becton Dickinson, Sparks, MD Specimen: cervical The prevalence for <i>C trachomatis</i> was: 15.7%
Flow and timing	Time interval between index test and reference standard: at the same time
Comparative	Source of funding: Sponsorship of the rapid test kits from the company BD Probetek ET.
Notes	Source of funding: sponsorship of the rapid test kits from the company BD Probetek ET

Hesse 2011 (Continued)

Methodological quality

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
		Low	Unclear
DOMAIN 2: Index Test All tests			
Were the index test results interpreted without knowledge of the results of the reference standard?	Yes		
		Low	High
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Unclear		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Yes		
		Low	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Yes		
Did patients receive the reference standard irrespective of the index test results ?	Yes		
Were withdrawals from the study explained?	Yes		
Were uninterpretable/intermediate test results reported?	Yes		
		Low	

Huang 2013
Study characteristics

Patient sampling	Study design: prospective cross-sectional; consecutive enrolment Recruitment period: April 2010-February 2011 Country: USA Clinical setting: Baltimore, Maryland, STD clinics Sample size: 149
Patient characteristics and setting	Population: overall, 62.8% of women reported 1 symptom. However, the study did not provide any extra information Age: median age 27 years Sex: women Inclusion criteria: age ≥ 18 years, ≥ 1 h since last urine void, and requiring a pelvic examination on the day of their visit Exclusion criteria: antibiotic treatment within the past 21 days
Index tests	Index test: not mentioned Specimen: vaginal
Target condition and reference standard(s)	Reference standard: Aptima Combo 2, Gen-Probe Inc, San Diego, California, USA Specimen: vaginal and urine The prevalence for <i>C trachomatis</i> was: 9.4%
Flow and timing	Time interval between index test and reference standard: at the same time
Comparative	Source of funding: project described was supported by NIH HPTN U-01 AI06813 and Award Number U-01 U54EB007958 and 3U54EB007958-03S1, issued under the American Recovery and Reinvestment act of 2009, from the National Institute of Biomedical Imaging and Bioengineering.
Notes	Source of funding: Supported by NIH HPTN U-01 AI06813 and Award Number U-01 U54EB007958 and 3U54EB007958-03S1, issued under the American Recovery and Reinvestment act of 2009, from the National Institute of Biomedical Imaging and Bioengineering.

Methodological quality

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
		Low	High
DOMAIN 2: Index Test All tests			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		

Huang 2013 (Continued)

	Unclear	Low
DOMAIN 3: Reference Standard		
Is the reference standards likely to correctly classify the target condition?	Unclear	
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear	
	Unclear	Low
DOMAIN 4: Flow and Timing		
Was there an appropriate interval between index test and reference standard?	Yes	
Did all patients receive the same reference standard?	Yes	
Were all patients included in the analysis?	Yes	
Did patients receive the reference standard irrespective of the index test results ?	Yes	
Were withdrawals from the study explained?	Yes	
Were uninterpretable/intermediate test results reported?	Yes	
	Low	

Hurly 2014 Acon

Study characteristics	
Patient sampling	Study design: prospective cross-sectional; consecutive enrolment Recruitment period: April-November 2010 Country: Port Vila, Vanuatu Clinical setting: KPH Clinic located at Port Vila, Vanuatu Sample size: 586
Patient characteristics and setting	Population: asymptomatic and symptomatic participants Age: median age 25 years Sex: men and women Inclusion criteria: > 18 years Exclusion criteria: antibiotic treatment within the past month, previous participation and menstruation
Index tests	Index test: Chlamydia Rapid Test Specimen: male urine and female vaginal swabs

Hurly 2014 Acon (Continued)

Target condition and reference standard(s)	Reference standard: COBAS TaqMan 48 PCR assay (Roche Diagnostic, Branchburg, New Jersey, USA) Specimen: male urine and female vaginal swabs The prevalence for <i>C trachomatis</i> was: 12% men and 8% women		
Flow and timing	Time interval between index test and reference standard: at the same time		
Comparative	Source of funding: The study was independent, with neither manufacturer involved in study design, implementation, analysis or manuscript writing.		
Notes	Source of funding: the study was independent, with neither manufacturer involved in study.		
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
		Low	Low
DOMAIN 2: Index Test All tests			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
		Unclear	Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		Low	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Yes		

Hurly 2014 Acon (Continued)

Did patients receive the reference standard irrespective of the index test results?	Yes
Were withdrawals from the study explained?	Unclear
Were uninterpretable/intermediate test results reported?	Yes
Low	

Hurly 2014 CRT

Study characteristics

Patient sampling	Study design: prospective cross-sectional; consecutive enrolment Recruitment period: April-November 2010 Country: Port Vila, Vanuatu Clinical setting: KPH Clinic located at Port Vila, Vanuatu Sample size: 586		
Patient characteristics and setting	Population: asymptomatic and symptomatic participants Age: median age 25 years Sex: men and women Inclusion criteria: > 18 years Exclusion criteria: antibiotic treatment within the past month, previous participation and menstruation		
Index tests	Index test: Chlamydia Rapid Test Specimen: male urine and female vaginal swabs		
Target condition and reference standard(s)	Reference standard: COBAS TaqMan 48 PCR assay (Roche Diagnostic, Branchburg, New Jersey, USA) Specimen: male urine and female vaginal swabs The prevalence for <i>C trachomatis</i> was: 12% men and 8% women		
Flow and timing	Time interval between index test and reference standard: at the same time		
Comparative			
Notes	Source of funding: the study was independent, with neither manufacturer involved in study.		

Methodological quality

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		

Hurly 2014 CRT *(Continued)*

Did the study avoid inappropriate exclusions?	Yes		
		Low	Low
DOMAIN 2: Index Test All tests			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
		Unclear	Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		Low	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Yes		
Did patients receive the reference standard irrespective of the index test results ?	Yes		
Were withdrawals from the study explained?	Unclear		
Were uninterpretable/intermediate test results reported?	Yes		
		Low	

Lauderdale 1999

Study characteristics			
Patient sampling	Study design: prospective cross-sectional; consecutive enrolment Recruitment period: June 1997-November 1997 Country: USA Clinical setting: University of South Alabama Sample size: 65		
Patient characteristics and setting	Population: asymptomatic and symptomatic population Age: not mentioned Sex: women Inclusion criteria: not provided		

Lauderdale 1999 (Continued)

Exclusion criteria: not provided

Index tests	Index test: Clearview EIA Specimen: endocervical
Target condition and reference standard(s)	Reference standard: LCx assays (Abbott Laboratories) for <i>C trachomatis</i> Specimen: endocervical The prevalence for <i>C trachomatis</i> was: 15%
Flow and timing	Time interval between index test and reference standard: at the same time
Comparative	Source of funding: Gen-Probe Inc. and Abbott Laboratories supported this study.
Notes	Source of funding: Gen-Probe Inc. and Abbott Laboratories supported this study.

Methodological quality

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
		Low	Low
DOMAIN 2: Index Test All tests			
Were the index test results interpreted without knowledge of the results of the reference standard?	Yes		
		Low	Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Unclear		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
		Unclear	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Did all patients receive the same reference standard?	Unclear		

Lauderdale 1999 (Continued)

Were all patients included in the analysis?	Unclear
Did patients receive the reference standard irrespective of the index test results ?	Unclear
Were withdrawals from the study explained?	Unclear
Were uninterpretable/intermediate test results reported?	Unclear
Unclear	

Mahilum-Tapay 2007
Study characteristics

Patient sampling	Study design: prospective cross-sectional; consecutive enrolment Recruitment period: November 2005-March 2006 Country: UK Clinical setting: Brook in Birmingham and 2 genitourinary medicine clinics, Ambrose King Centre and Barts Sexual Health Centre Sample size: 1349
Patient characteristics and setting	Population: asymptomatic and symptomatic participants Age: mean age 18 years at site 1, 25 years at site 2, and 27 years at site 3 Sex: women Inclusion criteria: ≥ 16 years old, had not taken antibiotics in the previous month, were not menstruating at the time of their visit, and were able to understand the written information forms for the study Exclusion criteria: not provided
Index tests	Index test: Chlamydia Rapid Test Specimen: vaginal
Target condition and reference standard(s)	Reference standard: ProbeTec ET strand displacement amplification assay (Becton- Dickinson Diagnostic Systems, Sparks, MD) Specimen: endocervical The prevalence for <i>C trachomatis</i> was: 8.4% at site 1; 9.4% at site 2; and 6.0% at site 3
Flow and timing	Time interval between index test and reference standard: at the same time
Comparative	Source of funding: Competing interests. Two authors equity holders of a spin-off company, Diagnostics for the Real World, based on the rapid test technologies developed at the University of Cambridge. Both the University of Cambridge and the Wellcome Trust are also equity holders of the company.
Notes	Source of funding: competing interests. Two authors equity holders of a spin-off company, Diagnostics for the Real World, based on the rapid test technologies developed at the University of Cambridge.

Methodological quality

Item	Authors' judgement	Risk of bias	Applicability concerns
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Mahilum-Tapay 2007 (Continued)

DOMAIN 1: Patient Selection

Was a consecutive or random sample of patients enrolled?	Yes	
Was a case-control design avoided?	Yes	
Did the study avoid inappropriate exclusions?	Yes	
	Low	Low

DOMAIN 2: Index Test All tests

Were the index test results interpreted without knowledge of the results of the reference standard?	Yes	
	Low	Low

DOMAIN 3: Reference Standard

Is the reference standards likely to correctly classify the target condition?	Yes	
Were the reference standard results interpreted without knowledge of the results of the index tests?	Yes	
	Low	Low

DOMAIN 4: Flow and Timing

Was there an appropriate interval between index test and reference standard?	Yes	
Did all patients receive the same reference standard?	Yes	
Were all patients included in the analysis?	Yes	
Did patients receive the reference standard irrespective of the index test results ?	Yes	
Were withdrawals from the study explained?	Yes	
Were uninterpretable/intermediate test results reported?	Unclear	
	Unclear	

Michel 2009
Study characteristics

Patient sampling	Study design: prospective cross-sectional; consecutive enrolment
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Michel 2009 (Continued)

Recruitment period: May 2008

Country: Philippines

Clinical setting: Social Hygiene Clinic (SHC) at the Western Visayas Medical Center in Iloilo City

Sample size: 132

Patient characteristics and setting	Population: symptomatic and asymptomatic sex workers who attended the clinic for a weekly health check Age: median age of participants not mentioned Sex: women Inclusion criteria: ≥ 18 years old, had not taken antibiotics during the previous month, had not used a vaginal cream or feminine wash during the previous 24 h, could understand the provided forms and were willing to participate in the study Exclusion criteria: not provided
Index tests	Index test: HandiLab-C. Test based on the detection of an enzyme (Peptidase 123A) specific to <i>C trachomatis</i> Specimen: vaginal
Target condition and reference standard(s)	Reference standard: Abbott M-2000 <i>C trachomatis</i> test (Abbott Molecular Division, Abbott Park, Illinois) Specimen: vaginal The prevalence for <i>C trachomatis</i> was: 23%
Flow and timing	Time interval between index test and reference standard: at the same time
Comparative	Source of funding: The study was funded by a grant from The Wellcome Trust (081371/Z/06/Z).
Notes	Source of funding: the study was funded by a grant from The Wellcome Trust (081371/Z/06/Z)

Methodological quality

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
		Low	High
DOMAIN 2: Index Test All tests			
Were the index test results interpreted without knowledge of the results of the reference standard?	Yes		
		Low	Low
DOMAIN 3: Reference Standard			

Michel 2009 (Continued)

Is the reference standards likely to correctly classify the target condition?	Yes
Were the reference standard results interpreted without knowledge of the results of the index tests?	Yes
	Low
	Low
DOMAIN 4: Flow and Timing	
Was there an appropriate interval between index test and reference standard?	Yes
Did all patients receive the same reference standard?	Yes
Were all patients included in the analysis?	Yes
Did patients receive the reference standard irrespective of the index test results?	Yes
Were withdrawals from the study explained?	Unclear
Were uninterpretable/intermediate test results reported?	Unclear
	Unclear

Nadala 2009
Study characteristics

Patient sampling	Study design: prospective cross-sectional; consecutive enrolment Recruitment period: March-November 2007 Country: UK Clinical setting: young people's sexual health centre (Brook in Birmingham, site 1) and a genitourinary medicine clinic (Ambrose King Centre in London, site 2) Sample size: 1211
Patient characteristics and setting	Population: most participants at site 1 attended the sexual health center for contraception and other reproductive health services and were asymptomatic. In contrast, 62% of the participants at site 2 (genitourinary medicine clinic) presented with symptoms that included urethral discharge and dysuria Age: median age 18 years (range 16.0-25.0) at site 1 and 29 years (16.5-73.4) at site 2 Sex: men Inclusion criteria: men > 16 years, had not taken antibiotics in the previous month, and were able to understand the written information forms for the study Exclusion criteria: not mentioned
Index tests	Index test: Chlamydia Rapid Test Specimen: urine

Nadala 2009 (Continued)

Target condition and reference standard(s)

Reference standard: the Roche Amplicor CT/NG polymerase chain
Specimen: urine
The prevalence for *C trachomatis* was: 4% at site 1 and 12% at site 2

Flow and timing

Time interval between index test and reference standard: at the same time

Comparative

Source of funding: Three authors are equity holders in Diagnostics for the Real World, which markets the rapid test technologies developed at the University of Cambridge. Both the University of Cambridge and the Wellcome Trust are also equity holders of the company. The study was funded by a Wellcome Trust grant to the University of Cambridge and additional support from the NIHR Cambridge Biomedical Research Centre.

Notes

Source of funding: Three authors are equity holders in Diagnostics for the Real World, which markets the rapid test technologies developed at the University of Cambridge. Both the University of Cambridge and the Wellcome Trust are also equity holders of the company.

Methodological quality

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
		Low	High
DOMAIN 2: Index Test All tests			
Were the index test results interpreted without knowledge of the results of the reference standard?	Yes		
		Low	Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Yes		
		Low	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		

Nadala 2009 (Continued)

Did all patients receive the same reference standard?	Yes
Were all patients included in the analysis?	Yes
Did patients receive the reference standard irrespective of the index test results?	Yes
Were withdrawals from the study explained?	Yes
Were uninterpretable/intermediate test results reported?	Yes
Low	

Núñez-Forero 2016 Acon

Study characteristics	
Patient sampling	Study design: prospective cross-sectional; consecutive enrolment Recruitment period: during 2010 Country: Colombia Clinical setting: private sexual and reproductive health clinic (PROFAMILIA) and at the ambulatory services of 2 public general hospitals: Engativá and Fontibón Hospitals, in Bogotá, Colombia Sample size: 1444
Patient characteristics and setting	Population: women having symptoms of lower urinary tract infection. 113 women stated that they were sex workers (8.9%) Age: median age 31 years Sex: women Inclusion criteria: sexually active women aged 14-49 years Exclusion criteria: pregnant women, those suffering medical conditions requiring hospitalization, those hysterectomized or those who had received systemic or local antibiotic treatment for the urinary tract during the previous 7 days
Index tests	Index test: ACON Plate CT RT Specimen: endocervical
Target condition and reference standard(s)	Reference standard: PCR with the COBAS AMPLICOR CT/NG system (Roche) Specimen: endocervical The prevalence for <i>C trachomatis</i> was: 9.7%
Flow and timing	Time interval between index test and reference standard: at the same time
Comparative	Source of funding: Work supported by Colciencias Grant 621/2009, Universidad Nacional de Colombia Bogotá Research Division; the Bogotá District Secretariat of Health and the Global Network for Perinatal & Reproductive Health, FUNDARED-MATERNA, Bogotá, Colombia.
Notes	Source of funding: work supported by Colciencias Grant 621/2009, Universidad Nacional de Colombia Bogotá Research Division; the Bogotá District Secretariat of

Núñez-Forero 2016 Acon (Continued)

Health and the Global Network for Perinatal & Reproductive Health, FUNDARED-MATERNA, Bogotá, Colombia

Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
		Low	High
DOMAIN 2: Index Test All tests			
Were the index test results interpreted without knowledge of the results of the reference standard?	Yes		
		Low	Unclear
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Yes		
		Low	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Yes		
Did patients receive the reference standard irrespective of the index test results ?	Yes		
Were withdrawals from the study explained?	Yes		
Were uninterpretable/intermediate test results reported?	Yes		
		Low	

Núñez-Forero 2016 Acon Duo

Study characteristics

Patient sampling	Study design: prospective cross-sectional; consecutive enrolment Recruitment period: during 2010 Country: Colombia Clinical setting: private sexual and reproductive health clinic (PROFAMILIA) and at the ambulatory services of 2 public general hospitals: Engativá and Fontibón Hospitals, in Bogotá, Colombia Sample size: 1444
Patient characteristics and setting	Population: women having symptoms of lower urinary tract infection. 113 women stated that they were sex workers (8.9%) Age: median age of participants was 31 years Sex: women Inclusion criteria: sexually active women aged 14-49 years Exclusion criteria: pregnant women, those suffering medical conditions requiring hospitalization, those hysterectomized or those who had received systemic or local antibiotic treatment for the urinary tract during the previous 7 days
Index tests	Index test: ACON Plate duo Specimen: endocervical
Target condition and reference standard(s)	Reference standard: PCR with the COBAS AMPLICOR CT/NG system (Roche) Specimen: endocervical The prevalence for <i>C trachomatis</i> was: 9.7%
Flow and timing	Time interval between index test and reference standard: at the same time
Comparative	
Notes	Source of funding: work supported by Colciencias Grant 621/2009, Universidad Nacional de Colombia Bogotá Research Division; the Bogotá District Secretariat of Health and the Global Network for Perinatal & Reproductive Health, FUNDARED-MATERNA, Bogotá, Colombia.

Methodological quality

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
		Low	High
DOMAIN 2: Index Test All tests			

Núñez-Forero 2016 Acon Duo (Continued)

Were the index test results interpreted without knowledge of the results of the reference standard?	Yes
Low	
Unclear	
DOMAIN 3: Reference Standard	
Is the reference standards likely to correctly classify the target condition?	Yes
Were the reference standard results interpreted without knowledge of the results of the index tests?	Yes
Low	
Low	
DOMAIN 4: Flow and Timing	
Was there an appropriate interval between index test and reference standard?	Yes
Did all patients receive the same reference standard?	Yes
Were all patients included in the analysis?	Yes
Did patients receive the reference standard irrespective of the index test results?	Yes
Were withdrawals from the study explained?	Yes
Were uninterpretable/intermediate test results reported?	Yes
Low	

Núñez-Forero 2016 QuickVue

Study characteristics	
Patient sampling	Study design: prospective cross-sectional; consecutive enrolment Recruitment period: during 2010 Country: Colombia Clinical setting: private sexual and reproductive health clinic (PROFAMILIA) and at the ambulatory services of 2 public general hospitals: Engativá and Fontibón Hospitals, in Bogotá, Colombia Sample size: 1444
Patient characteristics and setting	Population: women having symptoms of lower urinary tract infection. 113 women stated that they were sex workers (8.9%) Age: median age 31 years Sex: women Inclusion criteria: sexually active women aged 14-49 years

Núñez-Forero 2016 QuickVue (Continued)

Exclusion criteria: pregnant women, those suffering medical conditions requiring hospitalization, those hysterectomized or those who had received systemic or local antibiotic treatment for the urinary tract during the previous 7 days

Index tests	Index test: QuickVue Chlamydia RT Specimen: endocervical
Target condition and reference standard(s)	Reference standard: PCR with the COBAS AMPLICOR CT/NG system (Roche) Specimen: endocervical The prevalence for <i>C trachomatis</i> was: 9.7%
Flow and timing	Time interval between index test and reference standard: at the same time
Comparative	
Notes	Source of funding: work supported by Colciencias Grant 621/2009, Universidad Nacional de Colombia Bogotá Research Division; the Bogotá District Secretariat of Health and the Global Network for Perinatal & Reproductive Health, FUNDARED-MATERNA, Bogotá, Colombia.

Methodological quality

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
		Low	High
DOMAIN 2: Index Test All tests			
Were the index test results interpreted without knowledge of the results of the reference standard?	Yes		
		Low	Unclear
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Yes		
		Low	Low
DOMAIN 4: Flow and Timing			

Núñez-Forero 2016 QuickVue (Continued)

Was there an appropriate interval between index test and reference standard?	Yes
Did all patients receive the same reference standard?	Yes
Were all patients included in the analysis?	Yes
Did patients receive the reference standard irrespective of the index test results?	Yes
Were withdrawals from the study explained?	Yes
Were uninterpretable/intermediate test results reported?	Yes
Low	

Pate 1998
Study characteristics

Patient sampling	Study design: prospective cross-sectional; consecutive enrolment Recruitment period: 2 November-30 December 1994 Country: USA Clinical setting: urban STD Clinic in Birmingham, Alabama Sample size: 306
Patient characteristics and setting	Population: 56% acknowledged symptoms including genital discharge, dysuria, or abdominal pain Age: median age 27 years Sex: women Inclusion criteria: not mentioned Exclusion criteria: not mentioned
Index tests	Index test: Biostar Chlamydia (Biostar, Inc., Boulder, CO) Specimen: endocervical
Target condition and reference standard(s)	Reference standard: Roche Amplicor (Roche, Branchburg, NJ) Specimen: endocervical The prevalence for <i>C trachomatis</i> was: 16%
Flow and timing	Time interval between index test and reference standard: at the same time
Comparative	Source of funding: Not mentioned
Notes	Source of funding: not mentioned
Methodological quality	

Pate 1998 (Continued)

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
		Low	High
DOMAIN 2: Index Test All tests			
Were the index test results interpreted without knowledge of the results of the reference standard?	Yes		
		Low	Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Unclear		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Yes		
		Low	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Yes		
Did patients receive the reference standard irrespective of the index test results?	Yes		
Were withdrawals from the study explained?	Unclear		
Were uninterpretable/intermediate test results reported?	Unclear		
		Unclear	

Rani 2002

Study characteristics			
Patient sampling	Study design: prospective; consecutive enrolment Recruitment period: not mentioned		

Rani 2002 (Continued)

	Country: UK Clinical setting: genitourinary medicine clinic (Bolton Centre for Sexual Health) and the gynaecology department at Royal Bolton Hospital Sample size: 200		
Patient characteristics and setting	Population: not mentioned Age: median age of participants not provided Sex: women Inclusion criteria: not mentioned Exclusion criteria: not mentioned		
Index tests	Index test: QuickVue chlamydia test (Quidel Corp., San Diego, USA) Specimen: endocervical		
Target condition and reference standard(s)	Reference standard: PCR (Roche COBAS Amplicor, Roche Diagnostics Inc.) Specimen: endocervical The prevalence for <i>C trachomatis</i> was: 10%		
Flow and timing	Time interval between index test and reference standard: at the same time		
Comparative	Source of funding: BioStat Ltd, Stockport, Cheshire provided QuickVue kits.		
Notes	Source of funding: BioStat Ltd, Stockport, Cheshire provided QuickVue kits		
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
		Low	Unclear
DOMAIN 2: Index Test All tests			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
		Unclear	Unclear
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Unclear		

Rani 2002 (Continued)

Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear	
		Unclear
		Unclear
DOMAIN 4: Flow and Timing		
Was there an appropriate interval between index test and reference standard?	Yes	
Did all patients receive the same reference standard?	Yes	
Were all patients included in the analysis?	Yes	
Did patients receive the reference standard irrespective of the index test results ?	Yes	
Were withdrawals from the study explained?	Unclear	
Were uninterpretable/intermediate test results reported?	Unclear	
		Unclear

Sabido 2009

Study characteristics	
Patient sampling	Study design: prospective; consecutive enrolment Recruitment period: April-August 2007 Country: Guatemala Clinical setting: 3 STI clinics located in the province of Escuintla, Guatemala Sample size: 278
Patient characteristics and setting	Population: all participants were asymptomatic Age: not mentioned Sex: women Inclusion criteria: ≥ 18 years of age, willing to participate, and not currently menstruating Exclusion criteria: antibiotics within the previous 3 weeks
Index tests	Index test: Chlamydia Test Card (Ultimed Products, GmbH, Germany) Specimen: cervical
Target condition and reference standard(s)	Reference standard: Amplicor CT/NG test (Roche Molecular Systems, Inc., Branchburg, NJ) Specimen: cervical The prevalence for <i>C trachomatis</i> was: 9.7%
Flow and timing	Time interval between index test and reference standard: at the same time

Sabido 2009 (Continued)

Comparative

Source of funding: The National AIDS Programme in Guatemala and the CEEISCAT. The authors have no interest in the manufacturer of the rapid *C. trachomatis* test.

Notes

Source of funding: the National AIDS Programme in Guatemala and the CEEISCAT.

Methodological quality

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	No		
		Low	Low
DOMAIN 2: Index Test All tests			
Were the index test results interpreted without knowledge of the results of the reference standard?	Yes		
		Low	Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Yes		
		Low	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Yes		
Did patients receive the reference standard irrespective of the index test results ?	Yes		
Were withdrawals from the study explained?	Yes		
Were uninterpretable/intermediate test results reported?	Yes		
		Low	

Saison 2007 Clearview

Study characteristics

Patient sampling	Study design: prospective cross-sectional; consecutive enrolment Recruitment period: August 2002-March 2006 Country: Philippines Clinical setting: Iloilo City, Philippines at Social hygiene clinic Sample size: 1155
Patient characteristics and setting	Population: female sex workers attending the SHC in Iloilo City for routine STI screening for gonorrhea, syphilis, and nongonococcal urethritis. Most of the study participants were asymptomatic at the time of specimen collection, with only 28% reporting genitourinary symptoms. Age: median age 28 years Sex: women Inclusion criteria: female, ≥ 18 years of age, willing to participate, literate, and not currently menstruating and had not taken antibiotics within the previous month Exclusion criteria: not provided
Index tests	Index test: Clearview (Chlamydia MF; Inverness Medical, Bedford, United Kingdom) Specimen: endocervical
Target condition and reference standard(s)	Reference standard: Amplicor CT/NG PCR (Roche Diagnostic Systems, Branchburg, NJ) Specimen: performed with vaginal or endocervical swab specimens The prevalence for <i>C trachomatis</i> was: 9%
Flow and timing	Time interval between index test and reference standard: at the same time
Comparative	Source of funding: This work was supported by a grant (049366/Z/96/Z) from The Wellcome Trust, United Kingdom.
Notes	Source of funding: this work was supported by a grant (049366/Z/96/Z) from The Wellcome Trust, UK.

Methodological quality

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
		Low	High
DOMAIN 2: Index Test All tests			

Saison 2007 Clearview (Continued)

Were the index test results interpreted without knowledge of the results of the reference standard?	Yes	
		Low
DOMAIN 3: Reference Standard		
Is the reference standards likely to correctly classify the target condition?	Yes	
Were the reference standard results interpreted without knowledge of the results of the index tests?	Yes	
		Low
DOMAIN 4: Flow and Timing		
Was there an appropriate interval between index test and reference standard?	Yes	
Did all patients receive the same reference standard?	Yes	
Were all patients included in the analysis?	Yes	
Did patients receive the reference standard irrespective of the index test results ?	Yes	
Were withdrawals from the study explained?	Yes	
Were uninterpretable/intermediate test results reported?	Yes	
		Low

Saison 2007 CRT

Study characteristics		
Patient sampling	Study design: prospective cross-sectional; consecutive enrolment Recruitment period: August 2002-March 2006 Country: Philippines Clinical setting: Iloilo City, Philippines at Social hygiene clinic Sample size: 1155	
Patient characteristics and setting	Population: female sex workers attending the SHC in Iloilo City for routine STI screening for gonorrhea, syphilis, and nongonococcal urethritis. Most of the study participants were asymptomatic at the time of specimen collection, with only 28% reporting genitourinary symptoms. Age: median age 28 years Sex: women	

Saison 2007 CRT (Continued)

Inclusion criteria: female, ≥ 18 years of age, willing to participate, literate, and not currently menstruating and had not taken antibiotics within the previous month

Exclusion criteria: not provided

Index tests	<p>Index test: Chlamydia Rapid Test</p> <p>Specimen: vaginal</p>
Target condition and reference standard(s)	<p>Reference standard: AmpliCor CT/NG PCR (Roche Diagnostic Systems, Branchburg, NJ)</p> <p>Specimen: performed with vaginal or endocervical swab specimens</p> <p>The prevalence for <i>C trachomatis</i> was: 9%</p>
Flow and timing	<p>Time interval between index test and reference standard: at the same time</p>
Comparative	
Notes	<p>Source of funding: this work was supported by a grant (049366/Z/96/Z) from The Wellcome Trust, UK.</p>

Methodological quality

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
		Low	High
DOMAIN 2: Index Test All tests			
Were the index test results interpreted without knowledge of the results of the reference standard?	Yes		
		Low	Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Yes		
		Low	Low
DOMAIN 4: Flow and Timing			

Saison 2007 CRT (Continued)

Was there an appropriate interval between index test and reference standard?	Yes
Did all patients receive the same reference standard?	Yes
Were all patients included in the analysis?	Yes
Did patients receive the reference standard irrespective of the index test results?	Yes
Were withdrawals from the study explained?	Yes
Were uninterpretable/intermediate test results reported?	Yes
Low	

Swain 2004
Study characteristics

Patient sampling	Study design: prospective cross-sectional; consecutive enrolment Recruitment period: not mentioned Country: USA Clinical setting: Milwaukee Health Department (MHD) Sexually Transmitted Disease Clinic Sample size: 1384
Patient characteristics and setting	Population: not provided Age: age of participants (range) 1-35 years Sex: women Inclusion criteria: consecutive female clients Exclusion criteria: presenting to the clinic for reasons other than an initial STD evaluation
Index tests	Index test: rapid optical immunoassay (Thermo Electron, Point of Care and Rapid Diagnostics, Louisville, CO) Specimen: cervical
Target condition and reference standard(s)	Reference standard: PCR (Microwell assay, Roche, Branchburg, NJ) Specimen: cervical The prevalence for <i>C trachomatis</i> was: 10.3%
Flow and timing	Time interval between index test and reference standard: at the same time
Comparative	Source of funding: Thermo Electron Corporation for providing OIA® test kits.
Notes	Source of funding: Thermo Electron Corporation for providing test kits

Methodological quality

Swain 2004 (Continued)

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
		Low	Unclear
DOMAIN 2: Index Test All tests			
Were the index test results interpreted without knowledge of the results of the reference standard?	Yes		
		Low	Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Yes		
		Low	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Yes		
Did patients receive the reference standard irrespective of the index test results ?	Yes		
Were withdrawals from the study explained?	Yes		
Were uninterpretable/intermediate test results reported?	Yes		
		Low	

Van der Helm 2012

Study characteristics			
Patient sampling	Study design: prospective cross-sectional; consecutive enrolment Recruitment period: July 2009-February 2010		

Van der Helm 2012 (Continued)

Country: Suriname

Clinical setting: multicenter, 2 sites: The Dermatological Service, an integrated outpatient clinic and The Lobi Foundation is a center for birth control and sexual health

Sample size: 912

Patient characteristics and setting	Population: symptomatic and asymptomatic population. Sex for money 2.3% of included women Age: median age of participants (range) from 27-30 years Sex: women Inclusion criteria: not mentioned Exclusion criteria: use of antibiotics in the past 7 days, age < 18 years and previous participation
Index tests	Index test: Chlamydia Rapid Test Specimen: vaginal
Target condition and reference standard(s)	Reference standard: Aptima, Gen-Probe, San Diego, USA Specimen: vaginal The prevalence for <i>C trachomatis</i> was: 11.1%
Flow and timing	Time interval between index test and reference standard: at the same time
Comparative	Source of funding: This work was supported by the Research and Development fund of the Municipal Health Service of Amsterdam [project no 2369 and 2371] and AGIS healthcare insurance [RVVZ no 1417000].
Notes	Source of funding: this work was supported by the Research and Development fund of the Municipal Health Service of Amsterdam (project no 2369 and 2371) and AGIS healthcare insurance (RVVZ no 1417000).

Methodological quality

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
		Low	Low
DOMAIN 2: Index Test All tests			
Were the index test results interpreted without knowledge of the results of the reference standard?	Yes		
		Low	Low
DOMAIN 3: Reference Standard			

Van der Helm 2012 (Continued)

Is the reference standards likely to correctly classify the target condition?	Yes
Were the reference standard results interpreted without knowledge of the results of the index tests?	Yes
Low	
Low	
DOMAIN 4: Flow and Timing	
Was there an appropriate interval between index test and reference standard?	Yes
Did all patients receive the same reference standard?	Yes
Were all patients included in the analysis?	Yes
Did patients receive the reference standard irrespective of the index test results?	Yes
Were withdrawals from the study explained?	Yes
Were uninterpretable/intermediate test results reported?	Yes
Low	

Van Dommelen 2010 Biorapid

Study characteristics	
Patient sampling	Study design: prospective cross-sectional; consecutive enrolment Recruitment period: September 2007-April 2008 Country: The Netherlands Clinical setting: Maastricht University Medical Centre Sample size: 772
Patient characteristics and setting	Population: not mentioned Age: median age 23 years Sex: women Inclusion criteria: women aged > 16 years applying for STI consultation Exclusion criteria: not mentioned
Index tests	Index test: 3 POC tests were validated: the Handilab-C (Zonda, Dallas, USA) enzymatic test Biorapid CHLAMYDIA Ag test (Biokit, SA, Barcelona, Spain) and QuickVue Chlamydia test (Quidel Corporation, San Diego, USA) Specimen: vaginal

Van Dommelen 2010 Biorapid (Continued)

Target condition and reference standard(s)	Reference standard: COBAS Amplicor CT/NG (Roche Diagnostics Systems, Basel, Switzerland) Specimen: vaginal The prevalence for <i>C trachomatis</i> was: 11%		
Flow and timing	Time interval between index test and reference standard: at the same time		
Comparative	Source of funding: Rapid tests were provided by the distributors.		
Notes	Source of funding: rapid tests were provided by the distributors.		
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
		Low	Unclear
DOMAIN 2: Index Test All tests			
Were the index test results interpreted without knowledge of the results of the reference standard?	Yes		
		Low	Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Yes		
		Low	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Yes		
Did patients receive the reference standard irrespective of the index test results ?	Yes		

Van Dommelen 2010 Biorapid (Continued)

Were withdrawals from the study explained?	Unclear
Were uninterpretable/intermediate test results reported?	Unclear
Unclear	

Van Dommelen 2010 Handilab-C

Study characteristics			
Patient sampling	Study design: prospective cross-sectional; consecutive enrolment Recruitment period: September 2007-April 2008 Country: The Netherlands Clinical setting: Maastricht University Medical Centre Sample size: 772		
Patient characteristics and setting	Population: not mentioned Age: median age 23 years Sex: women Inclusion criteria: women aged > 16 years applying for STI consulta- tion Exclusion criteria: not mentioned		
Index tests	Index test: 3 POC tests were validated: the Handilab-C (Zonda, Dal- las, USA) enzymatic test Biorapid CHLAMYDIA Ag test (Biokit, S.A., Barcelona, Spain) and QuickVue Chlamydia test (Quidel Corporation, San Diego, USA) Specimen: vaginal		
Target condition and reference standard(s)	Reference standard: COBAS Amplicor CT/NG (Roche Diagnostics Systems, Basel, Switzerland) Specimen: vaginal The prevalence for <i>C trachomatis</i> was: 11%		
Flow and timing	Time interval between index test and reference standard: at the same time		
Comparative			
Notes	Source of funding: rapid tests were provided by the distributors.		
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability con- cerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		

Van Dommelen 2010 Handilab-C (Continued)

Did the study avoid inappropriate exclusions?	Yes		
		Low	Unclear
DOMAIN 2: Index Test All tests			
Were the index test results interpreted without knowledge of the results of the reference standard?	Yes		
		Low	Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Yes		
		Low	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Yes		
Did patients receive the reference standard irrespective of the index test results ?	Yes		
Were withdrawals from the study explained?	Unclear		
Were uninterpretable/intermediate test results reported?	Unclear		
		Unclear	

Van Dommelen 2010 QuickVue

Study characteristics	
Patient sampling	Study design: prospective cross-sectional; consecutive enrolment Recruitment period: September 2007-April 2008 Country: The Netherlands Clinical setting: Maastricht University Medical Centre Sample size: 772
Patient characteristics and setting	Population: not mentioned Age: median age 23 years Sex: women Inclusion criteria: women aged > 16 years applying for STI consultation

Van Dommelen 2010 QuickVue (Continued)

Exclusion criteria: not mentioned

Index tests	Index test: 3 POC tests were validated: the Handilab-C (Zonda, Dallas, USA) enzymatic test Biorapid CHLAMYDIA Ag test (Biokit, S.A., Barcelona, Spain) and QuickVue Chlamydia test (Quidel Corporation, San Diego, USA) Specimen: vaginal
Target condition and reference standard(s)	Reference standard: COBAS Amplicor CT/NG (Roche Diagnostics Systems, Basel, Switzerland) Specimen: vaginal The prevalence for <i>C trachomatis</i> was: 11%
Flow and timing	Time interval between index test and reference standard: at the same time
Comparative	
Notes	Source of funding: Rapid tests were provided by the distributors.

Methodological quality

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
		Low	Unclear
DOMAIN 2: Index Test All tests			
Were the index test results interpreted without knowledge of the results of the reference standard?	Yes		
		Low	Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Yes		
		Low	Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		

Van Dommelen 2010 QuickVue (Continued)

Did all patients receive the same reference standard?	Yes
Were all patients included in the analysis?	Yes
Did patients receive the reference standard irrespective of the index test results?	Yes
Were withdrawals from the study explained?	Unclear
Were uninterpretable/intermediate test results reported?	Unclear
Unclear	

Widjaja 1999
Study characteristics

Patient sampling	Study design: prospective cross-sectional; consecutive enrolment Recruitment period: May-October 1996 Country: Indonesia Clinical setting: multicenter. No additional information provided. Sample size: 415
Patient characteristics and setting	Population: not mentioned Age: median age 32 years Sex: women Inclusion criteria: not mentioned Exclusion criteria: not provided
Index tests	Index test: Chlamydia OIA device (BioStar) Specimen: endocervical
Target condition and reference standard(s)	Reference standard: LCx <i>Chlamydia trachomatis</i> assay; Abbott Laboratories, Chicago, Ill Specimen: endocervical The prevalence for <i>C trachomatis</i> was: 9.2%
Flow and timing	Time interval between index test and reference standard: at the same time
Comparative	Source of funding: Supported by grants from the MotherCare Project, John Snow, Inc., and the Office of Health, Bureau of Global Programs, Field Support and Research, and the United States Agency for International Development.
Notes	Source of funding: supported by grants from the MotherCare Project, John Snow, Inc., and the Office of Health, Bureau of Global Programs, Field Support and Research, and the United States Agency for International Development

Methodological quality

Item	Authors' judgement	Risk of bias	Applicability concerns
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Widjaja 1999 (Continued)

DOMAIN 1: Patient Selection

Was a consecutive or random sample of patients enrolled?	Yes	
Was a case-control design avoided?	Yes	
Did the study avoid inappropriate exclusions?	Yes	
	Low	Unclear

DOMAIN 2: Index Test All tests

Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear	
	Unclear	Unclear

DOMAIN 3: Reference Standard

Is the reference standards likely to correctly classify the target condition?	Yes	
Were the reference standard results interpreted without knowledge of the results of the index tests?	Yes	
	Low	Low

DOMAIN 4: Flow and Timing

Was there an appropriate interval between index test and reference standard?	Yes	
Did all patients receive the same reference standard?	Yes	
Were all patients included in the analysis?	Yes	
Did patients receive the reference standard irrespective of the index test results ?	Yes	
Were withdrawals from the study explained?	Unclear	
Were uninterpretable/intermediate test results reported?	Unclear	
	Unclear	

Yin 2006
Study characteristics

Patient sampling	Study design: prospective cross-sectional; consecutive enrolment Recruitment period: not provided Country: China
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Yin 2006 (Continued)

Clinical setting: multicenter, 6 sites (Chengdu, Fuzhou, Nanjing, Shanghai, Guangzhou and Shenzhen) STD clinics, female re-education centers and sex entertainment venues

Sample size: 1497

Patient characteristics and setting	Population: 61.5% acknowledged symptoms including genital discharge Age: median age 28 years Sex: women Inclusion criteria: not mentioned Exclusion criteria: women who had used antibiotics in the previous 3 weeks were excluded		
Index tests	Index test: Clearview Chlamydia MF (Clearview, Unipath Ltd, Bedford, UK) Specimen: cervical		
Target condition and reference standard(s)	Reference standard: AmpliCor PCR assay (Roche, Branchburg, New Jersey, USA) Specimen: cervical The prevalence for <i>C trachomatis</i> was: 13.1%		
Flow and timing	Time interval between index test and reference standard: at the same time		
Comparative	Source of funding: Not mentioned.		
Notes	Source of funding: not mentioned		
Methodological quality			
Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
		Low	High
DOMAIN 2: Index Test All tests			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
		Unclear	Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		

Yin 2006 (Continued)

Were the reference standard results interpreted without knowledge of the results of the index tests? Yes

Low
Low
DOMAIN 4: Flow and Timing

Was there an appropriate interval between index test and reference standard? Yes

Did all patients receive the same reference standard? Yes

Were all patients included in the analysis? Yes

Did patients receive the reference standard irrespective of the index test results? Yes

Were withdrawals from the study explained? Yes

Were uninterpretable/intermediate test results reported? Yes

Low

CRT: Chlamydia Rapid Test; *C trachomatis*: *Chlamydia trachomatis*; **EIA:** enzyme immunoassay; **OIA:** optical immunoassay; **PCR:** polymerase chain reaction; **STD:** sexually transmitted disease; **STI:** sexually transmitted infection

DATA

Presented below are all the data for all of the tests entered into the review.

Table Tests. Data tables by test

Test	No. of studies	No. of participants
1 Assessment of diagnostic test accuracy: Overview	25	13676
2 Endocervical specimen	11	6687
3 Other specimen type	9	6990
4 Setting: Low/middle-income countries	8	4917
5 Setting: High-income countries	11	8759
6 Symptomatic participants	3	1384
7 Asymptomatic participants	3	637
8 Mixed participants	19	11655

Test 1. Assessment of diagnostic test accuracy: Overview.

Test 2. Endocervical specimen.

Test 3. Other specimen type.

Test 4. Setting: Low/middle-income countries.

Test 5. Setting: High-income countries.

Test 6. Symptomatic participants.

Test 7. Asymptomatic participants.

Test 8. Mixed participants.

ADDITIONAL TABLES

Table 1. Accuracy by point-of-care test brand

Point-of-care test brand	Number participants (studies)	Mean prevalence (range)	Sensitivity	Specificity
Chlamydia Rapid Test	4142 (6)	15% (range 8% to 31%)	0.64 (95% CI 0.47 to 0.78)	0.97 (95% CI 0.95 to 0.98)
Rapid Optical Immunoassay	2366 (4)	15% (range 9% to 28%)	0.54 (95% CI 0.42 to 0.66)	0.98 (95% CI 0.98 to 0.99)
Acon	927 (2)	10% (range 9% to 12%)	Range from 0.23 to 1.00	Range from 0.91 to 0.94
Clearview	2384 (3)	15% (range 13% to 19%)	Range from 0.50 to 0.53	Range from 0.98 to 1.00
QuickVue	1627	9%	Range from 0.25 to 0.55	Range from 0.99 to 1.00

Table 1. Accuracy by point-of-care test brand (Continued)
(3) (range 7% to 11%)

Handilab-C	866	17%	Range from 0.19 to 0.22	Range from 0.88 to 0.89
	(2)	(range 11% to 23%)		
Biorapid	763	11%	0.17	0.94
	(1)		(95% CI 0.09 to 0.26)	(95% CI 0.91 to 0.95)
BioVei	76	17%	0.54	0.51
	(1)		(95% CI 0.25 to 0.81)	(95% CI 0.38 to 0.64)
Chlamydia Test Card	276	9%	0.62	1.00
	(1)		(95% CI 0.42 to 0.81)	(95% CI 0.98 to 1.00)

Table 2. Heterogeneity sources

Heterogeneity source	Subgroup	Sensitivity	Specificity	P value for subgroup difference
Specimen	Endocervical	0.48 (95% CI 0.41 to 0.56)	0.99 (95% CI 0.97 to 0.99)	P = 0.27
	Urine or vaginal	0.49 (95% CI 0.32 to 0.67)	0.97 (95% CI 0.94 to 0.98)	
Study setting	Low/middle-income countries	0.42 (95% CI 0.32 to 0.53)	0.98 (95% CI 0.97 to 0.99)	P = 0.28
	High-income countries	0.54 (95% CI 0.40 to 0.68)	0.98 (95% CI 0.95 to 0.99)	

APPENDICES

Appendix 1. CENTRAL search strategy

1. ('point of care' adj5 test\$).tw.
2. (bedside adj5 test\$).tw.
3. ('point of care' adj5 device\$).tw.
4. ('point of care' adj5 diagnos\$).tw.
5. ('point of care' adj5 laborator\$).tw.
6. poc.tw.
7. poct.tw.
8. (rapid adj5 test\$).tw.
9. (self adj5 test\$).tw.
10. (self adj5 collect\$).tw.

- 11.(self adj5 swab\$).tw.
- 12.clearview.tw.
- 13.(chlamydia adj5 test).tw.
- 14.surescreen.tw.
- 15.quickvue.tw.
- 16.'magic lite'.tw.
- 17.surecell.tw.
- 18.or/1-17
- 19.exp Chlamydia Infections/
- 20.(chlamydia\$ adj5 infection\$).tw.
- 21.19 or 20
- 22.exp Chlamydia trachomatis/
- 23.chlamydia\$.tw.
- 24.22 or 23
- 25.exp Reproductive Tract Infections/
- 26.(genital adj5 infection\$).tw.
- 27.(reproductive adj5 infection\$).tw.
- 28.(urogenital adj5 infection\$).tw.
- 29.or/25-28
- 30.24 and 29
- 31.21 or 30
- 32.18 and 31

Appendix 2. MEDLINE search strategy

1. ('point of care' adj5 test\$).tw.
2. (bedside adj5 test\$).tw.
3. ('point of care' adj5 device\$).tw.
4. ('point of care' adj5 diagnos\$).tw.
5. ('point of care' adj5 laborator\$).tw.
6. poc.tw.
7. poct.tw.
8. (rapid adj5 test\$).tw.
9. (self adj5 test\$).tw.
- 10.(self adj5 collect\$).tw.
- 11.(self adj5 swab\$).tw.
- 12.clearview.tw.
- 13.(chlamydia adj5 test).tw.
- 14.surescreen.tw.
- 15.quickvue.tw.
- 16.'magic lite'.tw.
- 17.surecell.tw.
- 18.or/1-17
- 19.exp Chlamydia Infections/
- 20.(chlamydia\$ adj5 infection\$).tw.
- 21.19 or 20
- 22.exp Chlamydia trachomatis/
- 23.chlamydia\$.tw.
- 24.22 or 23
- 25.exp Reproductive Tract Infections/
- 26.(genital adj5 infection\$).tw.
- 27.(reproductive adj5 infection\$).tw.
- 28.(urogenital adj5 infection\$).tw.

29.or/25-28

30.24 and 29

31.21 or 30

32.18 and 31

Appendix 3. Embase search strategy

1. 'chlamydia rapid test'/exp
2. 'point of care testing'/exp
3. 'point of care':ab,ti AND test*:ab,ti
4. (bedside NEAR/5 test*):ab,ti
5. 'point of care':ab,ti AND device*:ab,ti
6. 'point of care':ab,ti AND diagnos*:ab,ti
7. 'point of care':ab,ti AND laborator*:ab,ti
8. poc:ab,ti
9. poct:ab,ti
- 10.(rapid NEAR/5 test*):ab,ti
- 11.(self NEAR/5 test*):ab,ti
- 12.(self NEAR/5 collect*):ab,ti
- 13.(self NEAR/5 swab*):ab,ti
- 14.clearview:ab,ti
- 15.(chlamydia NEAR/5 test):ab,ti
- 16.surescreen:ab,ti
- 17.quickvue:ab,ti
- 18.'magic lite':ab,ti
- 19.surecell:ab,ti
- 20.OR/1-19
- 21.'chlamydiasis'/exp
- 22.(chlamydia* NEAR/5 infection*):ab,ti
- 23.OR/21-22
- 24.'chlamydia trachomatis'/exp
- 25.chlamydia*:ab,ti
- 26.OR/24-25
- 27.'genital tract infection'/exp
- 28.'urogenital tract infection'/exp
- 29.(genital NEAR/5 infection*):ab,ti
- 30.(reproductive NEAR/5 infection*):ab,ti
- 31.(urogenital NEAR/5 infection*):ab,ti
- 32.OR/27-31
- 33.26 AND 32
- 34.23 OR 33
- 35.20 AND 34
- 36.35 AND [embase]/lim

Appendix 4. DARE search strategy

(test OR point of care) AND chlamydia

Appendix 5. LILACS search strategy

(mh:(chlamydia trachomatis)) OR (mh:(chlamydia infections)) OR (ab:(chlamydia*)) OR (ti:(chlamydia*)) AND (ab:(point of care)) OR (ti:(point of care)) OR (ab:(test*)) OR (ti:(test*)) AND (instance:"regional") AND (db:("LILACS") AND clinical_aspect:("diagnosis"))

Appendix 6. Web of Science search strategy

(TS=("point of care") OR TS=(test*)) AND TS=(chlamydia*) AND TI=(trial)

Appendix 7. International Clinical Trials Registry Platform search strategy

(point of care AND chlamydia*) OR (test* AND chlamydia*)

Appendix 8. Health Services Research Projects in Progress (HSRProj) search strategy

("point of care") AND (chlamydia*)

Appendix 9. Search strategies update (2018 - STI Group)

Search electronic report #1	
Search type	Update
Databases	<ul style="list-style-type: none"> MEDLINE MEDLINE In-Process & Other Non-Indexed Citations MEDLINE Daily Update
Platform	Ovid
Search date	18 April 2015
Update date	02 August 2018
Range of search date	2015-2018
Language restrictions	None
Other limits	None
Search strategy (results)	<p>1 ('point of care' adj5 test\$).tw. (4969)</p> <p>2 (bedside adj5 test\$).tw. (1628)</p> <p>3 ('point of care' adj5 device\$).tw. (1364)</p> <p>4 ('point of care' adj5 diagnos\$).tw. (2694)</p> <p>5 ('point of care' adj5 laborator\$).tw. (607)</p> <p>6 poc.tw. (3207)</p> <p>7 poct.tw. (1117)</p> <p>8 (rapid adj5 test\$).tw. (23240)</p> <p>9 (self adj5 test\$).tw. (11905)</p> <p>10 (self adj5 collect\$).tw. (8594)</p> <p>11 (self adj5 swab\$).tw. (488)</p> <p>12 clearview.tw. (102)</p> <p>13 (chlamydia adj5 test).tw. (744)</p> <p>14 surescreen.tw. (1)</p> <p>15 quickvue.tw. (108)</p> <p>16 'magic lite'.tw. (55)</p>

(Continued)

17 surecell.tw. (22)

18 or/1-17 (54367)

19 exp Chlamydia Infections/ (19971)

20 (chlamydia\$ adj5 infection\$).tw. (10542)

21 19 or 20 (23215)

22 exp Chlamydia trachomatis/ (11382)

23 chlamydia\$.tw. (25913)

24 22 or 23 (26858)

25 exp Reproductive Tract Infections/ (417)

26 (genital adj5 infection\$).tw. (8008)

27 (reproductive adj5 infection\$).tw. (1881)

28 (urogenital adj5 infection\$).tw. (1554)

29 or/25-28 (11349)

30 24 and 29 (3017)

31 21 or 30 (23595)

32 18 and 31 (1022)

33 limit 32 to yr="2015 -Current" (164)

# of records identified	164
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# of records without duplicates	160
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Search electronic report #2

Search type	Update
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Database	Embase
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Platform	Embase.com
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Search date	18 April 2015
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Update date	02 August 2018
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Range of search date	2015-2018
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Language restrictions	None
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Other limits	None
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Search strategy (results)	1. 'chlamydia rapid test'/exp (39)
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(Continued)

2. 'point of care testing'/exp (10173)
3. 'point of care':ab,ti AND test*:ab,ti (11368)
4. (bedside NEAR/5 test*):ab,ti (2370)
5. 'point of care':ab,ti AND device*:ab,ti (4156)
6. 'point of care':ab,ti AND diagnos*:ab,ti (8743)
7. 'point of care':ab,ti AND laborator*:ab,ti (4598)
8. poc:ab,ti (5022)
9. poct:ab,ti (1853)
10. (rapid NEAR/5 test*):ab,ti (31081)
11. (self NEAR/5 test*):ab,ti (15275)
12. (self NEAR/5 collect*):ab,ti (10731)
13. (self NEAR/5 swab*):ab,ti (717)
14. clearview:ab,ti (145)
15. (chlamydia NEAR/5 test):ab,ti (1001)
16. surescreen:ab,ti (5)
17. quickvue:ab,ti (133)
18. 'magic lite':ab,ti (64)
19. surecell:ab,ti (19)
20. #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 80439
21. 'chlamydiasis'/exp (21792)
22. (chlamydia* NEAR/5 infection*):ab,ti (12667)
23. #21 OR #22 (26700)
24. 'chlamydia trachomatis'/exp (17567)
25. chlamydia*:ab,ti (31822)
26. #24 OR #25 (34986)
27. 'genital tract infection'/exp (19077)
28. 'urogenital tract infection'/exp (151238)
29. (genital NEAR/5 infection*):ab,ti (10057)
30. (reproductive NEAR/5 infection*):ab,ti (2114)
31. (urogenital NEAR/5 infection*):ab,ti (2172)
32. #27 OR #28 OR #29 OR #30 OR #31 (158225)
33. #26 AND #32 (9541)
34. #23 OR #33 (29650)
35. #20 AND #34 (1452)

(Continued)

36. #20 AND #34 AND [embase]/lim AND [2015-2018]/py (312)

of records identified 312

of records without duplicates 241

Search electronic report #3

Search type Update

Database Cochrane Central Register of Controlled Trials (CENTRAL)

Platform Ovid

Search date 18 April 2015

Update date 02 August 2018

Range of search date 2015-2018

Language restrictions None

Other limits None

Search strategy (results)

- 1 ('point of care' adj5 test\$).tw. (428)
- 2 (bedside adj5 test\$).tw. (143)
- 3 ('point of care' adj5 device\$).tw. (102)
- 4 ('point of care' adj5 diagnos\$).tw. (143)
- 5 ('point of care' adj5 laborator\$).tw. (64)
- 6 poc.tw. (287)
- 7 poct.tw. (70)
- 8 (rapid adj5 test\$).tw. (1774)
- 9 (self adj5 test\$).tw. (2821)
- 10 (self adj5 collect\$).tw. (1288)
- 11 (self adj5 swab\$).tw. (100)
- 12 clearview.tw. (9)
- 13 (chlamydia adj5 test).tw. (58)
- 14 surescreen.tw. (0)
- 15 quickvue.tw. (5)
- 16 'magic lite'.tw. (1)
- 17 surecell.tw. (1)

(Continued)

18 or/1-17 (6603)

19 exp Chlamydia Infections/ (593)

20 (chlamydia\$ adj5 infection\$).tw. (564)

21 19 or 20 (911)

22 exp Chlamydia trachomatis/ (289)

23 chlamydia\$.tw. (1268)

24 22 or 23 (1298)

25 exp Reproductive Tract Infections/ (22)

26 (genital adj5 infection\$).tw. (691)

27 (reproductive adj5 infection\$).tw. (65)

28 (urogenital adj5 infection\$).tw. (86)

29 or/25-28 (842)

30 24 and 29 (130)

31 21 or 30 (926)

32 18 and 31 (87)

33 limit 32 to yr="2015 -Current" (27)

# of records identified	27
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# of records without duplicates	9
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Search electronic report #4

Search type	Update
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Database	LILACS http://lilacs.bvsalud.org/es/
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Platform	Biblioteca Virtual en Salud (BVS), interfaz iAHx
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Search date	18 April 2015
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Update date	02 August 2018
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Range of search date	2015-2018
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Language restrictions	None
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Other limits	None
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(Continued)

Search strategy (mh:(chlamydia trachomatis)) OR (mh:(chlamydia infections)) OR (ti:(chlamydia*)) OR (ab:(chlamydia*)) AND (ti:(point of care)) OR (ab:(point of care)) OR (ti:(test*)) OR (ab:(test*)) AND (instance:"regional") AND (db:("LILACS")) AND clinical_aspect:("diagnosis") AND year_cluster:("2016" OR "2015" OR "2017" OR "2018"))

of records identified 12

of records without duplicates 12

Search electronic report #5

Search type	Update
Database	Web of Science webofscience.com/
Platform	Thomson Reuters
Search date	18 April 2015
Update date	02 August 2018
Range of search date	2015-2018
Language restrictions	None
Other limits	None
Search strategy	(TS=("point of care") OR TS=(test*)) AND TS=(chlamydia*) AND TI=(trial)
# of records identified	53
# of records without duplicates	40

Search electronic report #6

Search type	Update
Database	International Clinical Trials Registry Platform www.who.int/ictpr/
Platform	ICTRP Portal
Search date	18 April 2015
Update date	02 August 2018

(Continued)

Range of search date	2015-2018
Language restrictions	None
Other limits	None
Search strategy	(point of care AND chlamydia*) OR (test* AND chlamydia*)
# of records identified	15
# of records without duplicates	15

Appendix 10. Search strategies update (2019- STI Group)

Search electronic report #1	
Search type	Update
Databases	<ul style="list-style-type: none"> MEDLINE MEDLINE In-Process & Other Non-Indexed Citations MEDLINE Daily Update
Platform	Ovid
Search date	18 April 2015
Update date	11 November 2019
Range of search date	2018-Current
Language restrictions	None
Other limits	None
Search strategy (results)	<ol style="list-style-type: none"> ('point of care' adj5 test\$).tw. (4947) (bedside adj5 test\$).tw. (1555) ('point of care' adj5 device\$).tw. (1333) ('point of care' adj5 diagnos\$).tw. (2662) ('point of care' adj5 laborator\$).tw. (600) poc.tw. (3527) poct.tw. (1211) (rapid adj5 test\$).tw. (22741) (self adj5 test\$).tw. (11441) (self adj5 collect\$).tw. (8284) (self adj5 swab\$).tw. (494) clearview.tw. (102) (chlamydia adj5 test).tw. (735) surescreen.tw. (1) quickvue.tw. (106) 'magic lite'.tw. (55) surecell.tw. (20)

(Continued)

- 18.or/1-17 (53321)
- 19.exp Chlamydia Infections/ (20640)
- 20.(chlamydia\$ adj5 infection\$.tw. (10359)
- 21.19 or 20 (23456)
- 22.exp Chlamydia trachomatis/ (11800)
- 23.chlamydia\$.tw. (25462)
- 24.22 or 23 (26447)
- 25.exp Reproductive Tract Infections/ (478)
- 26.(genital adj5 infection\$.tw. (7797)
- 27.(reproductive adj5 infection\$.tw. (1794)
- 28.(urogenital adj5 infection\$.tw. (1533)
- 29.or/25-28 (11064)
- 30.24 and 29 (2956)
- 31.21 or 30 (23806)
- 32.18 and 31 (1076)
- 33.limit 32 to yr="2018 -Current" (91)

# of records identified	91
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# of records without duplicates	86
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Search electronic report #2

Search type	Update
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Databases	EMBASE
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Platform	embase.com
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Search date	18 April 2015
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Update date	11 November 2019
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Range of search date	2018-Current
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Language restrictions	None
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Other limits	None
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Search strategy (results)	1. 'chlamydia rapid test'/exp (45)2. 'point of care testing'/exp (12352)3. 'point of care':ab,ti AND test*:ab,ti (14032)4. (bedside NEAR/5 test*):ab,ti (2564)5. 'point of care':ab,ti AND device*:ab,ti (5160)6. 'point of care':ab,ti AND diagnos*:ab,ti (11223)7. 'point of care':ab,ti AND laborator*:ab,ti (5458)8. poc:ab,ti (6127)9. poci:ab,ti (2228)10.(rapid NEAR/5 test*):ab,ti (34459)

(Continued)

- 11.(self NEAR/5 test*):ab,ti (17409)
- 12.(self NEAR/5 collect*):ab,ti (12806)
- 13.(self NEAR/5 swab*):ab,ti (872)
- 14.clearview:ab,ti (152)
- 15.(chlamydia NEAR/5 test):ab,ti (1084)
- 16.surescreen:ab,ti (5)
- 17.quickvue:ab,ti (139)
- 18.'magic lite':ab,ti (64)
- 19.surecell:ab,ti (20)
- 20.#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 (93015)
- 21.'chlamydiasis'/exp (22967)
- 22.(chlamydia* NEAR/5 infection*):ab,ti (13311)
- 23.#21 OR #22 (28066)
- 24.'chlamydia trachomatis'/exp (18365)
- 25.chlamydia*:ab,ti (33817)
- 26.#24 OR #25 (37114)
- 27.'genital tract infection'/exp (20192)
- 28.'urogenital tract infection'/exp (163815)
- 29.(genital NEAR/5 infection*):ab,ti (10671)
- 30.(reproductive NEAR/5 infection*):ab,ti (2367)
- 31.(urogenital NEAR/5 infection*):ab,ti (2322)
- 32.#27 OR #28 OR #29 OR #30 OR #31 (171295)
- 33.#26 AND #32 (10375)
- 34.#23 OR #33 (31390)
- 35.#20 AND #34 (1630)
- 36.#20 AND #34 AND [embase]/lim AND [2015-2018]/py (206)

# of records identified	206
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# of records without duplicates	158
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Search electronic report #3

Search type	Update
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Databases	The Cochrane Central Register of Controlled Trials (CENTRAL)
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Platform	Ovid
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Search date	18 April 2015
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Update date	11 November 2019
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Range of search date	2018-Current
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Language restrictions	None
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Other limits	None
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(Continued)

Search strategy (results)

1. ('point of care' adj5 test\$).tw. (623)
2. (bedside adj5 test\$).tw. (202)
3. ('point of care' adj5 device\$).tw. (146)
4. ('point of care' adj5 diagnos\$).tw. (204)
5. ('point of care' adj5 laborator\$).tw. (88)
6. poc.tw. (466)
7. poct.tw. (116)
8. (rapid adj5 test\$).tw. (2565)
9. (self adj5 test\$).tw. (4202)
- 10.(self adj5 collect\$).tw. (1998)
- 11.(self adj5 swab\$).tw. (157)
- 12.clearview.tw. (11)
- 13.(chlamydia adj5 test).tw. (107)
- 14.surescreen.tw. (0)
- 15.quickvue.tw. (8)
- 16.'magic lite'.tw. (2)
- 17.surecell.tw. (1)
- 18.or/1-17 (9873)
- 19.exp Chlamydia Infections/ (691)
- 20.(chlamydia\$ adj5 infection\$).tw. (736)
- 21.19 or 20 (1143)
- 22.exp Chlamydia trachomatis/ (340)
- 23.chlamydia\$.tw. (1677)
- 24.22 or 23 (1711)
- 25.exp Reproductive Tract Infections/ (23)
- 26.(genital adj5 infection\$).tw. (970)
- 27.(reproductive adj5 infection\$).tw. (105)
- 28.(urogenital adj5 infection\$).tw. (142)
- 29.or/25-28 (1205)
- 30.24 and 29 (173)
- 31.21 or 30 (1165)
- 32.18 and 31 (133)
- 33.limit 32 to yr="2018 -Current" (22)

# of records identified	22
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# of records without duplicates	11
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Search electronic report #4

Search type	Update
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Databases	LILACS http://lilacs.bvsalud.org/es/
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Platform	Biblioteca Virtual en Salud (BVS), interfaz iAHx
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(Continued)

Search date	18 April 2015
Update date	11 November 2019
Range of search date	2018-Current
Language restrictions	None
Other limits	None
Search strategy (results)	tw:((mh:(chlamydia trachomatis)) OR (mh:(chlamydia infections)) OR (ti:(chlamydia*)) OR (ab:(chlamydia*)) AND (ti:(point of care)) OR (ab:(point of care)) OR (ti:(test*)) OR (ab:(test*))) AND (db:("LILACS")) AND (year_cluster:[2018 TO 2019])
# of records identified	18
# of records without duplicates	18

Search electronic report #5

Search type	Update
Databases	Web of Science https://login.webofknowledge.com/
Platform	Thomson Reuters
Search date	18 April 2015
Update date	11 November 2019
Range of search date	2018-Current
Language restrictions	None
Other limits	None
Search strategy (results)	(TS=("point of care") OR TS=(test*)) AND TS=(chlamydia*) AND TI=(trial)
# of records identified	31
# of records without duplicates	26

Appendix 11. Quality Assessment Checklist (QUADAS-2)

Domain 1: participant selection

(Continued)

A. Risk of bias	The included study describes appropriately the methods of participant selection.
Was a consecutive or random sample of participants enrolled?	<p>Yes: the study reported a consecutive or a random sample of participants enrolled.</p> <p>Unclear: the method of sampling is not reported or is unclear.</p> <p>No: the study did not implement a consecutive or a random sample method for participants enrolled.</p>
Was a case-control design avoided?	<p>Yes: the study avoid implementation of 2 separate selection processes to sample participants with the target condition and participants without the target condition.</p> <p>Unclear: the method of selection processes is not reported or is unclear.</p> <p>No: the study did not avoid implementation of 2 separate selection processes to sample participants with the target condition and participants without the target condition.</p>
Did the study avoid inappropriate exclusions?	<p>Yes: the study included all outpatients (in primary or secondary care) without previous test results.</p> <p>Unclear: prior test history of participants in the study was not reported.</p> <p>No: the study included only participants who had received a previous test.</p>
Judgment: could the selection of patients have introduced bias?	Risk of bias: low/high/unclear
B. Concerns regarding applicability	The included study describes appropriately baseline information on participants: presentation at recruitment, prior testing, intended use of index test, and setting.
Judgment: is there concern that the included participants do not match the review question in terms of severity of the target condition, demographic features, presence of differential diagnosis or comorbidity, setting of the study, and previous testing protocols?	Concern: low/high/unclear

Domain 2: index test

A. Risk of bias	The included study describes appropriately the index test and how it was conducted and interpreted.
Were the index test results interpreted without knowledge of the results of the reference standard?	<p>Yes: the index tests were interpreted in a blind manner without knowledge of the results of the reference standard, or the index test was always performed and interpreted before results of the reference standard were known.</p> <p>Unclear: it is not reported whether the index test was conducted without knowledge of the results of the index test, or whether the index test was completed before the reference standard was known.</p> <p>No: the results of the reference standard were known to the reader of the index test.</p>

(Continued)

Judgment: could the conduct or interpretation of the index test have introduced bias?	Risk of bias: low/high/unclear
B. Concerns regarding applicability	Variations in test technology, execution, or interpretation may affect estimates of its diagnostic accuracy.
Judgment: is there concern that the index test, its conduct, or its interpretation differs from the review question?	Concern: low/high/unclear

Domain 3: reference standard

A. Risk of bias	The included study describes appropriately the reference standard and how it was conducted and interpreted.
Is the reference standard likely to correctly classify the target condition?	<p>Yes: the reference standard was conducted and interpreted by trained operatives.</p> <p>Unclear: it is not clear whether those individuals who interpreted or conducted the reference standard were trained.</p> <p>No: the reference standard was not conducted or interpreted by trained operatives.</p>
Were the reference standard results interpreted without knowledge of the results of the index test?	<p>Yes: the index tests were interpreted in a blind manner without knowledge of the results of the index test, or the reference standard was always performed and interpreted before the index test results were known.</p> <p>Unclear: it is not reported whether the reference standard was conducted without knowledge of the results of the index test, or whether the reference standard was completed before the index test results were known.</p> <p>No: the results of the index test were known to the reader of the reference standard.</p>
Judgment: could the reference standard, its conduct, or its interpretation have introduced bias?	Risk of bias: low/high/unclear
B. Concerns regarding applicability	The reference standard may be free of bias, but the target condition that it defines may differ from the target condition specified in the review question.
Judgment: is there concern that the target condition as defined by the reference standard does not match the review question?	Concern: low/high/unclear

Domain 4: flow and timing

A. Risk of bias	
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(Continued)

Was there an appropriate interval between index test and reference standard?	<p>Yes: the index test and reference standard were collected on the same participants at the same time.</p> <p>Unclear: it is unclear if the index test and the reference standard were collected on the same participants at the same time.</p> <p>No: the index test and the reference standard were not collected on the same participants at the same time.</p>
Did all participants receive the reference standard?	<p>Yes: the total of the study group received confirmation of the diagnosis by the reference standard.</p> <p>Unclear: in case insufficient information is available to make a judgment.</p> <p>No: the total of the study group did not receive confirmation of the diagnosis by the reference standard.</p>
Did participants receive the reference standard irrespective of the index test results?	<p>Yes: the total of the study group received the reference standard irrespective of the index test results.</p> <p>Unclear: in case insufficient information is available to make a judgment.</p> <p>No: participants received the reference standard according to the index test results.</p>
Were withdrawals from the study explained?	<p>Yes: if it is clear what happened to all participants who entered the study, for example, if a flow diagram of study participants is reported to explain any withdrawals or exclusions, or if the numbers recruited match those in the analysis.</p> <p>Unclear: if it is unclear how many participants entered and hence whether there were any withdrawals.</p> <p>No: if it appears that some of the participants who entered the study did not complete the study, i.e. did not receive both the index test and the reference standard, and if these participants were not accounted for.</p>
Were uninterpretable/intermediate test results reported?	<p>Yes: if the number of uninterpretable test results is stated, or if the number of results reported agrees with the number of participants recruited (indicating no uninterpretable test results).</p> <p>Unclear: if it is not possible to work out whether uninterpretable results occurred.</p> <p>No: if it states that uninterpretable test results occurred or were excluded and does not report how many.</p>
Could the participant flow have introduced bias?	Risk of bias: low/high/unclear

CONTRIBUTIONS OF AUTHORS

CFG-A wrote the first draft of the systematic review and subsequent amendments. MT contributed to the writing of the first draft of the review. HG commented on and revised the first draft of the systematic review.

DECLARATIONS OF INTEREST

HGG is an author on included studies Nuñez-Forero 2016 Acon, Nuñez-Forero 2016 Acon Duo and Nuñez-Forero 2016, and did not participate in selection or data extraction for those studies.

CFG-A and MT have no conflicts of interest.

SOURCES OF SUPPORT

Internal sources

- No sources of support supplied

External sources

- Universidad Nacional de Colombia, Colombia.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

We changed 'type of technology by brand' in the analysis because all the tests implemented the same technology regardless of the brand. From the clinical perspective, it was important to determine whether brand performance was different.

We also changed subgroup analyses. This was done from type of specimen (urine, urethral or endocervical) to endocervical and other specimens (vaginal or urinary), taking into account the best way to present the information for clinical practice.

Outcomes: we did not report the outcomes below because all the included studies were diagnostic accuracy studies, which usually do not include these types of outcomes:

- proportion of participants treated after diagnosis
- proportion of sexual partners reported as treated;
- proportion of participants with any complication associated with Chlamydia trachomatis infection;
- proportion of participants lost to follow-up after diagnostic testing;
- adverse events related to rapid tests and cost-effectiveness.

INDEX TERMS

Medical Subject Headings (MeSH)

*Chlamydia trachomatis; *Point-of-Care Systems [standards]; Chlamydia Infections [*diagnosis]; False Negative Reactions; False Positive Reactions; Randomized Controlled Trials as Topic; Sensitivity and Specificity; Sexually Transmitted Diseases, Bacterial [prevention & control]

MeSH check words

Adult; Female; Humans; Male