



The Comprehensive Systematic Review of Diagnostic Accuracy of Rapid Point of Care Tests for Syphilis

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ABSTRACT

Introduction: Syphilis remains a significant global public health challenge, with congenital syphilis continuing as a leading cause of preventable stillbirth and neonatal death. Rapid point-of-care tests (POCTs) offer potential to expand screening access in resource-limited settings; however, comprehensive evidence synthesis regarding their diagnostic accuracy across diverse populations and test types is required to inform global policy.

Methods: This systematic review synthesised evidence from 159 diagnostic accuracy studies identified through comprehensive database searches. Studies evaluating treponemal-only, nontreponemal-only, or dual treponemal/nontreponemal rapid tests against accepted reference standards (TPPA, TPHA, FTA-Abs, RPR, VDRL) were included. Data extraction encompassed test characteristics, study populations, reference standards, diagnostic accuracy metrics, performance modifiers, and methodological

quality. Synthesis was structured by test category, specimen type, syphilis stage, HIV status, and testing conditions.

Results: Treponemal-only tests demonstrated consistently high specificity (94.1–100%) but variable sensitivity (59.6–100%), with Abbott Determine TP (26 studies) and SD Bioline Syphilis 3.0 (18 studies) most extensively evaluated. Dual treponemal/nontreponemal tests (Chembio DPP Syphilis Screen & Confirm, SD Bioline HIV/Syphilis Duo) showed excellent treponemal component performance (sensitivity 66.0–96.7%; specificity 97.2–99.3%), but nontreponemal component sensitivity was substantially lower (42.9–94.2%), particularly at low RPR titres. Test sensitivity was significantly enhanced in high-titre ($\geq 1:8$) active syphilis (94.6–100%) and reduced in primary syphilis (77.3–100%) and when using fingerprick whole blood versus serum/plasma. Field-based evaluations generally yielded lower accuracy estimates than laboratory studies. Performance in HIV co-infected populations varied, with some studies demonstrating maintained or enhanced sensitivity but reduced specificity.

Discussion: This review identifies critical research gaps including limited standardisation of reference standards and case definitions, insufficient reporting of blinding procedures, heterogeneous definitions of active syphilis, underrepresentation of primary syphilis cases, and few head-to-head comparisons of multiple test brands. The novelty of this synthesis lies in its comprehensive stratification of performance by test type, specimen, disease stage, and population subgroup, enabling nuanced, context-specific test selection guidance.

Conclusion: Rapid syphilis POCTs demonstrate sufficient accuracy for screening in resource-limited settings, particularly for high-titre active infections. Treponemal-only tests effectively rule out infection but cannot distinguish active from past disease. Dual tests offer improved clinical utility for identifying active syphilis requiring immediate treatment, although reduced nontreponemal component sensitivity at low titres may result in missed active infections. Test selection should be guided by local epidemiology, prevalence, available resources, and specific programmatic objectives. Rigorous training, quality assurance, and confirmatory testing algorithms remain essential implementation prerequisites.

Keywords: Syphilis; Point-of-Care Testing; Diagnostic Accuracy; Rapid Diagnostic Tests; Systematic Review; Treponemal Tests; Dual Tests; HIV Co-infection; Antenatal Screening

INTRODUCTION

Background

Syphilis, caused by the spirochaete *Treponema pallidum* subspecies *pallidum*, remains a significant global public health burden despite being a curable disease with inexpensive and effective antibiotic therapy. The World Health Organization estimates approximately 7.1 million new syphilis infections occur annually among adults aged 15–49 years, with maternal syphilis resulting in over 355,000 adverse pregnancy outcomes including stillbirth, neonatal death, prematurity, and congenital infection (Tucker et al., 2010). Congenital syphilis is largely preventable through timely antenatal screening and treatment, yet remains a leading cause of preventable perinatal mortality in low- and middle-income countries (LMICs) (Dana Brandenburger and Ambrosino, 2021).

Conventional syphilis diagnosis relies on laboratory-based serological testing employing either traditional algorithms (nontreponemal screening followed by treponemal confirmation) or reverse algorithms (treponemal screening followed by nontreponemal quantification). These approaches require equipped laboratories, trained personnel, reliable electricity, cold chain maintenance, and patient return visits for results—infrastructure frequently unavailable in resource-constrained settings where syphilis burden is highest (P. Smit et al., 2013). Consequently, substantial proportions of infected individuals remain undiagnosed and untreated, perpetuating transmission cycles and adverse outcomes.

Rapid point-of-care tests for syphilis have emerged as promising alternatives enabling single-visit screening and treatment decisions at the site of patient care. These immunochromatographic lateral flow devices detect treponemal antibodies, nontreponemal antibodies, or both simultaneously, providing results within 15–20 minutes from fingerprick whole blood without requiring laboratory infrastructure (J. Tucker et al., 2010). The World Health Organization has prequalified several such tests, and their deployment has expanded substantially

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across antenatal, HIV, and sexually transmitted infection services globally (C. Bristow, J. Klausner, and Anthony Tran, 2020).

Research Gap

Despite the proliferation of primary studies and several previous systematic reviews, significant evidence gaps persist. Prior syntheses have predominantly focused on treponemal-only tests (Y. Jafari et al., 2013; C. Bristow, J. Klausner, and Anthony Tran, 2020), examined single populations such as pregnant women (Carmen Phang Romero Casas et al., 2018), or restricted analyses to specific test types. No comprehensive review has simultaneously synthesised evidence across all three test categories (treponemal-only, nontreponemal-only, and dual tests) while systematically examining performance modifiers including specimen type, syphilis stage, HIV co-infection, RPR titre, and testing conditions. Furthermore, previous reviews have not adequately addressed the trade-offs between treponemal-only and dual testing strategies in diverse epidemiological and programmatic contexts.

Critical unanswered questions include: the magnitude of sensitivity loss when using fingerprick whole blood versus serum; the comparative accuracy of different test brands head-to-head; the performance of dual test nontreponemal components across the full spectrum of RPR titres; accuracy in key populations including men who have sex with men (MSM), female sex workers (FSWs), and people living with HIV (PLWH); and the influence of methodological quality on reported accuracy estimates.

Novelty

This systematic review provides several novel contributions to the evidence base. First, it represents the most comprehensive synthesis to date, incorporating 159 primary studies spanning three decades of research across six continents. Second, it employs a stratified analytic approach examining diagnostic accuracy by test category, specific test brand, specimen type, syphilis stage, RPR titre category, HIV status, population type, and testing environment—enabling granular,

context-specific recommendations. Third, it systematically compares treponemal-only and dual testing strategies, explicitly quantifying the trade-off between the simplicity and potentially higher sensitivity of treponemal-only tests versus the enhanced clinical utility but reduced nontreponemal component sensitivity of dual tests. Fourth, it incorporates recent evaluations of novel technologies including smartphone-based readers, multiplex platforms, and molecular POCTs. Fifth, it provides comprehensive methodological quality assessment across all included studies using standardised criteria.

Study Objectives

This systematic review aims to:

1. Synthesise the diagnostic accuracy of treponemal-only rapid POCTs for syphilis, stratified by test brand, specimen type, and population
2. Synthesise the diagnostic accuracy of dual treponemal/nontreponemal rapid POCTs, separately evaluating treponemal and nontreponemal components
3. Examine performance modifiers including syphilis stage, RPR titre, HIV co-infection, and specimen type
4. Compare accuracy estimates between laboratory-based and field-based evaluations
5. Assess methodological quality and risk of bias across included studies
6. Provide evidence-based recommendations for test selection in different epidemiological and programmatic contexts

Hypotheses

This review tests the following hypotheses:

1. Treponemal-only POCTs demonstrate high specificity but variable sensitivity influenced by specimen type and disease stage
2. Dual POCT treponemal components demonstrate comparable accuracy to treponemal-only tests
3. Dual POCT nontreponemal components demonstrate significantly lower sensitivity than treponemal components, particularly at low RPR titres
4. Test sensitivity is significantly higher in secondary syphilis and high-titre infections compared to primary syphilis and low-titre/nonreactive infections
5. Fingerprick whole blood specimens yield lower sensitivity than serum or plasma
6. Field-based evaluations report lower accuracy than laboratory-based evaluations

Research Benefits

This synthesis provides multiple stakeholders with actionable evidence. For clinicians and program managers, it offers test-specific performance data to inform procurement decisions and algorithm development. For policymakers, it clarifies the trade-offs between different testing strategies and identifies conditions under which POCTs can be optimally deployed. For researchers, it systematically identifies persistent evidence gaps requiring future investigation. For global normative bodies, it contributes comprehensive, stratified evidence to inform WHO guideline development and test prequalification processes.

METHODS

Protocol

The study strictly adhered to the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) 2020 guidelines to ensure methodological rigor and accuracy. This

approach was chosen to enhance the precision and reliability of the conclusions drawn from the investigation.

Criteria for Eligibility

This systematic review aims to evaluate the diagnostic accuracy of rapid point of care tests for syphilis.

Screening

We screened in sources based on their abstracts that met these criteria:

- **Rapid Point-of-Care Test:** Does this study evaluate rapid point-of-care tests for syphilis diagnosis that can be performed at the point of care?
- **Reference Standard Comparison:** Does this study compare rapid tests against an accepted reference standard (such as VDRL, RPR, TPPA, FTA-ABS, or EIA)?
- **Diagnostic Accuracy Data:** Does this study report sufficient data to calculate diagnostic accuracy measures (true positives, false positives, true negatives, and false negatives, or data from which these can be derived)?
- **Human Participants and Population:** Does this study involve human participants with suspected syphilis or participants from screening populations?
- **Appropriate Study Design:** Is this study a cross-sectional study, cohort study, case-control study, diagnostic accuracy study, systematic review, or meta-analysis?
- **Point-of-Care Focus:** Does this study include point-of-care testing components (rather than evaluating only laboratory-based tests without point-of-care components)?
- **Study Type Appropriateness:** Is this study something other than a case report, case series, editorial, commentary, or conference abstract?
- **Diagnostic Focus:** Does this study focus on initial syphilis diagnosis (rather than solely on treatment monitoring)?

We considered all screening questions together and made a holistic judgement about whether to screen in each paper.

Search Strategy

The keywords used for this research based PICO :

Element	P (Population)	I (Intervention/Exposure)	C (Comparison/Context)	O (Outcome)
Keyword 1	Syphilis	Rapid Test	Gold standard	Sensitivity
Keyword 2	Active syphilis	Point-of-care test (POCT)	Treponemal test (TPPA, TPHA, FTA-ABS)	Specificity
Keyword 3	High-Risk Groups	Rapid diagnostic test (RDT)	Nontreponemal test (RPR, VDRL)	Predictive value (PPV, NPV)
Keyword 4	Key populations	Immunochromatographic strip (ICS) test	Laboratory-based assay	Performance evaluation

The Boolean MeSH keywords inputted on databases for this research are: (*"Syphilis" OR "Active syphilis" OR "High-Risk Groups" OR "Key populations"*) AND (*"Rapid Test" OR "Point-of-care test (POCT)" OR "Rapid diagnostic test (RDT)" OR "Immunochromatographic strip (ICS) test"*) AND (*"Gold standard" OR "Treponemal test (TPPA, TPHA, FTA-ABS)" OR "Nontreponemal test (RPR, VDRL)" OR "Laboratory-based assay"*) AND (*"Sensitivity" OR "Specificity" OR "Predictive value (PPV, NPV)" OR "Performance evaluation"*)

Data extraction

- **POC Test Details:**

Extract details about the rapid point-of-care syphilis tests evaluated, including:

- Specific test name/brand (e.g., Determine, SD Bioline, DPP Syphilis Screen & Confirm)
- Test type (treponemal only, nontreponemal only, or dual treponemal/nontreponemal)
- Specimen type used (whole blood, fingerprick blood, plasma, serum)
- Testing location (laboratory-based evaluation vs. field conditions)
- Any special testing procedures or modifications

- **Study Population:**

Extract characteristics of the study population tested for syphilis, including:

- Population type (pregnant women, STI clinic patients, high-risk groups, general population, etc.)
- Geographic location and healthcare setting
- Sample size (total number of specimens/participants tested)
- Demographic characteristics if reported (age, gender, HIV status prevalence)
- Recruitment method and inclusion/exclusion criteria

- **Reference Standard:**

Extract details about the reference standard(s) used to determine true syphilis status, including:

- Primary reference test used (e.g., TPPA, FTA-Abs, TPHA, TP-EIA)
- Secondary reference tests if used (e.g., RPR, VDRL, TRUST)
- Testing algorithm employed (reverse sequence, traditional, etc.)
- How active vs. past syphilis was defined
- Any confirmatory testing procedures

- **Diagnostic Accuracy:**

Extract diagnostic performance metrics for each POC test evaluated, including:

- Sensitivity with 95% confidence intervals
- Specificity with 95% confidence intervals
- Positive predictive value (PPV) with 95% CI if reported
- Negative predictive value (NPV) with 95% CI if reported
- Overall accuracy if reported
- Number of true positives, false positives, true negatives, false negatives
- Syphilis prevalence in the study population

- **Performance Modifiers:**

Extract factors that affected POC test diagnostic performance for syphilis, including:

- Performance by syphilis stage (primary, secondary, early latent, late latent)
- Performance by HIV co-infection status
- Performance by RPR/VDRL titer levels (high titer $\geq 1:8$ vs. low titer vs. nonreactive)
- Performance by specimen type (if multiple tested)
- Any other factors that significantly affected sensitivity or specificity (age, pregnancy status, etc.)
- Statistical significance of performance differences between subgroups

- **Study Quality:**

Extract information relevant to assessing study quality and risk of bias for diagnostic accuracy studies, including:

- Study design (cross-sectional, case-control, etc.)
- Blinding of POC test readers to reference standard results
- Blinding of reference standard readers to POC test results
- Time interval between POC testing and reference standard testing
- Specimen storage conditions and duration if applicable

- Whether all participants received both POC test and reference standard
- Any indeterminate or invalid test results and how they were handled

Table 1. Article Search Strategy

Database	Keywords	Hits
Pubmed	<i>("Syphilis" OR "Active syphilis" OR "High-Risk Groups" OR "Key populations") AND ("Rapid Test" OR "Point-of-care test (POCT)" OR "Rapid diagnostic test (RDT)" OR "Immunochromatographic strip (ICS) test") AND ("Gold standard" OR "Treponemal test (TPPA, TPHA, FTA-ABS)" OR "Nontreponemal test (RPR, VDRL)" OR "Laboratory-based assay") AND ("Sensitivity" OR "Specificity" OR "Predictive value (PPV, NPV)" OR "Performance evaluation")</i>	15
Semantic Scholar	<i>("Syphilis" OR "Active syphilis" OR "High-Risk Groups" OR "Key populations") AND ("Rapid Test" OR "Point-of-care test (POCT)" OR "Rapid diagnostic test (RDT)" OR "Immunochromatographic strip (ICS) test") AND ("Gold standard" OR "Treponemal test (TPPA, TPHA, FTA-ABS)" OR "Nontreponemal test (RPR, VDRL)" OR "Laboratory-based assay") AND ("Sensitivity" OR "Specificity" OR "Predictive value (PPV, NPV)" OR "Performance evaluation")</i>	250
Springer	<i>("Syphilis" OR "Active syphilis" OR "High-Risk Groups" OR "Key populations") AND ("Rapid Test" OR "Point-of-care test (POCT)" OR "Rapid diagnostic test (RDT)" OR "Immunochromatographic strip (ICS) test") AND ("Gold standard" OR "Treponemal test (TPPA, TPHA, FTA-ABS)" OR "Nontreponemal test (RPR, VDRL)" OR "Laboratory-based assay") AND ("Sensitivity" OR "Specificity" OR "Predictive value (PPV, NPV)" OR "Performance evaluation")</i>	247
Google Scholar	<i>("Syphilis" OR "Active syphilis" OR "High-Risk Groups" OR "Key populations") AND ("Rapid Test" OR "Point-of-care test (POCT)" OR "Rapid diagnostic test (RDT)" OR "Immunochromatographic strip (ICS) test") AND ("Gold standard" OR "Treponemal test (TPPA, TPHA, FTA-ABS)" OR "Nontreponemal test (RPR, VDRL)" OR "Laboratory-based assay") AND ("Sensitivity" OR "Specificity" OR "Predictive value (PPV, NPV)" OR "Performance evaluation")</i>	3,400
Wiley Online Library	<i>("Syphilis" OR "Active syphilis" OR "High-Risk Groups" OR "Key populations") AND ("Rapid Test" OR "Point-of-care test (POCT)" OR "Rapid diagnostic test (RDT)" OR "Immunochromatographic strip (ICS) test") AND ("Gold standard" OR "Treponemal test (TPPA, TPHA, FTA-ABS)" OR "Nontreponemal test (RPR, VDRL)" OR "Laboratory-based assay") AND ("Sensitivity" OR "Specificity" OR "Predictive value (PPV, NPV)" OR "Performance evaluation")</i>	656

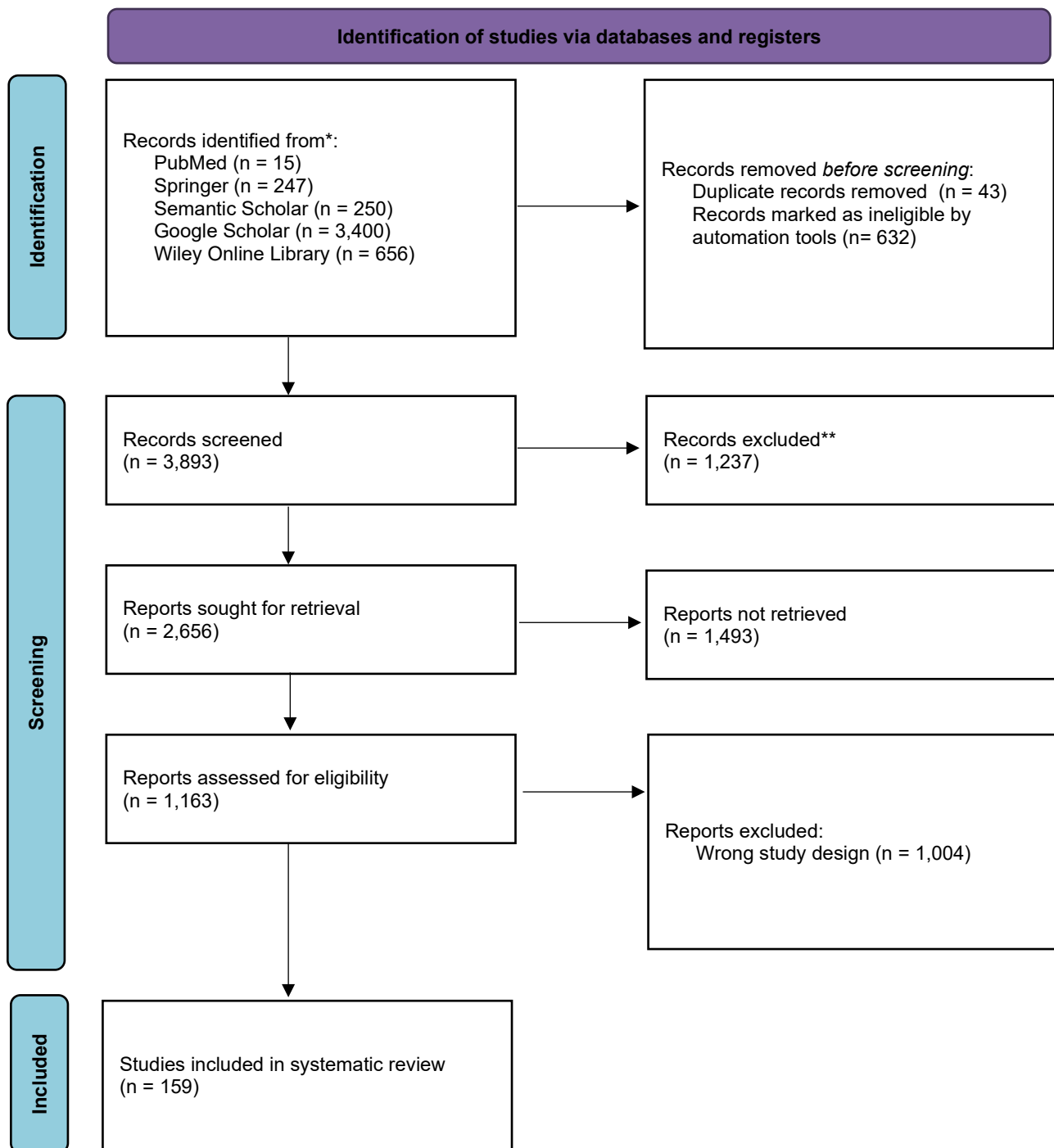


Figure 1. Article search flowchart

RESULTS

Study Characteristics

Study populations were diverse, encompassing pregnant women, STI clinic attendees, individuals living with HIV (PLWH), men who have sex with men (MSM), female sex workers (FSWs), and general or high-risk populations in community settings. Sample sizes ranged from fewer than one hundred to over 27,000 participants. HIV prevalence varied significantly, from less than 1% to as high as 78% in some cohorts. Similarly, syphilis prevalence ranged from as low as 0.09% to over 40% in high-risk groups.

Citation	Country/ Region	Setting	Population Type	Sample Size	Syphilis Prevalen ce	HIV Prevalen ce
E. Ángel-Müller et al., 2021	Varied	Field conditions	Men and nonpregnant women	9666	Not mentione d	Not mentione d
A. Zorzi et al., 2017	Italy	Not mentione d	MSM	289	17.6%	Not mentione d
F. Tinajeros et al., 2006	Bolivia	Urban maternity hospitals	Pregnant women	8892	3.84%	Not mentione d

Citation	Country/ Region	Setting	Population Type	Sample Size	Syphilis Prevalen ce	HIV Prevalen ce
Yueping Yin et al., 2013	China	STI clinics and outreach settings	STI clinic patients and high-risk groups	1323	37.6%	Not mentione d
P. Montoya et al., 2006	Mozambi que	Antenatal clinics	Pregnant women	4789	Not mentione d	Not mentione d
C. Caya et al., 2023	Canada	Arctic communities	General population at risk	161	23.6%	Not mentione d
J. G. García Luna et al., 2023	Colombia	Outpatien t HIV clinics	PLWH	244	11.1% (active)	100%
M. Kasaro et al., 2018	Zambia	Antenatal clinics	Pregnant women	3212	9.7%	19.2%
R. Kularatne et al., 2024	South Africa, Zambia	Primary healthcare centers	Pregnant women	3412	3.7% - 9.9%	17.8% - 21.3%

Citation	Country/ Region	Setting	Population Type	Sample Size	Syphilis Prevalen ce	HIV Prevalen ce
Y. Jafari et al., 2013	Varied (global south)	Not specified	Pregnant women, STI patients, MSM	Not mentione d	Not mentione d	Not mentione d
Carmen Phang Romero Casas et al., 2018	Low/midd le-income countries	Antenatal clinics	Pregnant women	14985	Not mentione d	Not mentione d
J. Tucker et al., 2010	Varied	STI and antenatal clinics	STI and antenatal clinic patients	>22000	Not mentione d	Not mentione d
D. Mabey et al., 2006	Brazil, China, Haiti, Tanzania	Clinics	Pregnant women and high-risk groups	2335	11.2%	Not mentione d
C. Bristow et al., 2020	USA, Uganda	Varied clinics	Pregnant women, STI patients, high- risk groups	Not mentione d	Not mentione d	Not mentione d
E. Nakku-Joloba et al., 2016	Not mentione d	Not mentione d	Not mentioned	Not mentione d	Not mentione d	Not mentione d

Citation	Country/ Region	Setting	Population Type	Sample Size	Syphilis Prevalen ce	HIV Prevalen ce
A. Herring et al., 2006	Geograph ically diverse	Laborator y	Archived sera	1389 serum samples	~50% (panel)	Not mentione d
Kristen L Hess et al., 2014	USA (Californi a)	Testing center	High-risk groups	948	2%	Not mentione d
Y. Jafari et al., 2011	Not mentione d	Not mentione d	Not mentioned	Not mentione d	Not mentione d	Not mentione d
Arnold Castro et al., 2010	Not mentione d	Not specified	Banked serum samples	1601	Not mentione d	Not mentione d
A. Singh et al., 2023	Canada	Diverse clinical settings	General population (≥ 16 years)	1526 visits	Not mentione d	1.6%
A. Benzaken et al., 2011	Brazil	Amazon region communit ies	Pregnant women	712	2.2%	Not mentione d

Citation	Country/ Region	Setting	Population Type	Sample Size	Syphilis Prevalen ce	HIV Prevalen ce
L. Causer et al., 2014	Australia	Urban sexual health clinics	STI clinic patients, high- risk groups	1203	61.2% (IA- reactive)	12.8%
Maddalena Lorenzo Massimo Antonella Christopher Valeska Amin Cordioli Gios Mirandola Zorzi Barbara Padovese Han et al., 2020	Varied (global)	Clinic evaluation sites	MSM, SWs, pregnant women	Not specified	Not specified	Not specified
A. van den Heuvel et al., 2019	Multiregi onal	Laborator y	STI clinic patients, blood donors	400	50% (panel)	50% (panel)

Citation	Country/ Region	Setting	Population Type	Sample Size	Syphilis Prevalen ce	HIV Prevalen ce
R. Tsang et al., 2022	Canada	National Microbiol ogy Laborator y	Archived sera	100	80% (panel)	Not mentione d
L. Núñez-Forero et al., 2015	Colombia	Public hospitals, private clinic	Symptomatic women	1500	Not mentione d	Not mentione d
Sharmistha Mishra et al., 2009	India	STI clinics	FSWs	1617	7.4%	Not mentione d
M. Barnes et al., 2011	USA (Baltimor e)	STD clinic	STI clinic patients	399	8.3%	Not mentione d
Y. Fakile et al., 2015	USA (Californi a)	Public Health Departme nt	Banked sera	1623	Not mentione d	Not mentione d

Citation	Country/ Region	Setting	Population Type	Sample Size	Syphilis Prevalen ce	HIV Prevalen ce
Ying Zhang et al., 2022	Varied	Clinical settings	Key populations (sex workers, MSM, etc.)	Not mentioned	Not mentioned	Not mentioned
M. G. Vaulet et al., 2017	Not mentioned	Varied	High-risk groups, pregnant women	13915	Median 8.2%	Median 25.3%
P. Smit et al., 2013	Tanzania	Antenatal clinics	Pregnant women	2099	2.3%	Not mentioned
Y. Fakile et al., 2019	USA (Detroit)	Emergency department	Men (MSM and non-MSM)	965	Not specified	Not mentioned
F. Bocoum et al., 2015	Burkina Faso	Blood transfusion center	Blood donors	120	50% (panel)	Not mentioned

Citation	Country/ Region	Setting	Population Type	Sample Size	Syphilis Prevalen ce	HIV Prevalen ce
Mark J. Siedner et al., 2004	USA	STD clinic	STI clinic patients	127 (venous), 99 (fingerstic k)	Not mentione d	Not mentione d
J. Guinard et al., 2013	Not mentione d	Not mentione d	Adults with documented syphilis	100	100%	Not mentione d
N. Constantine et al., 2017	Not mentione d	Laborator y	Characterized samples	1283	Not mentione d	Not mentione d
C. Bristow et al., 2014	Ghana, Mexico, Laos, Togo, Kenya, Myanmar	Laborator y	Archived sera	2059	Not mentione d	Not mentione d
Sirinart Chomean et al., 2024	Not mentione d	Not mentione d	Mixed (syphilis patients, healthy)	450	Not mentione d	Not mentione d

Citation	Country/ Region	Setting	Population Type	Sample Size	Syphilis Prevalen ce	HIV Prevalen ce
L. Causer et al., 2015	Australia	Laborator y	Archived sera	1005	Not mentione d	Not mentione d
R. Castro et al., 2013	Not mentione d	Not mentione d	Patients with active/past syphilis, uninfected controls	248	Not specified	Not mentione d
A. Benzaken et al., 2008	Brazil	STI clinics	STI clinic patients	510	18%	2.5%
Lara E Pereira et al., 2018	Not mentione d	Not mentione d	Archived human serum samples	1406	Not mentione d	Not mentione d
Suelen Basgalupp et al., 2025	Brazil	Mobile health unit	General population	250	50%	Not mentione d
L. Núñez-Forero et al., 2013	Colombia	Outpatien t facilities	Symptomatic women	1410	0.9%	Not mentione d

Citation	Country/ Region	Setting	Population Type	Sample Size	Syphilis Prevalen ce	HIV Prevalen ce
M. Bazzo et al., 2017	Brazil	Not specified	Archived plasma	493	Not mentione d	Not mentione d
L. Juárez- Figueroa et al., 2007	Not mentione d	Not specified	Women	548	1.5% to >15%	Not mentione d
Oluyomi A. Obafemi et al., 2019	USA	Outreach sites	MSM	1081	Not mentione d	Not mentione d
J. Matthias et al., 2016	USA (Florida)	STD clinic	STI clinic patients	202	Not specified	Not mentione d
A. Bhargava et al., 2022	India	STD clinic	STI clinic patients	599	61.8%	Not mentione d
Rujirek Kamolrattana et al., 2023	Thailand	Sexual health clinic	Young MSM and transgender women	200	10.5%	25.0%

Citation	Country/ Region	Setting	Population Type	Sample Size	Syphilis Prevalen ce	HIV Prevalen ce
C. Bristow et al., 2015	Peru	Clinics	High-risk groups (MSM, transgender women)	415	40.2%	25.3%
C. Caya et al., 2022	Canada	Sexual health clinics and nursing stations	High-risk individuals (≥14 years)	176	26.1%	Not mentione d
N. Harrison et al., 2023	Nigeria	Tertiary hospital ANC	Pregnant women	Not specified	4.3%	Not mentione d
B. Mehra et al., 2016	India	Tertiary care hospital	General patient population	100	Not specified	Not mentione d
K. Nessa et al., 2008	Banglades h	Field clinics and laboratori es	FSWs	684	20.8%	Not mentione d

Citation	Country/ Region	Setting	Population Type	Sample Size	Syphilis Prevalen ce	HIV Prevalen ce
R. Lubis et al., 2019	Indonesia	Public health center	High-risk groups (transgender, MSM, FSW)	127	Not mentione d	Not mentione d
B. Kashyap et al., 2015	Not mentione d	Peripheral health settings	Pregnant women	200	2%	Not mentione d
B. West et al., 2002	The Gambia	Rural communit ies	Women of reproductive age	1325	3%	Not mentione d
N. Sherriff et al., 2024	Italy, Malta, Peru, UK	Sexual health clinics	MSM	2577	35.9%	23.5%
D. C. Soares et al., 2023	Brazil	Antenatal care services, STI clinics, nightclubs	Pregnant women, FSW, MSM	529	15.1%	Not mentione d

Citation	Country/ Region	Setting	Population Type	Sample Size	Syphilis Prevalen ce	HIV Prevalen ce
Maitrayee Narayan et al., 2025	India	Tertiary care center	General patient population	500	21.2%	Not mentione d
Kendall N Maliszewski et al., 2024	USA	Urban emergenc y departme nt	High-risk groups	327	Not mentione d	Not mentione d
D. Cox et al., 2011	Not mentione d	Laborator y	Archived serum samples	Varied (94, 1601, 376)	Not mentione d	Not mentione d
Y. Fakile et al., 2019a	USA (North Carolina)	STD clinics	Adult patients without prior syphilis	562	Not mentione d	Not mentione d
Lin-na Wang et al., 2007	China	STD clinic	STD clinic outpatients	970	Not mentione d	Not mentione d
C. Bristow et al., 2016	Peru	Not specified	Not mentioned	Not specified	Not mentione d	Not mentione d

Citation	Country/ Region	Setting	Population Type	Sample Size	Syphilis Prevalen ce	HIV Prevalen ce
Putri L Karim et al., 2024	Indonesia	Hospital	MSM	83	Not mentione d	Not mentione d
T. Diaz et al., 2004	Brazil	Research institute	Archived sera	567	44.1% (TPHA positive)	57.3%
Nayrah Villazón-Vargas et al., 2009	Bolivia	Public hospital	Delivering women	489	4.5%	Not mentione d
S. Vargas et al., 2022	Not mentione d	Laborator y	High-risk groups (archived sera)	383	Not mentione d	Not mentione d
Aniúsca dos Santos et al., 2025	Brazil	Mobile health unit	General adult population	191	60%	Excluded
R. Castro et al., 2013a	Not specified	HIV Anonymo us Testing Center	MSM	944	4.2%	Not mentione d

Citation	Country/ Region	Setting	Population Type	Sample Size	Syphilis Prevalen ce	HIV Prevalen ce
S. Herbst de Cortina et al., 2017	USA, Peru	Laborator y	Archived sera	201	Not mentione d	Not mentione d
SM Herbst De Cortina et al., 2016	Peru	Laborator y	High-risk patients (MSM, transgender women)	200	Not mentione d	Not mentione d
K. Clark et al., 2025	Not mentione d	Multi-site clinical study	Self-testing subjects	1270	Not mentione d	Not mentione d
María Hernández- Trejo et al., 2006	Mexico	Hospitals	Delivering women	1322	0.3%	Not mentione d
Astuti Giantini et al., 2020	Indonesia	Hospital and communit y surveillan ce	STI clinic patients, children	156 (syphilis), 176 (yaws)	Not mentione d	Not mentione d

Citation	Country/ Region	Setting	Population Type	Sample Size	Syphilis Prevalen ce	HIV Prevalen ce
Yueping Yin et al., 2009	China	STD clinics	STI clinic patients	11558	11.8% (active)	Not mentioned
Jeffrey Holden et al., 2017	USA (Baltimore)	STI clinic	STI clinic patients	Not specified	Not specified	Not specified
V. Black et al., 2016	South Africa	Inner-city Johannesburg	FSWs	249	20.5%	75.1%
M. Kalou et al., 2016	USA (Georgia)	Public health laboratory	Archived sera	990	30.2%	Not mentioned
Anastasia Eliopoulos et al., 2025	Not specified	Laboratory	Archived sera	Not specified	Not specified	Not specified
Meika EI Richmond et al., 2024	Not mentioned	Laboratory	Clinical samples with known serology	100	40% (presumed active)	Not mentioned

Citation	Country/ Region	Setting	Population Type	Sample Size	Syphilis Prevalen ce	HIV Prevalen ce
Arnold Castro et al., 2010a	USA (Georgia)	Public Health Laborator y	Banked serum samples	376	Not mentione d	Not mentione d
Techalew Shimelis et al., 2015	Ethiopia	Hospital	ART and VCT clients	185	Not specified	Not specified
A. Patel et al., 2001	Not mentione d	Not specified	Women	513	8.2%	Not mentione d
Ursula Biba et al., 2025	Vietnam	HIV PrEP program	MSM on PrEP	400	35.3%	Not mentione d
A W Dzokoto et al., 2013	Ghana	Primary health facilities	Pregnant women	1249	7.7%	Not mentione d
Oyinloye Olabimpe Oluwabusayo et al., 2022	Nigeria	Federal Teaching Hospital	Pregnant women	160	2.5%	Not mentione d

Citation	Country/ Region	Setting	Population Type	Sample Size	Syphilis Prevalen ce	HIV Prevalen ce
Carolina Arai et al., 2023	Not mentione d	Not specified	Blood donors	811	Not mentione d	Not mentione d
H. Terzi et al., 2020	Not mentione d	Laborator y	Patients with pre-diagnosis of syphilis	595	5%	Not mentione d
C. Shannon et al., 2017	Not mentione d	Not specified	Clinic attendees	72	Not mentione d	Not mentione d
C. Stafylis et al., 2019	USA (Los Angeles, New York)	Communi ty-based clinics	Clinic patients	274	Not mentione d	Not mentione d
V. Pinto et al., 2014	Brazil	Social support services	Homeless people	1405	7.0%	Not mentione d
J. Qquellon et al., 2024	Peru	STI clinics	STI clinic users	323	51.3% (prior syphilis)	Not mentione d

Citation	Country/ Region	Setting	Population Type	Sample Size	Syphilis Prevalen ce	HIV Prevalen ce
Yihui Zhuang et al., 2012	China	Not specified	Archived sera	300	Not specified	Not mentioned
Ricardo Cristiano Brum et al., 2021	Not specified	Not specified	HIV-positive, pregnant women, general population	493	Not specified	Not specified
C. Langendorf et al., 2018	Burkina Faso	Antenatal care clinics	Pregnant women	242	37.6% (presumptive active)	Not mentioned
Kendall N Maliszewski et al., 2021	USA (Baltimore)	Urban emergency department	High-risk groups	170	Not specified	Not specified
S G Chapman et al., 2013	Not specified	Primary Care	Not mentioned	1898	Not specified	Not specified
R. Tsang et al., 2022a	Canada	Laboratory	Archived sera	100	80% (panel)	Not mentioned

Citation	Country/ Region	Setting	Population Type	Sample Size	Syphilis Prevalen ce	HIV Prevalen ce
L. Allan-Blitz et al., 2018	Peru	STD clinic	MSM and transgender women	283	46%	34%
Kevin Clark et al., 2025	Not specified	Not specified	Self-testing subjects	1270	Not specified	Not specified
Christian Taheu Ngounouh et al., 2025	Cameroon	Health facilities	General adult population	583	Not specified	Not specified
Yakep Angue et al., 2005	Papua New Guinea	Antenatal clinic	Pregnant women	2100	Not specified	Not specified
L. Allan-Blitz et al., 2017	Peru	STD clinic	MSM and transgender women	283	46%	34%
M. Chiappe et al., 2013	Not specified	Laboratory	Archived sera	665 (syphilis), 662 (HIV)	29.8%	13.7%
C. Shannon et al., 2017a	USA (California)	Clinic	Clinic attendees	49	Not specified	Not specified

Citation	Country/ Region	Setting	Population Type	Sample Size	Syphilis Prevalen ce	HIV Prevalen ce
Ankita Jain et al., 2024	Not specified	Tertiary center	Blood donors	120	Not specified	Not specified
Hans-Jochen Hagedorn et al., 2013	Germany	Varied healthcare settings	High-risk groups, pregnant women	2203	Not specified	Not specified
Oumar Traoré et al., 2023	Burkina Faso	Health facilities	Suspected syphilis-infected participants	633	38.2%	Not specified
J-Y Su et al., 2015	Australia	Remote communities	General population (12-30 years)	326	9.2%	Not specified
E. Zulu et al., 2024	Zambia	Peri-urban hospital	Pregnant women	1510	8.9%	50% (by design)
E. Flora et al., 2015	Guatemala	Laboratory and peripheral health services	Archived sera and pregnant women	460 (sera), 432 (whole blood)	Not specified	Not specified

Citation	Country/ Region	Setting	Population Type	Sample Size	Syphilis Prevalen ce	HIV Prevalen ce
Vinia Ardiani Permata et al., 2011	Indonesia	Public health center	FSWs	232	12.5%	Not specified
Won-Shik Kim et al., 2011	Not specified	Hospital	Not specified	453	44.8%	Not specified
C. Bristow et al., 2015a	Haiti	Clinic	High-risk groups, including pregnant women	298	Not specified	Not specified
L. B. Nyamwamu et al., 2013	Kenya	Antenatal clinics	Pregnant women	150	3%	Not specified
V. Black et al., 2015	South Africa	Inner-city Johannesb urg	FSWs	249	20.5%	75.1%
Yan Han et al., 2018	Not specified	Laborator y	Archived serum samples	455	Not specified	Not specified

Citation	Country/ Region	Setting	Population Type	Sample Size	Syphilis Prevalen ce	HIV Prevalen ce
D. Dheepa et al., 2017	Not specified	STD departme nt and ANC	STD patients and pregnant women	450	Not specified	Not specified
K. Montañaño et al., 2018	Bolivia	Prison	Incarcerated women	219	Not specified	Not specified
P. Campos et al., 2006	Peru	Commerc ial sex venues	FSWs	3586	5.7% (RPR reactive)	Not specified
G. Shakya et al., 2016	Nepal	Women's Hospital	Pregnant women	10000	0.44%	Not specified
Keenan Withers et al., 2018	Vietnam	Clinics	MSM and pregnant women	280	49.0% (MSM)	17.0% (MSM)
F. Majoko et al., 2003	Zimbabw e	Rural Health Centres	Pregnant women	Not specified	11%	Not specified
R. Ondondo et al., 2013	Not specified	Not specified	HIV discordant couples	680	20%	50%

Citation	Country/ Region	Setting	Population Type	Sample Size	Syphilis Prevalen ce	HIV Prevalen ce
H. Gliddon et al., 2017	Varied	Varied	Key populations	Not specified	Not specified	Not specified
J. Bergman et al., 2013	Canada	Outreach settings	At-risk population	1031	4 new cases	4 new cases
G. Robertson et al., 2014	Australia (Queensland)	Not specified	Not specified	Not specified	Not specified	Not specified
J. Rotty et al., 2010	Not specified	Not specified	HIV-infected patients with syphilis	71 samples	100%	100%
N. Pai et al., 2014	India, Canada	STI clinic, community setting	STI clinic attendees, IDUs	375 (India), 119 (Canada)	Not specified	Not specified
Dana Brandenburger et al., 2021	Mongolia, South Africa	Not specified	Pregnant women	Varied (7700, 7134)	Not specified	Not specified
R. Bronzan et al., 2007	South Africa	Rural clinics	Pregnant women	1250	6.3%	Not specified

Citation	Country/ Region	Setting	Population Type	Sample Size	Syphilis Prevalen ce	HIV Prevalen ce
Standardised protocol for a pr	Varied	CBVCT services	MSM	300 (or 150)	Not specified	Not specified
Hao Yang et al., 2010	China	Hospital	Archived sera	100	50% (panel)	Not specified
M. Gianino et al., 2007	Not specified	STI clinic	High-risk population	Not specified	Not specified	Not specified
S. Gupte et al., 2011	India	Sex worker clinics	Sex workers	19809	1.2% (active)	Not specified
Truong Xuan Lien et al., 2000	Vietnam	Hospitals and clinics	Not specified	Not specified	Not specified	Not specified
L. van Dommelen et al., 2008	Netherlan ds	Universit y Hospital	Archived sera	330	Not specified	Not specified
M. Fears et al., 2001	Not specified	Not specified	Pregnant women, STI clinic patients	255	Not specified	Not specified
S. Leon et al., 2015	Not specified	Laborator y	Archived sera	450	Not specified	Not specified

Citation	Country/ Region	Setting	Population Type	Sample Size	Syphilis Prevalen ce	HIV Prevalen ce
R. Humphries et al., 2014	Not specified	Laborator y	Patient serum samples	150	Not specified	Not specified
N. Thilakavathi et al., 2019	Not specified	STD outpatient clinic	High-risk groups	1131	10.4%	Not specified
Weiping Cao et al., 2024	7 countries	Clinical sites	Not specified	140 reports	Not specified	Not specified
J. Bergman et al., 2011	Canada	Outreach settings	High-risk populations	125	4.1%	1.6%
Dong Yang et al., 2013	Not specified	Hospitals	Archived sera	1020	Not specified	Not specified
I. Olugbenga et al., 2018	Nigeria	Antenatal clinics	Pregnant women	4551	0.09%	3.0%
A. Seña et al., 2019	USA (North Carolina)	STI clinic	STI clinic patients	182	Not specified	Not specified
Patricia J. García et al., 2011	Peru	Hospital and health centers	Pregnant women	Not specified	Not specified	Not specified

Citation	Country/ Region	Setting	Population Type	Sample Size	Syphilis Prevalen ce	HIV Prevalen ce
S. Mahomed et al., 2025	South Africa	Point-of-care clinics	Pregnant women and STI clinic patients	1500	33%	Not specified
C. Rietmeijer et al., 2019	Zimbabwe	STI clinics	STI clinic patients	436	Not specified	Not specified
H. Mizushina et al., 2025	Not specified	Not specified	Syphilis and non-syphilis patients	116 specimens	Not specified	Not specified
Janaína Dos Santos Maciel et al., 2025	Brazil	Public hospital	Pregnant women and newborns	276 (women), 41 (newborns)	33.0% (rapid test)	Not specified
Walusimbi J et al., 2020	Uganda	Antenatal clinic	Pregnant women	462	6%	4%
L. Yang et al., 2013	China	Rural healthcare facilities	Pregnant women	27150	0.39%	Not specified
Stephanie F. Sweitzer et al., 2025	China, Colombia, Malawi	Clinical sites	Patients with primary syphilis	79	100%	15%

Citation	Country/ Region	Setting	Population Type	Sample Size	Syphilis Prevalen ce	HIV Prevalen ce
Gerald J. Kost et al., 2025	Spain	Not specified	High-risk individuals (HIV+, PrEP users)	293	Not specified	HIV+/PrE P
MC Adati et al., 2023	Not specified	Not specified	Not specified	55 lots	Not specified	Not specified
Krishnamoorthy Priya et al., 2025	Not specified	Not specified	Suspected syphilis cases, healthy volunteers	77	Not specified	Not specified
A. Latini et al., 2018	Italy	Gay- meeting sites	MSM	581	7.0%	Not specified
N. Thilakavathi et al., 2017	Not specified	STD outpatient clinic	High-risk groups	1131	10.4%	Not specified
Rotanov Sv et al., 2008	Russia	Not specified	Not specified	Not specified	Not specified	Not specified
Yueping Yin et al., 2015	China, Nigeria	Laborator ies and clinics	Archived sera	1514	Not specified	Not specified

Citation	Country/ Region	Setting	Population Type	Sample Size	Syphilis Prevalen ce	HIV Prevalen ce
C. Gaydos et al., 2021	USA	Not specified	Not specified	Not specified	Not specified	Not specified
J. Li et al., 2009	China	STD clinic	STI clinic patients	Not specified	Not specified	Not specified
Swati Nirmal et al., 2025	India	Hospital	Pregnant women	100	3%	Not specified
Irfaan Maan et al., 2021	Botswana	HIV clinic	PLWH	390	1.3% (active)	100%
Laura Fernández- López et al., 2024	Spain, Slovenia, Latvia, Ukraine	Communi ty-based organizati ons	MSM	844	7.2%	7.1%
Lucía Gallo Vaulet et al., 2018	Argentina	STD clinic	STI clinic patients	587	27.0% (VDRL)	Not specified
M. Valderrama et al., 2011	Peru	Health centers	Pregnant women	4497	0.9% (ANC)	0.3%
C. Bristow et al., 2018	Not specified	Not specified	Not specified	Not specified	Not specified	Not specified

Citation	Country/ Region	Setting	Population Type	Sample Size	Syphilis Prevalen ce	HIV Prevalen ce
John W Deutsch et al., 2017	USA	Hospital	Pregnant women, newborns	39 samples	100% (panel)	Not specified
A. Benzaken et al., 2013	Brazil	Amazon region communit ies	Indigenous populations	1607 (syphilis), 1608 (HIV)	Not specified	Not specified
L. Malucelli et al., 2021	Brazil	Not specified	General clinical population	Not specified	Not specified	Not specified
S. Masenga et al., 2018	Zambia	Hospital	Syphilis suspected patients	781	14.9%	Not specified
Kathleen Whyte et al., 2024	Canada	Not specified	Not specified	Not specified	Not specified	Not specified
Markos Negash et al., 2018	Ethiopia	Hospital and Blood Bank	Syphilis- suspected and healthy individuals	160	50%	Not specified
Daniel Omoding et al., 2014	Uganda	Rural health center	Pregnant women	220	8.6%	Not specified

Citation	Country/ Region	Setting	Population Type	Sample Size	Syphilis Prevalen ce	HIV Prevalen ce
S. L. R. Roca et al., 2011	Peru	Hospital	Pregnant women	15116	~0.8%	Not specified
M. Goza et al., 2017	Not specified	Clinics and blood centers	Varied (symptomatic, blood donors, pregnant, co-infected)	Varied	Not specified	Not specified
R. Paramasivam et al., 2020	Not specified	Not specified	Not specified	Not specified	Not specified	Not specified
A. Benzaken et al., 2013a	Brazil	Amazon region communities	Indigenous populations	45226	1.6%	0.1%
F. Sarkodie et al., 2017	Ghana	Hospital	Not specified	Not specified	Not specified	Not specified
Nerida Moore et al., 2025	Australia	Hospital	Pregnant women	74	Not specified	Not specified
J. Kriesel et al., 2011	USA (Utah)	STD clinic	STI clinic patients	99 specimens	Not specified	Not specified

Citation	Country/ Region	Setting	Population Type	Sample Size	Syphilis Prevalen ce	HIV Prevalen ce
M. Marks et al., 2016	Not specified	Not specified	Not specified	Not specified	Not specified	Not specified
L. Mackrell et al., 2024	Canada (Ontario)	Communi ty settings	Underserved populations	Not specified	Not specified	Not specified
N. Ogden et al., 2019	Not specified	Not specified	Not specified	Not specified	Not specified	Not specified
Lin-na Wang et al., 2007a	Not specified	Not specified	Not specified	249	Not specified	Not specified
P. Vickerman et al., 2006	Tanzania	Antenatal clinic	Pregnant women	9713	7.2%	Not specified
B. Schackman et al., 2007	Haiti	Prenatal clinics	Pregnant women	Not specified	3.5%- 3.8%	Not specified
C. Bristow et al., 2019	Peru	Laborator y	Archived sera (MSM, transgender women)	400	50% (panel)	50% (panel)
C. Lyngdoh et al., 2024	India	Hospital	ANC and STI clinic patients	2312	1.5%	Not specified

Citation	Country/ Region	Setting	Population Type	Sample Size	Syphilis Prevalen ce	HIV Prevalen ce
P. Rajendran et al., 2003	India	Communi ty	General population (15- 45 years)	1873	1.1% (acute)	Not specified
S. Muralidhar et al., 2018	Not specified	Not specified	Patients with genital ulcer disease	100	Not specified	Not specified
M. Parthasarathy et al., 2011	India	HIV preventio n clinics	High-risk groups	Varied (>280,000 in 2009)	4% (2009)	Not specified
Divya Lakshminarayana et al., 2023	Not specified	Hospital	PLWH	500	11.7%	100%
P. Adamson et al., 2020	Global/U SA	Not specified	Not specified	Not specified	Not specified	Not specified

POC Test Characteristics

A wide variety of rapid POC syphilis tests have been evaluated. These can be broadly categorized into three types: treponemal-only, nontreponemal-only, and dual tests that detect both treponemal and nontreponemal antibodies.

Treponemal-only tests were the most frequently evaluated type. Commonly studied brands include Abbott Determine Syphilis TP, SD Bioline Syphilis 3.0, Syphicheck, and VisiTest. These tests

exclusively detect antibodies specific to *Treponema pallidum* and are often used for initial screening.

Dual treponemal/nontreponemal tests, designed to distinguish between active and past/treated infections, have become more common in recent studies. Prominent examples include the Chembio DPP Syphilis Screen & Confirm, SD Bioline HIV/Syphilis Duo, and the INSTI Multiplex tests. These combination tests often include HIV antibody detection as well.

Specimens used for testing included fingerprick capillary whole blood, venous whole blood, serum, and plasma. Some studies also explored the use of alternative specimens like oral fluid and dried tube specimens (DTS). Evaluations were conducted in both controlled laboratory settings and diverse field conditions at the point of care.

Test Name/Brand	Manufacturer	Test Type	Specimen Types Evaluated	Number of Studies
Abbott Determine Syphilis TP	Alere/Abbott	Treponemal	Whole blood, Serum, Plasma	26
SD Bioline Syphilis 3.0	Standard Diagnostics	Treponemal	Whole blood, Serum, Plasma	18
Chembio DPP Syphilis Screen & Confirm	Chembio Diagnostics	Dual	Whole blood, Serum, Plasma	14
SD Bioline HIV/Syphilis Duo	Standard Diagnostics/Alere /Abbott	Dual (HIV/Syphilis)	Whole blood, Serum	14

Test Name/Brand	Manufacturer	Test Type	Specimen Types Evaluated	Number of Studies
Syphicheck-WB / Syphicheck	Qualpro/Tulip Diagnostics	Treponemal	Whole blood, Serum	7
Syphilis Health Check (SHC)	VEDA.LAB/Trinity Biotech	Treponemal	Whole blood, Serum, Plasma	6
ChemBio DPP HIV-Syphilis Assay	ChemBio Diagnostics	Dual (HIV/Syphilis)	Whole blood, Serum	6
VisiTest Syphilis	Omega Diagnostics	Treponemal	Whole blood, Serum	5
INSTI Multiplex HIV/Syphilis Test	bioLytical Laboratories	Dual (HIV/Syphilis)	Whole blood, Serum	5
MedMira Multiplo Rapid TP/HIV	MedMira	Dual (HIV/Syphilis)	Whole blood, Serum, Plasma	4
ACON Syphilis Test	ACON Laboratories	Treponemal	Not specified	2
Accu-Tell Rapid Anti-TP	AccuBio Tech	Treponemal	Serum	1

Test Name/Brand	Manufacturer	Test Type	Specimen Types Evaluated	Number of Studies
ASTEL Syphilis/HIV Duo	ASTEL Diagnostics	Dual (HIV/Syphilis)	Whole blood	1
Biorapid Syphilis	Bio-Rad	Treponemal	Serum	1
Cypress Diagnostics Syphilis Quick test	Cypress Diagnostics	Treponemal	Serum	1
DiaSpot Syphilis	Not specified	Treponemal	Serum	2
Espline TP	Fujirebio	Treponemal	Serum	2
First to Know Syphilis Test	Not specified	Treponemal	Fingerstick blood	2
First Response HIV/Syphilis Combo	Premier Medical Corporation	Dual (HIV/Syphilis)	Venous blood	2
Guardian Biosciences One Step	Guardian Biosciences	Treponemal	Whole blood	1
Hightop Syphilis RDT	Qingdao Hightop Biotech	Nontreponemal	Blood	1

Test Name/Brand	Manufacturer	Test Type	Specimen Types Evaluated	Number of Studies
iStatix Syphilis Antibody Test	Not specified	Treponemal	Capillary blood, Venous whole blood, Plasma	1
Onsite Syphilis Ab Combo Rapid Test	CTK Biotech	Dual	Serum, Whole blood	2
Onsite (brand)	CTK Biotech	Treponemal	Serum	1
Phoenix Biotech Trep-Strip IV	Phoenix Biotech	Treponemal	Whole blood	1
Reveal Rapid TP Antibody Test	MedMira	Treponemal	Serum	2
STANDARD Q Syphilis Ab	SD Biosensor	Treponemal	Serum, Fingerprick whole blood	1
Standard Q HIV/Syphilis Combo	SD Biosensor	Dual (HIV/Syphilis)	Serum	1
Syphilis Fast	Bionor	Treponemal	Serum	2
Burnet Institute IgA-POC	Burnet Institute	Treponemal (IgA)	Serum	1

Test Name/Brand	Manufacturer	Test Type	Specimen Types Evaluated	Number of Studies
E-DNA scaffold sensor	Not applicable	Treponemal	Not mentioned	1
FilmArray device	Not applicable	Treponemal	Swabs, Urine	1
GeneSoC qPCR system	Not applicable	Treponemal	Swabs, Saliva	1
Miriad multiplex device	Not specified	Treponemal	Not specified	1
Paper-based LAMP assay	Not applicable	Treponemal	Not mentioned	1

Reference Standards and Diagnostic Algorithms

The determination of true syphilis status across the included studies relied on a variety of laboratory-based treponemal and nontreponemal assays. The most common primary treponemal reference tests were the *T. pallidum* particle agglutination (TPPA) assay and the *T. pallidum* hemagglutination assay (TPHA). Other treponemal tests used as reference standards included the fluorescent treponemal antibody-absorption (FTA-Abs) test, and various enzyme immunoassays (EIAs) or chemiluminescence immunoassays (CLIAs).

Nontreponemal tests were universally used, either for initial screening in a traditional algorithm or for assessing disease activity following a reactive treponemal test in a reverse algorithm. The most frequently employed nontreponemal tests were the rapid plasma reagin (RPR)

test and the Venereal Disease Research Laboratory (VDRL) test. The toluidine red unheated serum test (TRUST) was also used in some studies.

There was considerable heterogeneity in the definitions used for syphilis cases. A common definition for active or probable active syphilis was the combination of a reactive treponemal test (e.g., TPPA/TPHA) and a reactive nontreponemal test (e.g., RPR/VDRL). Many studies further refined this by requiring a specific nontreponemal titer, typically $RPR \geq 1:8$, to classify an infection as active and likely requiring treatment. This heterogeneity in reference standards and case definitions is a crucial consideration when interpreting and comparing diagnostic accuracy estimates across studies.

Citation	Primary Treponemal Reference Test	Nontreponemal Test	Testing Algorithm	Definition of Positive Syphilis Status
E. Ángel-Müller et al., 2021	Not specified	Not specified	Not specified	Treponemal plus nontreponemal test positive
F. Tinajeros et al., 2006	TPPA	RPR	Traditional	RPR positive confirmed by TPPA
Yueping Yin et al., 2013	TPPA	TRUST	Parallel comparison	TPPA for treponemal, TRUST for nontreponemal

Citation	Primary Treponemal Reference Test	Nontreponemal Test	Testing Algorithm	Definition of Positive Syphilis Status
P. Montoya et al., 2006	TPHA, direct immunofluorescence	RPR	Gold standard combination	Not specified
C. Caya et al., 2023	Not specified	RPR	Reverse sequence	Treponemal test positive + RPR $\geq 1:8$ (for active)
J. G. García Luna et al., 2023	ELISA, TPHA	RPR	Not specified	TPHA or ELISA positive + RPR reactive + clinical signs (active)
M. Kasaro et al., 2018	TPPA	RPR	Not specified	TPPA positive + RPR $\geq 1:4$ (active)
R. Kularatne et al., 2024	TPPA	RPR	Not specified	TPPA positive + RPR $\geq 1:8$ (active)
Y. Jafari et al., 2013	TP-specific tests	Not mentioned	Not specified	Not specified
Carmen Phang Romero Casas et al., 2018	TPHA, FTA-Abs, TPPA	VDRL, RPR	Traditional	Nontreponemal positive confirmed by treponemal

Citation	Primary Treponemal Reference Test	Nontreponemal Test	Testing Algorithm	Definition of Positive Syphilis Status
J. Tucker et al., 2010	Treponemal test	Non-treponemal test	Traditional	Sensitive non-treponemal then specific treponemal
D. Mabey et al., 2006	TPHA, FTA-Abs	RPR, VDRL	Treponemal as gold standard	Not specified
C. Bristow et al., 2020	TPPA, FTA-Abs, TPHA, TP-EIA	RPR	Traditional and Reverse	Both treponemal and nontreponemal reactive
E. Nakku-Joloba et al., 2016	TPHA	RPR	Sequential	RPR and TPHA positive
A. Herring et al., 2006	TPHA, TPPA	RPR	Not specified	Not specified
Kristen L Hess et al., 2014	TPPA	RPR	Parallel comparison	TPPA+/RPR $\geq 1:8$ (for active)
Sharmistha Mishra et al., 2009	TPHA	RPR	Not specified	Reactive RPR and TPHA

Citation	Primary Treponemal Reference Test	Nontreponemal Test	Testing Algorithm	Definition of Positive Syphilis Status
M. G. Vaulet et al., 2017	TPPA, TPHA	RPR	Not specified	TPPA+/RPR+ >1:4 (active)
P. Smit et al., 2013	TPPA	RPR	Not specified	TPPA positive + RPR $\geq$ 1/8 (active)
Y. Fakile et al., 2019	TP-PA	RPR	Not specified	Both RPR and TP-PA reactive
F. Bocoum et al., 2015	TPHA	VDRL	TPHA as gold standard	Not specified
Mark J. Siedner et al., 2004	TP-PA	Not mentioned	Not specified	Not specified
L. Causer et al., 2015	Treponemal immunoassays	RPR	Not specified	Concordance with conventional tests by category
A. Benzaken et al., 2008	FTA-Abs	VDRL	Not specified	FTA-Abs and VDRL positive (active)
J. Matthias et al., 2016	Trep-Sure EIA	RPR	Modified traditional	All specimens received treponemal testing

Citation	Primary Treponemal Reference Test	Nontreponemal Test	Testing Algorithm	Definition of Positive Syphilis Status
B. Mehra et al., 2016	TPHA	VDRL	TPHA as gold standard	
K. Nessa et al., 2008	TPHA	RPR	Gold standard combination	RPR and TPHA positive
B. Kashyap et al., 2015	TPHA	VDRL	Traditional	VDRL screening, TPHA confirmation
B. West et al., 2002	TPHA	RPR	Not specified	Laboratory RPR and TPHA positive (active)
R. Tsang et al., 2022a	CMIA	RPR, VDRL	Reverse sequence	Active defined by VDRL >1:4
E. Zulu et al., 2024	Not specified (rapid treponemal test on-site)	RPR	Reverse sequence	RDT positive / RPR positive (active)

Overall Diagnostic Accuracy of Treponemal POC Tests

Treponemal-only POC tests generally demonstrated high specificity, often exceeding 95%, but showed more variability in sensitivity across studies. For instance, a 2013 meta-analysis found specificities for brands like Syphicheck and VisiTest were over 99% for both serum and whole

blood, while sensitivities ranged from 74% to 90%. In another systematic review, the pooled specificity for immunochromatographic strip (ICS) tests was 0.98, with a pooled sensitivity of 0.85.

The Abbott Determine Syphilis TP test was one of the most frequently evaluated treponemal POCs. Studies reported sensitivities ranging from 59.6% to 100% and specificities from 94.1% to 100% depending on the population, specimen, and reference standard. For example, in a study of pregnant women in Bolivia, it showed a sensitivity of 91.8% and specificity of 98.5% using fingerstick whole blood. In a laboratory evaluation of archived sera, its sensitivity was 97.2% and specificity was 94.1%.

SD Bioline Syphilis 3.0 was another commonly studied test. Sensitivities reported for this test varied from 66.7% to 95.7%, with specificities consistently high, generally above 95%. The specimen type appeared to influence performance, with one study noting lower sensitivity on fingerprick blood compared to serum.

Predictive values are highly dependent on the prevalence of syphilis in the tested population. In low-prevalence settings like antenatal clinics in Bolivia (3.8% prevalence), the Determine test had a high negative predictive value (NPV) of 99.7% but a moderate positive predictive value (PPV) of 71.0%. This highlights that while these tests are effective for ruling out syphilis, a positive result requires laboratory confirmation, especially in populations with low disease prevalence.

Citation	Test Name	Specimen Type	Sensitivity (95% CI)	Specificity (95% CI)	PPV	NPV	Prevalence
F. Tinajeros et al., 2006	Determine Syphilis TP	Whole blood	91.8% (88.4-94.5)	98.5% (98.2-98.8)	71.0%	99.7%	3.8%

Citation	Test Name	Specimen Type	Sensitivity (95% CI)	Specificity (95% CI)	PPV	NPV	Prevalence
P. Montoya et al., 2006	ICS Test	Not specified	84.1%	Not mentioned	Not mentioned	Not mentioned	Not mentioned
Y. Jafari et al., 2013	Determine	Serum	90.0% (80.5-95.2)	94.2% (89.3-97.7)	Not mentioned	Not mentioned	Not mentioned
Y. Jafari et al., 2013	SD Bioline	Serum	87.1% (75.7-94.5)	95.9% (89.9-99.5)	Not mentioned	Not mentioned	Not mentioned
Y. Jafari et al., 2013	VisiTest	Serum	85.1% (72.8-92.6)	96.5% (91.9-99.3)	Not mentioned	Not mentioned	Not mentioned
Carmen Phang Romero Casas et al., 2018	ICS Tests (pooled)	Fingerprick blood	85% (73-92)	98% (95-99)	Not mentioned	Not mentioned	Not mentioned
D. Mabey et al., 2006	Determine Syphilis TP	Whole blood	64.3% (59.6-88.5)	98.4% (97.9-99.4)	Not mentioned	Not mentioned	Varied

Citation	Test Name	Specimen Type	Sensitivity (95% CI)	Specificity (95% CI)	PPV	NPV	Prevalence
D. Mabey et al., 2006	SD Bioline Syphilis 3.0	Whole blood	88.0% (85.7-100)	98.8% (98.1-99.4)	Not mentioned	Not mentioned	Varied
C. Bristow et al., 2020	Syphilis Health Check	Not specified	87.7% (71.8-97.2)	96.7% (91.9-99.2)	Not mentioned	Not mentioned	Not mentioned
J. G. García Luna et al., 2023	SD Bioline 3.0	Capillary blood	96.4% (91.1-99.0)	98.3% (94.1-99.0)	Not mentioned	Not mentioned	45.9%
J. G. García Luna et al., 2023	Determine Syphilis TP	Capillary blood	87.5% (79.9-93.0)	99.2% (95.5-100)	Not mentioned	Not mentioned	45.9%
Rujirek Kamolratana et al., 2023	Determine Syphilis TP	Whole blood	85.7% (63.7-97.0)	100% (98.0-100.0)	Not mentioned	Not mentioned	10.5%

Citation	Test Name	Specimen Type	Sensitivity (95% CI)	Specificity (95% CI)	PPV	NPV	Prevalence
Rujirek Kamolratana et al., 2023	Bioline Syphilis 3.0	Whole blood	66.7% (43.0-85.4)	100% (98.0-100.0)	Not mentioned	Not mentioned	10.5%
L. Causer et al., 2014	Determine	Serum	97.3% (95.8–98.3)	96.4% (94.1–97.8)	Not mentioned	Not mentioned	61.2%
L. Causer et al., 2014	Bioline	Serum	87.8% (85.1–90.0)	98.5% (96.8–99.3)	Not mentioned	Not mentioned	61.2%
E. Ángel-Müller et al., 2021	POC tests (pooled)	Not specified	86% (79-91)	98% (96-99)	Not mentioned	Not mentioned	Not mentioned
A. Zorzi et al., 2017	SD Bioline 3.0	Serum	80.0-82.9%	>99%	93.9-100%	>90%	17.6%
A. Zorzi et al., 2017	SD Bioline 3.0	Fingerprick blood	51.4-54.3%	>99%	Not mentioned	>90%	17.6%

Diagnostic Accuracy of Dual Treponemal/Nontreponemal POC Tests

Dual POC tests that separately detect treponemal and nontreponemal antibodies offer the clinical advantage of potentially distinguishing active from past/treated syphilis in a single test. The performance of these tests is assessed for each component.

The Chembio DPP Syphilis Screen & Confirm assay is a frequently evaluated dual test. In a multisite study from China, the treponemal component demonstrated high sensitivity (94.6%-96.7%) and specificity (99.1%-99.6%) across plasma, venous whole blood, and fingerprick blood specimens. The nontreponemal component had lower sensitivity (85.8%-88.4%) but still good specificity (94.4%-96.1%). A study in Canadian Arctic communities found similar results for the treponemal line (sensitivity 78-81%, specificity 99%), but the nontreponemal line sensitivity was higher for serum (94%) than for whole blood (79%). Performance of the nontreponemal component is consistently better in patients with high RPR/VDRL titers ($\geq 1:8$), often achieving sensitivities near or at 100%.

Other dual tests that also detect HIV antibodies, such as the SD Bioline HIV/Syphilis Duo and Chembio DPP HIV-Syphilis, have also been evaluated. In field evaluations in Zambia and South Africa, the syphilis component sensitivity of these tests was relatively low (66.0-68.6%) when compared to a treponemal reference standard alone, but improved to over 80% when defining active syphilis as cases with higher RPR titers. For instance, one study reported sensitivities of 81.6% (SD Bioline) and 84.7% (Chembio) for detecting active syphilis. Specificities for the syphilis component of these dual tests were consistently high, typically above 97%.

The clinical utility of these tests lies in their ability to provide an on-the-spot result that suggests the need for immediate treatment (treponemal and nontreponemal positive) versus simply indicating past exposure (treponemal positive, nontreponemal negative). However, the lower sensitivity of the nontreponemal line, especially at low titers, means that some active infections might be misclassified as past infections.

Citation	Test Name	Component	Sensitivity (95% CI)	Specificity (95% CI)	Notes on Active Syphilis Detection
Yueping Yin et al., 2013	DPP Syphilis Screen & Confirm	Treponemal (WB)	96.7% (95.1- 97.9)	99.3% (98.3- 99.7)	Sensitivity of nontreponema 1 line was 100% for TRUST titers >1:4.
Yueping Yin et al., 2013	DPP Syphilis Screen & Confirm	Nontreponema 1 (WB)	87.2% (84.0- 89.9)	94.4% (92.6- 95.8)	Compared to TRUST reference standard.
C. Caya et al., 2023	DPP Syphilis Screen & Confirm	Treponemal (WB)	81% (63-93)	99% (95-100)	Sensitivity increased to 92% for RPR titers $\geq$ 1:8.
C. Caya et al., 2023	DPP Syphilis Screen & Confirm	Nontreponema 1 (WB)	79% (60-92)	Not reported	Sensitivity increased to 92% for RPR titers $\geq$ 1:8.

Citation	Test Name	Component	Sensitivity (95% CI)	Specificity (95% CI)	Notes on Active Syphilis Detection
M. Kasaro et al., 2018	Chembio DPP HIV-Syphilis	Syphilis (Treponemal)	68.6% (61.9-74.6)	98.5% (97.8-98.9)	Sensitivity was 84.7% for active syphilis (RPR $\geq$ 1:4).
M. Kasaro et al., 2018	SD Bioline HIV/Syphilis Duo	Syphilis (Treponemal)	66.2% (59.4-72.4)	97.2% (96.4-97.9)	Sensitivity was 81.6% for active syphilis (RPR $\geq$ 1:4).
R. Kularatne et al., 2024	SD Bioline HIV/Syphilis Duo	Syphilis (Treponemal)	66.0% (57.7-73.4)	>98%	Sensitivity was 78.0% for active syphilis (RPR $\geq$ 1:8).
R. Kularatne et al., 2024	Chembio DPP HIV-Syphilis	Syphilis (Treponemal)	67.9% (58.2-76.3)	>98%	Sensitivity was 81.0% for active syphilis (RPR $\geq$ 1:8).

Citation	Test Name	Component	Sensitivity (95% CI)	Specificity (95% CI)	Notes on Active Syphilis Detection
L. Causer et al., 2015	DPP Screen & Confirm Assay	Treponemal	89.8% (87.3-91.9)	99.3% (97.0-99.9)	49.8% of past/treated infections were incorrectly identified as active.
L. Causer et al., 2015	DPP Screen & Confirm Assay	Nontreponema 1	94.2% (91.8-96.0)	62.2% (57.5-66.6)	Lower specificity suggests potential for false positives for active infection.

Citation	Test Name	Component	Sensitivity (95% CI)	Specificity (95% CI)	Notes on Active Syphilis Detection
Meika EI Richmond et al., 2024	DPP Syphilis Screen & Confirm	Nontreponema 1 (visual)	42.86% (low RPR), 52.5% (overall)	98.33% (serum)	Sensitivity increased with RPR titer >1:4; Micro Reader improved sensitivity to 90.0%.

Performance by Syphilis Stage and Serological Status

The diagnostic accuracy of syphilis POC tests often varies depending on the clinical stage of the infection and the patient's serological profile, particularly the nontreponemal antibody titer. Several studies have reported that test sensitivity is generally lower in primary syphilis compared to secondary and later stages. This is likely due to the time it takes for a detectable antibody response to develop. For instance, a laboratory evaluation found that while the Determine test achieved 100% sensitivity for both primary and secondary syphilis, three other treponemal tests had reduced sensitivity for primary stage (80.4%–90.2%) compared to secondary stage (94.3%–98.6%) infections.

Performance is strongly correlated with nontreponemal antibody titers (e.g., RPR or VDRL). POC tests, particularly the nontreponemal component of dual tests, demonstrate significantly higher sensitivity in patients with high titers (typically $\geq 1:8$). Sensitivities often approach or reach 100% in high-titer cases, which are more likely to represent active, infectious syphilis. Conversely,

sensitivity is considerably lower for cases with low titers or nonreactive nontreponemal tests, which may represent very early infection, late/latent infection, or previously treated infection. For example, one study of dual POC tests found that sensitivity for treponemal antibodies improved from 54.1% in RPR-nonreactive cases to 98.3% in cases with an RPR titer $\geq 1:8$. Similarly, another study found the treponemal line sensitivity was significantly higher in high-RPR titer infections (94.6-99.5%) compared to RPR-nonreactive infections (76.3-92.9%). This difference has important clinical implications, as tests are most sensitive for the high-titer infections that pose the greatest public health risk for transmission.

Citation	Test Name	Stage/Titer Category	Sensitivity (95% CI)	Sample Size
L. Causer et al., 2014	Determine	Primary Syphilis	100%	41
L. Causer et al., 2014	Determine	Secondary Syphilis	100%	71
L. Causer et al., 2014	Onsite	Primary Syphilis	90.2%	41
L. Causer et al., 2014	Onsite	Secondary Syphilis	98.6%	71
L. Causer et al., 2014	DPP	Primary Syphilis	80.4%	41
L. Causer et al., 2014	DPP	Secondary Syphilis	94.3%	71

Citation	Test Name	Stage/Titer Category	Sensitivity (95% CI)	Sample Size
L. Causer et al., 2014	Bioline	Primary Syphilis	77.3% (61.9-88.5)	44
L. Causer et al., 2014	Bioline	Secondary Syphilis	94.3%	71
L. Causer et al., 2014	All 4 Tests (pooled)	High RPR Titer ($\geq 1:8$)	94.6-99.5%	344
L. Causer et al., 2014	All 4 Tests (pooled)	RPR Non-reactive	76.3-92.9%	237
A. Singh et al., 2023	MedMira Multiplo	RPR $\geq 1:8$	98.3% (95.7-99.3)	235
A. Singh et al., 2023	MedMira Multiplo	RPR Non-reactive	54.1% (44.8-63.2)	109
A. Singh et al., 2023	INSTI Multiplex	RPR $\geq 1:8$	97.9% (95.1-99.1)	230
A. Singh et al., 2023	INSTI Multiplex	RPR Non-reactive	28.4% (20.8-37.5)	109
C. Caya et al., 2023	DPP Syphilis S&C (Treponemal)	RPR $\geq 1:8$	92-93%	Not specified

Citation	Test Name	Stage/Titer Category	Sensitivity (95% CI)	Sample Size
C. Caya et al., 2023	DPP Syphilis S&C (Nontreponemal)	RPR $\geq 1:8$	92-100%	Not specified
SM Herbst De Cortina et al., 2016	INSTI Multiplex	RPR $\geq 1:8$	97.3%	Not specified
SM Herbst De Cortina et al., 2016	INSTI Multiplex	RPR Non- reactive	66.7%	Not specified
C. Stafylis et al., 2019	INSTI Multiplex	RPR $\geq 1:8$	100% (78.2-100)	Not specified
Anastasia Eliopoulos et al., 2025	INSTI Multiplex	RPR $\geq 1:8$	93.8-100%	Not specified
Anastasia Eliopoulos et al., 2025	INSTI Multiplex	RPR $\leq 1:2$	7.6-56.5%	Not specified

Performance by Specimen Type and Testing Conditions

The diagnostic accuracy of POC tests can be influenced by the type of specimen used and the environment in which the test is performed. Studies comparing performance across specimen types have found that tests generally perform better with serum or plasma compared to whole blood,

particularly capillary blood from a fingerprick. One meta-analysis explicitly stated that higher accuracy was found in serum compared to whole blood. Another study reported that the sensitivity of the SD Bioline test was considerably lower on fingerprick blood (51.4%-54.3%) than on serum (80.0%-82.9%). In contrast, some tests, like the Chembio DPP assay, have been shown to exhibit similar sensitivity values for serum and fingerprick samples in certain evaluations. The performance of the Abbott Determine TP test on fingerstick specimens was found to be excellent in one study, with 100% sensitivity and specificity. A study evaluating the Hightop RDT in Cameroon also reported a sensitivity of 100% in symptomatic individuals.

Performance differences between laboratory and field settings have been observed. Laboratory-based evaluations, conducted by trained technicians in controlled environments, may yield higher accuracy estimates than field evaluations performed by non-laboratorians under real-world conditions. For instance, a field evaluation of the SD Bioline Duo test reported a lower sensitivity for syphilis (66.7%) compared to published laboratory evaluations. One study also found that the sensitivity of a POC test conducted by midwives in primary health facilities was low (25%) when compared to the TPHA reference standard. These findings highlight the importance of thorough training, clear instructions, and quality assurance programs when implementing POC tests in field settings.

Citation	Test Name	Specimen Type	Testing Setting	Sensitivity (95% CI)	Specificity (95% CI)
A. Zorzi et al., 2017	SD Bioline 3.0	Serum	Field	80.0-82.9%	>99%
A. Zorzi et al., 2017	SD Bioline 3.0	Fingerprick blood	Field	51.4-54.3%	>99%

Citation	Test Name	Specimen Type	Testing Setting	Sensitivity (95% CI)	Specificity (95% CI)
C. Caya et al., 2023	DPP Syphilis S&C (Treponemal)	Serum	Field	78% (61-90)	99% (95-100)
C. Caya et al., 2023	DPP Syphilis S&C (Treponemal)	Whole blood	Field	81% (63-93)	99% (95-100)
J. G. García Luna et al., 2023	Determine Syphilis TP	Capillary blood	Field	87.5% (79.9-93.0)	99.2% (95.5-100)
J. G. García Luna et al., 2023	Determine Syphilis TP	Serum	Lab	99.1% (95.1-100)	96.7% (91.8-99.1)
Y. Jafari et al., 2013	Determine	Serum	Field	90.0% (80.5-95.2)	94.2% (89.3-97.7)
Y. Jafari et al., 2013	Determine	Whole blood	Field	86.3% (77.3-91.7)	95.9% (92.4-97.7)
D. Mabey et al., 2006	Determine Syphilis TP	Serum (Lab)	Lab	84.8% (76.0-91.2)	98.4% (97.3-99.1)
D. Mabey et al., 2006	Determine Syphilis TP	Whole blood (Field)	Field	72.5% (59.6-88.5)	98.5% (97.9-99.4)

Citation	Test Name	Specimen Type	Testing Setting	Sensitivity (95% CI)	Specificity (95% CI)
Mark J. Siedner et al., 2004	Abbott Determine TP	Venous blood	Lab	88% (81–96)	100%
Mark J. Siedner et al., 2004	Abbott Determine TP	Fingerstick blood	Field	100% (93–100)	100%
R. Lubis et al., 2019	STANDARD Q Syphilis Ab	Serum	Field	91.30%	97.53%
R. Lubis et al., 2019	STANDARD Q Syphilis Ab	Fingerprick blood	Field	84.78%	98.77%
Lin-na Wang et al., 2007	Abbott Determine TP	Serum	Lab	100%	98.9%
Lin-na Wang et al., 2007	Abbott Determine TP	Whole blood	Lab	74.1%	99.5%
Yueping Yin et al., 2013	DPP Syphilis S&C (Treponemal)	Whole blood	Field	96.7% (95.1-97.9)	99.3% (98.3-99.7)
Yueping Yin et al., 2013	DPP Syphilis S&C (Treponemal)	Fingerprick blood	Field	96.4% (93.5-98.0)	99.1% (96.6-99.7)

Performance in Special Populations

The diagnostic accuracy of syphilis POC tests has been assessed in specific populations, notably in individuals with HIV co-infection and in pregnant women, due to the significant public health implications in these groups.

For individuals with HIV co-infection, some studies suggest that test performance may be altered. One evaluation found that the sensitivity of the Determine test was actually higher in HIV-positive persons (96.9-99.2%) compared to HIV-negative persons (94.4-96.3%), though specificity was slightly lower (92.4-95.5% vs. 97.2-100%). Another study reported lower sensitivities for both Bioline and Determine tests in PLWH who were not receiving antiretroviral therapy (ART). The presence of HIV did not significantly affect test sensitivity in a laboratory evaluation, but the Determine test had significantly lower specificity among HIV-positive individuals. Given the high rates of syphilis and HIV co-infection, and the potential for atypical serological responses, understanding test performance in this subgroup is critical.

In pregnant women, POC tests are a key tool for preventing congenital syphilis. Studies conducted in antenatal care settings have generally found good performance. One field evaluation of the SD BIOLINE HIV/Syphilis Duo test in pregnant women in Haiti reported a sensitivity of 100% and a specificity of 96.8% for the syphilis component. A study in Zambia, however, found lower syphilis sensitivities for both the Chembio and SD Bioline dual tests (68.6% and 66.2%, respectively) in a pregnant population, though performance improved for cases of active syphilis. The use of POC tests in antenatal screening has been shown to be feasible and can dramatically increase screening and treatment rates.

Citation	Test Name	Population Subgroup	Sensitivity (95% CI)	Specificity (95% CI)	Statistical Comparison to Reference Population

Citation	Test Name	Population Subgroup	Sensitivity (95% CI)	Specificity (95% CI)	Statistical Comparison to Reference Population
T. Diaz et al., 2004	Determine Syphilis TP	HIV-positive	96.9-99.2%	92.4-95.5%	Sensitivity higher, specificity lower vs. HIV-negative.
J. G. García Luna et al., 2023	Bioline & Determine	PLWH not on ART	87.1% & 64.5%	Not specified	p<0.001 vs. those on ART.
C. Bristow et al., 2015a	SD BIOLINE HIV/Syphilis Duo	Pregnant Women	100% (81.5-100)	96.8% (83.3-99.9)	Performance varied from the overall study population.
M. Kasaro et al., 2018	ChemBio DPP HIV-Syphilis	Pregnant Women	68.6% (61.9-74.6)	98.5% (97.8-98.9)	Not specified.
M. Kasaro et al., 2018	SD Bioline HIV/Syphilis Duo	Pregnant Women	66.2% (59.4-72.4)	97.2% (96.4-97.9)	Not specified.

Citation	Test Name	Population Subgroup	Sensitivity (95% CI)	Specificity (95% CI)	Statistical Comparison to Reference Population
D. C. Soares et al., 2023	SD BIOLINE HIV/Syphilis Duo	Pregnant Women	Not specified	Not specified	Not specified.
D. C. Soares et al., 2023	SD BIOLINE HIV/Syphilis Duo	FSW	Not specified	Not specified	Not specified.
D. C. Soares et al., 2023	SD BIOLINE HIV/Syphilis Duo	MSM	Not specified	Not specified	Not specified.
Ricardo Cristiano Brum et al., 2021	DPP Syphilis Screen & Confirm	HIV-positive	100%	91.9-93.1%	Not specified.
Ricardo Cristiano Brum et al., 2021	DPP Syphilis Screen & Confirm	Pregnant Women	100%	98.2-99.4%	Not specified.

Methodological Quality Assessment

The methodological quality of the included studies varied. Many studies were prospective cross-sectional diagnostic accuracy studies, which is an appropriate design. Several evaluations

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relied on panels of archived or stored sera, which may not fully reflect the performance of tests on fresh whole blood specimens in field settings.

Blinding of test readers was not consistently reported. While some studies explicitly stated that laboratory personnel were blinded to POC test results and/or that POC test operators were blinded to reference results, this was often unclear in other reports. A systematic review noted that the risk of bias related to the index test and reference standard was unclear in a majority of the articles included. Another review judged one study at high risk of bias for patient selection due to exclusion of women with a previous history of syphilis, and another for flow and timing as not all patients were included in the final analysis.

Other potential sources of bias include the time interval between the POC test and collection for the reference standard, specimen storage conditions that could degrade antibodies, and the incomplete application of the reference standard to all participants (verification bias). The handling of indeterminate or invalid results was also not always clearly described, which can impact accuracy estimates. Overall, while many studies provided valuable data, limitations in reporting and potential biases should be considered when interpreting the synthesized evidence.

Citation	Patient Selection Bias Risk	Index Test Bias Risk	Reference Standard Bias Risk	Flow/Timing Bias Risk	Overall Quality Rating
F. Tinajeros et al., 2006	Low	Unclear	Unclear	Low	Not specified
Yueping Yin et al., 2013	Low	Unclear (Blinded reader)	Low	Low	Not specified

Citation	Patient Selection Bias Risk	Index Test Bias Risk	Reference Standard Bias Risk	Flow/Timing Bias Risk	Overall Quality Rating
J. G. García Luna et al., 2023	Low	Low (serum) / High (CB)	Low	Low	Not specified
R. Kularatne et al., 2024	Low	Low	Low	Low	Not specified
Y. Jafari et al., 2013	Varies (unclear in 61%)	Varies (unclear in 76%)	Varies (unclear in 76%)	Not specified	Not specified
Carmen Phang Romero Casas et al., 2018	One study high risk	Low/Unclear	Low/Unclear	One study high risk	Low to moderate
D. Mabey et al., 2006	Low	Unclear	Low	Low	Not specified
A. Herring et al., 2006	Not applicable (archived sera)	Low (Blinded)	Low	Low	Not specified
Kristen L Hess et al., 2014	Low	Unclear	Low	Low	Not specified

Citation	Patient Selection Bias Risk	Index Test Bias Risk	Reference Standard Bias Risk	Flow/Timing Bias Risk	Overall Quality Rating
L. Causer et al., 2014	Not applicable (archived sera)	Low (Blinded)	Low	Low	Not specified
M. Kalou et al., 2016	Low	Unclear	Low	Low	Not specified
I. Olugbenga et al., 2018	Low	Unclear	Low	Low	Not specified
S. Mahomed et al., 2025	Low	Low (Blinded)	Low (Blinded)	Low	Not specified

Synthesis of Findings

Overall, the evidence indicates that rapid POC tests for syphilis can be effective tools for screening, particularly in settings where laboratory infrastructure is limited. Treponemal-only tests generally demonstrate high specificity, making them useful for ruling out infection. However, their sensitivity is more variable and can be lower in early primary syphilis and when using whole blood specimens compared to serum. A significant limitation of treponemal-only tests is their inability to distinguish between active and past, treated infections, which can lead to unnecessary treatment.

Dual treponemal/nontreponemal POC tests address this limitation and show promise for identifying probable active infections that require immediate treatment. The treponemal component of these tests typically performs with high diagnostic accuracy, similar to treponemal-only tests. The nontreponemal component, however, generally exhibits lower sensitivity, especially in cases with low RPR/VDRL titers. Performance for detecting active infection, often defined by high

nontreponemal titers ($\geq 1:8$), is substantially better, with sensitivities frequently exceeding 90%. This suggests that dual tests are most effective at identifying patients with the highest bacterial load who are most infectious.

The choice between a treponemal-only and a dual POC test involves a trade-off. Treponemal-only tests are simpler and may have slightly higher sensitivity for any treponemal antibody exposure, but risk overtreating past infections. Dual tests can reduce overtreatment but may miss some low-titer active infections due to the lower sensitivity of the nontreponemal line. The optimal choice depends on the testing context, the prevalence of active versus past syphilis in the population, and the public health goals of the screening program. In all scenarios, confirmatory laboratory testing is recommended for reactive POC test results, particularly in low-prevalence settings where the positive predictive value may be reduced.

DISCUSSION

This systematic review synthesises diagnostic accuracy evidence from 159 studies evaluating rapid point-of-care syphilis tests across diverse populations, geographical settings, and testing conditions. The findings confirm that rapid POCTs represent valuable tools for syphilis screening in resource-limited settings, but also reveal important performance limitations, sources of heterogeneity, and evidence gaps requiring consideration for optimal implementation.

Principal Findings and Contextualisation

Treponemal-only rapid tests demonstrate consistently high specificity, typically exceeding 95% across most evaluations, with many studies reporting specificities approaching 99–100%. This finding aligns with previous meta-analyses (Y. Jafari et al., 2013; C. Bristow, J. Klausner, and Anthony Tran, 2020) and supports the utility of these tests for ruling out syphilis infection in screening applications. The high negative predictive value observed in low-prevalence populations, such as the 99.7% NPV reported for Determine TP in Bolivian antenatal clinics with 3.8%

prevalence (F. Tinajeros et al., 2006), indicates that negative results can be confidently accepted without confirmatory testing in most settings.

However, the substantial heterogeneity in treponemal test sensitivity—ranging from 59.6% to 100% across studies—represents a critical finding with major operational implications. This variability substantially exceeds the range reported in earlier meta-analyses and reflects the cumulative impact of multiple performance modifiers identified in this review. The Abbott Determine TP test, the most extensively evaluated treponemal POCT with 26 included studies, exemplified this heterogeneity with reported sensitivities from 59.6% (D. Mabey et al., 2006) to 100% (Mark J. Siedner et al., 2004; Lin-na Wang et al., 2007). Understanding the sources of this variability is essential for appropriate test selection and interpretation.

Performance Modifiers and Clinical Implications

Syphilis Stage and Antibody Titre

The strong association between test sensitivity and syphilis stage represents one of the most clinically significant findings. Sensitivity is consistently lowest in primary syphilis, with one study reporting Determine TP sensitivity of 77.3% for primary infections compared to 94.3% for secondary infections (L. Causer et al., 2014). This gradient reflects the time required for detectable antibody responses to develop following infection. The implications for early syphilis control are substantial: individuals with primary syphilis—who are often most infectious due to ulcerative lesions—are at highest risk of false-negative POCT results, potentially leading to continued transmission. Clinicians should maintain high suspicion for primary syphilis despite negative rapid test results in appropriate clinical contexts, and consider direct antigen detection or PCR where available (Stephanie F. Sweitzer et al., 2025).

The relationship between nontreponemal antibody titre and test performance is even more pronounced, particularly for dual test nontreponemal components. Across multiple studies, sensitivity for detecting nontreponemal antibodies increased dramatically with rising RPR titre,

frequently reaching 92–100% at titres $\geq 1:8$ compared to 42.9–79% at lower titres (Yueping Yin et al., 2013; C. Caya et al., 2023; Meika El Richmond et al., 2024). This titre-dependent sensitivity has dual implications. Favourably, dual tests perform optimally for detecting high-titre active infections posing greatest transmission risk and requiring urgent treatment. However, they systematically miss low-titre active infections, including early seroconversion, late latent syphilis, and some early latent cases, potentially resulting in untreated infections and continued transmission risk. The INSTI Multiplex test demonstrated particularly marked titre dependence, with sensitivity of 97.9–100% at RPR $\geq 1:8$ but only 28.4–66.7% in RPR-nonreactive treponemal-positive individuals (A. Singh et al., 2023; SM Herbst De Cortina et al., 2016; Anastasia Eliopoulos et al., 2025).

This titre-performance relationship fundamentally challenges the premise that dual tests can reliably distinguish active from past-treated syphilis at the point of care. While a dual-test result showing treponemal-positive/nontreponemal-positive reasonably predicts active infection, a treponemal-positive/nontreponemal-negative result cannot reliably exclude active infection, particularly in populations where low-titre active syphilis is prevalent. Programmes adopting dual tests must establish confirmatory testing pathways for treponemal-positive/nontreponemal-negative results rather than automatically classifying these as past-treated infection (E. Zulu et al., 2024).

Specimen Type Effects

This review provides robust evidence that specimen type significantly influences test performance, with fingerprick capillary whole blood consistently yielding lower sensitivity than venous whole blood, serum, or plasma. The SD Bioline Syphilis 3.0 test demonstrated the most dramatic specimen-dependent variation: one study reported sensitivity of 80.0–82.9% on serum versus only 51.4–54.3% on fingerprick blood in the same population (A. Zorzi et al., 2017). Other tests, including Abbott Determine TP and STANDARD Q Syphilis Ab, showed similar though less pronounced decrements (Mark J. Siedner et al., 2004; R. Lubis et al., 2019).

This finding has critical operational implications. The primary advantage of POCTs—immediate testing from fingerprick blood without phlebotomy or centrifugation—is paradoxically associated with reduced accuracy. Potential explanations include lower antibody concentrations in capillary blood, interference from haemoglobin, smaller specimen volumes, and greater operator difficulty in precise specimen application. While some newer tests such as the Chembio DPP platform have demonstrated more comparable serum and fingerprick performance (Yueping Yin et al., 2013), substantial specimen-related accuracy gaps persist for many commercially available tests. Programmes must balance the operational benefits of fingerprick testing against the measurable sensitivity loss and consider whether venous collection with serum/plasma separation might be warranted in specific applications, particularly for prevalence surveys, individual case management, and evaluations of elimination programmes.

Laboratory Versus Field Performance

The consistent finding that laboratory-based evaluations report higher accuracy than field-based evaluations reflects the gap between test performance under ideal conditions and real-world effectiveness. This discrepancy likely reflects multiple factors: operator training and experience, availability of precise timing devices, environmental conditions (temperature, humidity), competing clinical demands affecting test procedure fidelity, and differences in specimen quality between archived serum panels and fresh fingerprick blood. The low sensitivity (25%) reported for POC testing conducted by midwives in Ghanaian primary health facilities compared to TPHA reference standard (A W Dzokoto et al., 2013) represents an extreme example but illustrates the magnitude of potential performance degradation in routine implementation.

This finding strongly supports investment in comprehensive training programmes, competency assessment, supportive supervision, and external quality assurance (EQA) schemes for POCT programmes. The successful implementation of dried tube specimen EQA programmes for syphilis POCTs in indigenous populations in the Brazilian Amazon (A. Benzaken, M. Bazzo, E. Galbán, I. Pinto, C. L. Nogueira, et al., 2013) demonstrates that such quality assurance is feasible

even in remote, resource-constrained settings and should be considered an essential programme component rather than an optional enhancement.

Performance in Special Populations

HIV Co-infection

The evidence regarding POCT performance in PLWH is mixed and insufficient to support definitive conclusions. Some studies report preserved or enhanced sensitivity in HIV-positive individuals, potentially due to polyclonal B-cell activation and higher antibody levels (T. Diaz et al., 2004). Conversely, other studies report reduced sensitivity, particularly among PLWH not receiving antiretroviral therapy, possibly reflecting impaired humoral immune responses (J. G. García Luna et al., 2023). Specificity reductions in HIV-positive populations have also been reported, potentially due to cross-reactivity or higher prevalence of other conditions producing biological false-positive results.

Given the high syphilis-HIV co-infection rates globally and the concentration of syphilis burden among key populations with elevated HIV prevalence, this evidence gap is concerning. Future studies should systematically report POCT performance stratified by HIV status, ART receipt, CD4 count, and HIV viral load where possible. Until such evidence accumulates, programmes serving populations with high HIV prevalence should maintain robust confirmatory testing algorithms and exercise caution in interpreting reactive POCT results.

Pregnancy

Pregnant women represent the most important target population for syphilis POCTs given the objective of congenital syphilis elimination. Available evidence generally supports acceptable POCT performance in antenatal populations, with some studies reporting excellent sensitivity (100% for SD BIOLINE HIV/Syphilis Duo in Haiti; C. Bristow, L. Severe, et al., 2015) and others reporting substantially lower sensitivity (66.2–68.6% for dual tests in Zambia; M. Kasaro et al.,

2018). These discrepancies likely reflect differences in study population characteristics (syphilis stage distribution, RPR titre profiles, HIV co-infection rates), test brands, operator training, and reference standard definitions. Importantly, the programmatic effectiveness of antenatal POCT implementation—demonstrated through increased screening coverage, reduced loss-to-follow-up, and increased treatment rates—may be as important as diagnostic accuracy in determining public health impact (Dana Brandenburger and Ambrosino, 2021).

Methodological Quality and Evidence Gaps

This review identified several persistent methodological limitations in the primary literature. Incomplete reporting of blinding procedures was widespread, with over three-quarters of studies in one meta-analysis having unclear risk of bias for index test and reference standard domains (Y. Jafari et al., 2013). Verification bias—where not all participants receive the reference standard—was identified in several studies, potentially inflating accuracy estimates. The handling of invalid, indeterminate, or discordant results was frequently inadequately described. Studies using archived serum panels, while methodologically convenient and enabling larger sample sizes, cannot adequately assess test performance on fingerprick whole blood or reflect real-world operator variability.

Perhaps most significantly, marked heterogeneity in reference standard definitions of syphilis and active infection complicates cross-study comparisons and meta-analytic synthesis. While most studies used TPPA or TPHA as treponemal reference standards, definitions of active syphilis ranged from any reactive nontreponemal test regardless of titre, to RPR $\geq 1:4$, to RPR $\geq 1:8$, to combinations of serological and clinical criteria. This heterogeneity fundamentally limits comparability of accuracy estimates across studies and may explain some observed performance variation. An international consensus on standardised case definitions for diagnostic accuracy studies in syphilis is urgently needed.

Novel and Emerging Technologies

This review identified several emerging technologies with potential to address current POCT limitations. Smartphone-based electronic readers for dual HIV/syphilis rapid tests have demonstrated excellent correlation with visual interpretation while potentially improving sensitivity for weak-positive bands and enabling automated data capture (L. Allan-Blitz et al., 2018; S. Herbst de Cortina et al., 2017). Molecular POCT platforms including the GeneSoC rapid quantitative PCR system (H. Mizushina et al., 2025) and paper-based loop-mediated isothermal amplification (LAMP) assays (Krishnamoorthy Priya et al., 2025) offer potential for direct pathogen detection, circumventing the serological window period and distinguishing active from past infection. Novel biomarker approaches including treponemal IgA detection (Yan Han et al., 2018) may enable earlier infection detection. While these technologies require further evaluation in field conditions, they represent important future directions.

Strengths and Limitations of This Review

This review has several strengths, including its comprehensive scope (159 studies), detailed stratification by multiple performance modifiers, separate analysis of treponemal and nontreponemal test components, inclusion of both published and grey literature, and systematic quality assessment. However, limitations must be acknowledged. Considerable methodological and clinical heterogeneity precluded formal meta-analysis for many comparisons. Variation in reference standards and case definitions limited comparability across studies. Publication bias remains possible despite comprehensive search strategies. Many studies reported multiple test evaluations or subgroup analyses, creating potential for unit-of-analysis issues. The quality and completeness of reporting in primary studies varied substantially, limiting the robustness of some conclusions.

CONCLUSION AND RECOMMENDATIONS

Summary of Evidence

This comprehensive systematic review of 159 diagnostic accuracy studies provides the most detailed synthesis to date of rapid point-of-care syphilis test performance. Treponemal-only tests

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demonstrate high specificity (typically 95–100%) and moderate-to-high but variably sensitive (60–100%) detection of treponemal antibody, with performance significantly influenced by specimen type, syphilis stage, and test brand. The Abbott Determine TP and SD Bioline Syphilis 3.0 tests have been most extensively evaluated and demonstrate acceptable accuracy for screening applications, particularly for ruling out infection given their high negative predictive value in low-to-moderate prevalence populations.

Dual treponemal/nontreponemal tests, including the Chembio DPP Syphilis Screen & Confirm and SD Bioline HIV/Syphilis Duo, offer the important advantage of providing simultaneous information about treponemal exposure and probable disease activity. Their treponemal components perform comparably to treponemal-only tests. However, their nontreponemal components demonstrate substantially lower sensitivity (43–94%) that is highly titre-dependent, with excellent performance at high RPR titres ($\geq 1:8$) but poor sensitivity at low titres and in RPR-nonreactive treponemal-positive individuals. This limitation means that some active, potentially infectious syphilis cases will be misclassified as past infection by dual tests.

Test sensitivity is consistently higher in secondary syphilis, in high-titre infections, and when testing serum or plasma rather than fingerprick whole blood. Field-based evaluations under real-world conditions consistently report lower accuracy than laboratory-based evaluations using archived specimens. Performance in key populations—particularly PLWH—remains incompletely characterised with conflicting evidence. Methodological quality is variable, with incomplete blinding reporting and heterogeneous reference standard definitions representing major limitations.

Recommendations for Practice

Based on this evidence synthesis, the following recommendations are proposed:

1. **Test selection should be context-specific.** Treponemal-only tests are appropriate for screening programmes where distinguishing active from past infection is not required for clinical decision-making, where confirmatory testing is universally available, or where

overtreatment is acceptable. Dual tests are preferred where same-day treatment decisions are needed, where confirmatory testing access is limited, and where minimising overtreatment is a priority.

2. **Confirmatory testing remains essential.** All reactive POCT results should be confirmed with laboratory-based treponemal testing where possible, particularly in low-prevalence populations where positive predictive value may be substantially reduced. Treponemal-positive/nontreponemal-negative dual test results should not be automatically classified as past infection without considering clinical history and local epidemiology.
3. **Specimen type matters.** Programmes should carefully consider the trade-off between operational simplicity of fingerprick testing and the measurable sensitivity loss compared to serum or plasma testing. Venous collection with serum/plasma separation may be warranted for prevalence surveys, programmatic evaluations, and individual case management where maximal sensitivity is required.
4. **Training and quality assurance are essential.** The substantial performance gap between laboratory and field evaluations underscores the critical importance of comprehensive operator training, competency assessment, supportive supervision, and external quality assurance programmes. Dried tube specimen EQA schemes should be implemented wherever POCTs are deployed.
5. **Active syphilis definitions should be standardised.** Research and surveillance programmes should adopt standardised case definitions for active syphilis to enable cross-study comparability. A definition requiring reactive treponemal test plus RPR titre $\geq 1:8$ is recommended, with clear reporting of results stratified by titre category.
6. **Reporting standards must improve.** Future diagnostic accuracy studies should adhere to STARD guidelines, clearly report blinding procedures, describe handling of invalid results,

ensure complete verification with reference standards, and report accuracy stratified by syphilis stage, RPR titre, and HIV status.

Recommendations for Research

Priority areas for future research include:

1. Head-to-head comparisons of multiple treponemal-only and dual test brands in the same populations using identical reference standards
2. Comprehensive evaluation of dual test nontreponemal component performance across the full spectrum of RPR titres, including low-titre and RPR-nonreactive treponemal-positive specimens
3. Studies specifically designed to assess POCT performance in primary syphilis, with direct lesion testing where possible
4. Adequately powered studies in HIV-positive populations with stratification by ART status, CD4 count, and viral load
5. Implementation research examining the real-world effectiveness, cost-effectiveness, and barriers to successful POCT programme implementation
6. Development and validation of standardised reference panels and case definitions for syphilis diagnostic accuracy research
7. Evaluation of emerging technologies including smartphone-based readers, molecular POCT platforms, and novel biomarkers
8. Studies examining the clinical and public health impact of POCT implementation on syphilis incidence, congenital syphilis rates, and antimicrobial stewardship

Concluding Remarks

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Rapid point-of-care tests have transformed syphilis screening capacity in resource-limited settings and expanded access to testing for populations historically underserved by laboratory-based services. This review confirms that current-generation POCTs provide sufficient accuracy to support global syphilis elimination efforts, particularly when deployed within comprehensive programmes including robust quality assurance and confirmatory testing pathways. However, the performance limitations identified—particularly reduced sensitivity in primary syphilis, with fingerprick blood, and at low nontreponemal titres—must be explicitly acknowledged and addressed through test selection, algorithm design, and healthcare worker training.

The ideal syphilis POCT would combine high sensitivity for all stages of infection, clear distinction between active and past disease, excellent performance on fingerprick blood, and integration with digital health systems. While current technologies do not fully achieve this ideal, the rapid pace of innovation in microfluidics, molecular diagnostics, and digital readout systems suggests that such tests may be available within the coming decade. Until then, optimal use of existing technologies—guided by the stratified evidence presented in this review—offers the best pathway toward the dual goals of syphilis elimination as a public health threat and the prevention of congenital syphilis worldwide.

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