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Diagnostic Accuracy of ELISA Compared to Rapid Diagnostic Tests for Toxoplasmosis: A Systematic Review

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Abstract

Background: *Toxoplasma gondii* is an obligate intracellular protozoan responsible for toxoplasmosis, a globally prevalent parasitic infection affecting more than one-third of the world's population. Accurate and timely diagnosis is crucial, particularly for pregnant women and immunocompromised individuals, to prevent severe complications such as congenital toxoplasmosis and encephalitis. The enzyme-linked immunosorbent assay (ELISA) is widely regarded as a reference serological method due to its high sensitivity and specificity. In contrast, rapid diagnostic tests (RDTs) offer practical advantages but show variable diagnostic performance.

Method: This systematic review evaluated and compared the diagnostic accuracy of ELISA and RDTs for toxoplasmosis. Literature searches were conducted in PubMed and Google Scholar for studies published between 2015 and 2025. Eligible studies assessed the diagnostic performance of ELISA and RDTs for detecting *T. gondii* infection in human populations, including sensitivity, specificity, and overall accuracy.

Result: Five studies met the inclusion criteria. Across diverse populations, ELISA consistently demonstrated high diagnostic accuracy, with sensitivity and specificity exceeding 90% in most studies. In contrast, RDTs showed lower performance and greater heterogeneity, particularly in individuals with low antibody titers and in immunocompromised individuals. Nevertheless, RDTs provided operational advantages for rapid screening in low-resource settings.

Conclusion: ELISA remains the most reliable method for serological diagnosis of toxoplasmosis, while RDTs may serve as complementary tools for initial screening. The integration of both approaches, along with the adoption of advanced ELISA formats such as recombinant antigen-based or Nano-Gold ELISA, may improve early detection and enhance diagnostic capacity across different healthcare settings.

Keywords: *Toxoplasma gondii*, toxoplasmosis, ELISA, rapid diagnostic test, diagnostic accuracy

1. INTRODUCTION

Toxoplasma gondii is an obligate intracellular protozoan that causes toxoplasmosis, a parasitic infection with a global distribution. It is estimated that more than one-third of the world's population has been exposed to this parasite, with prevalence varying across regions influenced by environmental factors, lifestyle, and dietary habits (1,2). Infection is generally asymptomatic in immunocompetent individuals but can lead to serious complications in immunocompromised patients and pregnant women, including encephalitis, retinochoroiditis, and congenital toxoplasmosis (3). Transmission occurs through the consumption of undercooked meat containing tissue cysts, contaminated water

or food, and vertical transmission from mother to fetus (3,4).

Early diagnosis of toxoplasmosis is crucial to prevent morbidity and mortality, especially in high-risk groups. Serological testing is the primary method for detecting T. gondii infection, with Enzyme-Linked Immunosorbent Assay (ELISA) being the most widely used approach due to its high sensitivity and specificity.5 However, ELISA requires laboratory infrastructure, longer processing times, and trained personnel. In contrast, immunochromatography-based Rapid Diagnostic Tests (RDTs) offer fast results, simple procedures, and lower costs, making them a potential option for use in healthcare facilities with limited resources (6,7).

Recent primary studies indicate variability in diagnostic performance between ELISA and RDTs. For example, RDT showed lower sensitivity but higher specificity than ELISA in community serosurveys, with sensitivities ranging from 34.3% to 89.3% and specificities ranging from 89.3% to 100% in a cross-sectional study in Nepal (8). Similarly, research in Ghana reported fair diagnostic agreement between RDT-IgG and ELISA IgG (sensitivity 36% and specificity 91.2%) (9). Recent meta-analyses highlight that no single serological or molecular method consistently performs better across all contexts, and that selection of a diagnostic technique should consider clinical needs and resource availability (10).

Comparing the diagnostic accuracy of ELISA and RDTs for toxoplasmosis is essential given the need for efficient, accurate, and implementable methods across diverse healthcare settings. Systematic reviews and meta-analyses provide strong scientific evidence regarding the strengths and limitations of each technique, as well as their implications for clinical practice and public health screening programs (11,12).

2. MATERIALS AND METHODS

A systematic literature search was conducted in PubMed and Google Scholar. The search was performed on 20 September 2025 using the following Boolean strategy:

("Toxoplasma gondii" OR "toxoplasmosis") AND ("ELISA" OR "enzyme-linked immunosorbent assay") AND ("rapid diagnostic test" OR "RDT" OR "rapid test" OR "immunochromatographic test" OR "ICT") AND ("diagnostic accuracy" OR "sensitivity" OR "specificity" OR "performance").

The search was restricted to articles published between January 2015 and September 2025, written in English, conducted in human populations, and available in full text. The reference lists of eligible studies were also screened to identify additional publications.

a. Eligibility Criteria

Studies were considered eligible if they were original research articles that employed cross-sectional, cohort, or case–control designs and were conducted in human populations. Included studies were required to perform a direct head-to-head comparison between ELISA and RDT/ICT for the detection of Toxoplasma gondii antibodies, and to report at least one diagnostic accuracy parameter, such as sensitivity, specificity, predictive values, or overall diagnostic accuracy.

Studies were excluded if they were animal-based or in vitro investigations, review articles, editorials, or conference abstracts. In addition, studies that evaluated only ELISA or only RDT/ICT without a direct comparison, assessed only molecular assays without a serological comparison, or lacked sufficient diagnostic accuracy data were not included.

b. Data Extraction

Data extraction was independently performed by two reviewers following the predefined protocol. Any discrepancies between reviewers were resolved through discussion, and when consensus could not be achieved, a third reviewer acted as an adjudicator. Extracted information included study characteristics (author, publication year, country, and study setting), population characteristics and sample size, the type and manufacturer of ELISA and RDT/ICT assays used, the reference standard applied when available, and the reported diagnostic accuracy parameters.

c. Risk of Bias Assessment

Methodological quality was assessed using QUADAS-2 across four domains: patient selection, index test, reference standard, and flow/timing. Results were summarised narratively and in

tabular form. This systematic review was not prospectively registered in PROSPERO.

d. Data Synthesis

Where datasets were sufficiently comparable, a random-effects model was planned to generate pooled sensitivity, pooled specificity, and a summary ROC (sROC) estimate. In cases of methodological or clinical heterogeneity, findings were synthesised narratively.

3. RESULTS

a. Study selection

A total of 438 records were identified through database searching. After removing 38 duplicates, 400 records were screened based on titles and abstracts. Of these, 340 articles were excluded because they were reviews, conference abstracts, animal or in-vitro studies, or did not evaluate diagnostic performance.

A total of 60 full-text articles were assessed for eligibility, and 55 were excluded for the following reasons were the study did not directly compare ELISA with RDT/ICT, diagnostic accuracy parameters were not reported, or the evaluated assay was molecular or recombinant-antigen based rather than an actual rapid test. Finally, 5 studies were included in the review.

The study selection process followed PRISMA guidelines and is summarized in the PRISMA flow diagram.

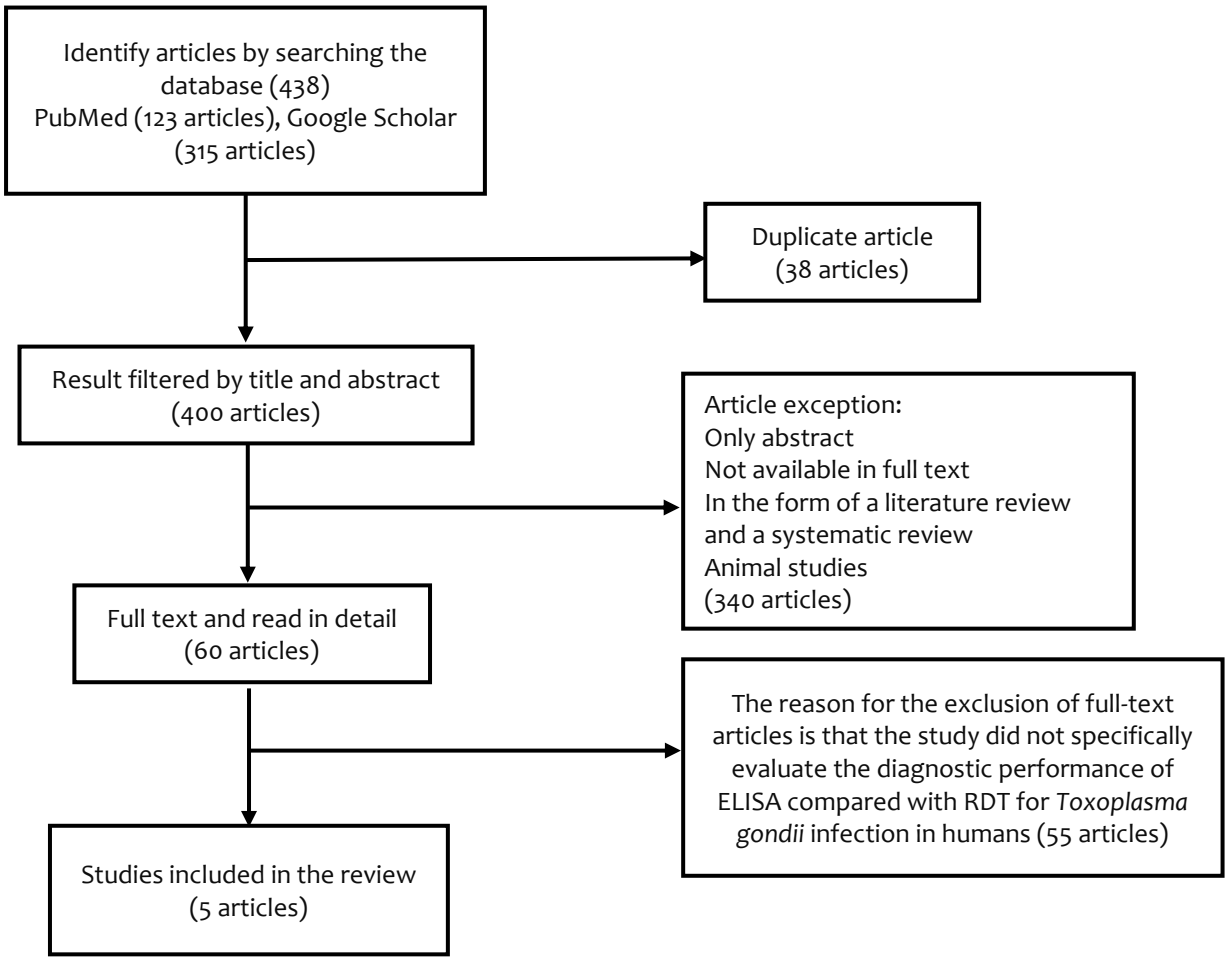

Figure 1. PRISMA flowchart

a. Risk of bias assessment

Overall, most included studies demonstrated a low to moderate risk of bias across the QUADAS-2 domains. The main concerns were related to patient selection, particularly the use of convenience samples, and variability in the reference standards used, with most studies relying on ELISA and only a limited number incorporating PCR confirmation. No study was judged to have a high risk of bias across all assessed domains.

Table 1. Diagnostic accuracy of ELISA and rapid diagnostic tests (RDTs) for toxoplasmosis

Study / Population	Index Test	Reference Standard	N	Sensitivity	Specificity	PPV	NPV	Notes on Interpreration
El Deeb et al., Egypt - Cancer patients (immunocompromised)[13]	ICT RDT (OnSite Toxo IgG/IgM)	ELISA	180	74%	87.5%	NR	NR	Overall agreement 78.8%. ICT more sensitive at low-titer sera
Gyodong-do, Korea - General population, 4-year follow-up[14]	RDT lateral-flow antibody test	ELISA	921–993–940–838	Lower than ELISA near cut-off	Good agreement overall	NR	NR	Reduced RDT sensitivity in borderline titers
LDBio ICT vs Abbott Architect - Pregnant women[15]	LDBio ICT (IgG/IgM)	Abbott Architect ELISA	181	Very high concordance (IgG 99.2%)	Very high	NR	NR	ICT able to distinguish recent vs past infection
SAG1 Nano-Gold ELISA vs conventional ELISA vs PCR - Pregnant women[16]	Nano-Gold ELISA	PCR	NR	97.3%	100%	98.9% accuracy	NR	Not an RDT, enhanced ELISA + molecular confirmation
Recombinant TgIMP1-iELISA validation[17]	IMP1-iELISA (recombinant antigen)	Characterized positive/negative sera	150	98.9%	96.7%	NR	NR	Not an RDT, antigen-development ELISA

4. DISCUSSION

Among the five included studies, comparisons between ELISA and RDTs, most of which were based on immunochromatographic test (ICT) principles, revealed substantial variability in diagnostic performance across assay formats and study populations. Mahinc et al. (2017) evaluated the LDBio immunochromatographic test in a large sample set of more than 1,000 serum specimens. They demonstrated high sensitivity and specificity comparable to those of the Abbott Architect ELISA, particularly for IgG and IgM detection, indicating that specific, well-validated ICT platforms may approach laboratory-based performance under optimal conditions.15 In contrast, Wassef et al. (2019) reported markedly lower sensitivity of an RDT (approximately 74%) when applied to cancer patients, a population characterized by immunosuppression and potentially atypical antibody responses.13 Similarly, Kim et al. (2017) observed reduced sensitivity of RDTs compared with ELISA in a general population survey, especially in samples with antibody titers near the diagnostic cut-off, underscoring the vulnerability of rapid tests to detect low-level seropositivity (14).

Beyond conventional RDTs, several studies included in this review assessed advanced ELISA-based approaches and reported superior diagnostic accuracy. Aly et al. (2023) demonstrated that Nano-Gold ELISA achieved sensitivity and specificity exceeding 95% in pregnant women and performed comparably to PCR in selected cases. Likewise, Dong et al. (2024) reported excellent performance of an indirect ELISA based on a recombinant TgIMP1 antigen, with 98.9% sensitivity, 96.7% specificity, minimal cross-reactivity, and strong assay reproducibility (17). Collectively, these findings highlight the impact of antigen selection and assay optimization on improving serological test performance (16,17).

Overall, ELISA consistently demonstrated high diagnostic accuracy across diverse populations and remains the laboratory reference standard for toxoplasmosis serodiagnosis. In contrast, RDTs offer operational advantages such as rapid turnaround time, simplicity, and lower cost. Still, their diagnostic performance appears highly dependent on the specific commercial kit used and the immune status of the tested population. This observation is consistent with systematic reviews reporting substantial heterogeneity in serological test accuracy for T. gondii, influenced by assay format, antigen composition, and population characteristics (18).

Notably, recent systematic and narrative reviews emphasize wide variability across RDT kits and validation studies and recommend independent local validation before routine clinical or field deployment (18,19). Emerging diagnostic technologies, including Nano-Gold ELISA, recombinant antigen-based assays, and microfluidic platforms, have been proposed as promising alternatives that can improve sensitivity while maintaining specificity.19 However, robust multicenter head-to-head comparisons across different diagnostic platforms remain limited, restricting the generalizability of current evidence.

ELISA remains one of the most widely applied methods for toxoplasmosis diagnosis due to its relatively high sensitivity and specificity. In Egypt, Aly et al. (2023) reported that PCR achieved a sensitivity of 97.3% and a specificity of 100%, while Nano-Gold ELISA and conventional ELISA demonstrated sensitivities of 89.2% and 83.8% and specificities of 94% and 88%, respectively (16). In contrast, rapid immunochromatographic tests have shown notable limitations in sensitivity. A study conducted in Port Harcourt, Nigeria, reported that ICT achieved only 46.7% sensitivity and 81.7% specificity compared with ELISA IgG.20 Furthermore, studies from Alexandria, Egypt, documented discrepancies between serological and molecular findings, including cases with positive serology but negative PCR and vice versa, particularly in placental tissues and abortion cases.21 These findings suggest that while molecular techniques are not suitable for routine screening, they may serve as valuable confirmatory tools in selected clinical scenarios.

The clinical implications of these findings are considerable. The high diagnostic accuracy of ELISA makes it a reliable tool in hospital and reference laboratory settings, particularly for

pregnant women and immunocompromised patients, where accurate diagnosis is critical. However, the higher cost and technical requirements of ELISA limit its routine use in primary healthcare facilities, especially in resource-constrained settings. In such contexts, RDTs may serve as useful screening tools due to their low cost, ease of use, and rapid results, although their lower sensitivity increases the risk of false-negative outcomes. Evidence from Ghana demonstrated that ELISA outperformed RDT in both sensitivity and specificity, while RDTs retained value for initial community-based screening (22). Similar observations have been reported in Nigeria, where ELISA detected more infections than RDT, but rapid tests facilitated preliminary diagnosis in peripheral health facilities (20).

Several limitations of the included studies should be acknowledged. Most investigations were hospital- or laboratory-based with relatively small sample sizes, potentially limiting extrapolation to asymptomatic or community populations (20). In addition, the limited number of eligible studies reflects the scarcity of head-to-head comparisons between ELISA and RDTs that met strict diagnostic accuracy criteria. Additionally, substantial heterogeneity in the diagnostic kits and antigen compositions used may partly explain inconsistencies in reported performance (16). Most studies used ELISA as the reference standard.

In contrast, only a limited number incorporated a molecular gold standard, such as PCR, thereby limiting confirmation of borderline or discordant serological results.22 Finally, detailed subgroup analyses for high-risk populations, including pregnant women and immunocompromised individuals, were inconsistently reported. These limitations highlight the need for larger, multicenter studies employing standardized diagnostic protocols.

Future research should prioritize harmonized evaluation of ELISA and RDT platforms to ensure comparability across brands and settings. Large-scale multicenter studies are needed to validate diagnostic accuracy across diverse populations, particularly in low-resource settings where rapid tests are most commonly deployed. Integrating improved serological assays with targeted molecular confirmation may enhance the detection of acute and atypical infections. At the same time, continued development of affordable, reliable point-of-care technologies will be essential to improve early diagnosis and clinical management of toxoplasmosis in high-risk groups.

5. CONCLUSION

This systematic review demonstrates that ELISA consistently provides high sensitivity and specificity for the serodiagnosis of toxoplasmosis across different populations and remains the laboratory reference standard. Nevertheless, its dependence on laboratory infrastructure, trained personnel, and higher operational costs limits its widespread implementation in primary healthcare and resource-limited settings. Rapid diagnostic tests (RDTs), including immunochromatographic assays, offer practical advantages such as fast turnaround time, ease of use, and low cost, making them suitable for large-scale screening. However, their variable and often lower sensitivity, particularly in cases with low antibody titers or in immunocompromised individuals, restricts their reliability as standalone diagnostic tools.

The findings indicate that a complementary diagnostic strategy, utilizing RDTs for initial screening followed by ELISA and, where appropriate, molecular confirmation, may provide a more accurate and clinically meaningful approach to toxoplasmosis diagnosis. Advances in ELISA technology, including recombinant antigen–based and nano-enhanced assays, show promise in improving diagnostic performance while maintaining feasibility for broader use. Strengthening diagnostic capacity through the development and validation of affordable, sensitive, and accessible tools is essential to support early detection and timely clinical management, particularly among high-risk populations such as pregnant women and immunocompromised patients.

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