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RCMOS - Multidisciplinary Scientific Journal The Knowledge.
ISSN: 2675-9128. São Paulo-SP.

Year VII, v.1 2026 | Submission: 05/20/2026 | Accepted: 05/23/2026 | Publication: 05/26/2026

Diagnostic approaches to congenital toxoplasmosis: laboratory implications and the biomedical scientist's contribution to analytical accuracy.

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Diagnostic approaches for congenital toxoplasmosis: laboratory implications and the biomedical contribution to analytical precision

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SUMMARY

Introduction: Congenital toxoplasmosis, caused by vertical transmission of *Toxoplasma Toxoplasmosis gondii* remains a serious public health problem due to the potential for severe neurological and ocular sequelae in the fetus. Early diagnosis in pregnant women is a challenge, given the complexity of differentiating acute from chronic infections in the early stages. Objective: To analyze, under the guidance of a biomedical scientist, the main diagnostic approaches for congenital toxoplasmosis, discussing the laboratory implications and the relevance of analytical precision. Methodology: This was an integrative literature review, with searches in the PubMed, SciELO, and LILACS databases. Articles published in the last 5 years were selected using descriptors such as "Congenital Toxoplasmosis," "Laboratory Diagnosis," and "Biomedicine." Results: It was identified that the combination of serology (IgG and IgM) with the IgG avidity test is the most effective protocol for dating the infection in pregnant women. Molecular diagnosis by PCR in amniotic fluid has become established as a highly specific method for confirming fetal transmission. Accuracy in the analytical phase and interpretation of results in the "gray area" have proven dependent on technical expertise to avoid iatrogenic interventions. Conclusion: This study confirms that the biomedical professional's role is crucial for diagnostic accuracy, ensuring the reliability of results that will guide therapeutic management, mitigating the risks of false positives, and ensuring the prompt initiation of treatment to protect maternal and infant health.

Descriptors: Congenital Toxoplasmosis; Laboratory Diagnosis; Biomedicine.

1 INTRODUCTION

Toxoplasmosis is a zoonotic disease with a worldwide distribution, caused by the protozoan obligate intracellular parasite *Toxoplasma gondii.* Although infection in individuals

Although immunocompetent, primary infection during pregnancy is often asymptomatic.

Toxoplasmosis represents a serious clinical risk due to its ability to be transmitted vertically.

Congenital infection occurs when tachyzoites cross the placental barrier, which can result in...

abortion, fetal death, or serious sequelae such as chorioretinitis and

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Intracranial calcifications (Public Prosecutor's Office & Brazil)

The severity of clinical manifestations in the fetus is inversely correlated with the gestational age at the time of infection. In this scenario, early diagnosis and dating are crucial. The need to detect maternal infection is a fundamental pillar of prenatal care. Currently, The screening is primarily based on the detection of IgG and IgM class antibodies; however, The persistence of IgM antibodies for prolonged periods can make it difficult to distinguish between a acute infection and chronic infection (GAZOLA et al., 2021).

To mitigate these uncertainties, new diagnostic approaches have been incorporated into routine laboratory work, with emphasis on the IgG Avidity Test and molecular diagnosis by Polymerase Chain Reaction (PCR) in amniotic fluid. The avidity test allows Differentiating the maturity of the immune response is crucial when performed up to the 16th week of... pregnancy. In parallel, PCR offers a highly specific way to confirm the fetal infection, allowing for targeted therapeutic intervention and reducing anxiety. parental (MURATA et al., 2021).

The accuracy of these results, however, depends not only on the technology employed, but also on the rigorous execution of the pre-analytical, analytical, and post-analytical phases. It is in this In this context, the role of the biomedical professional becomes essential. As the technical expert responsible for In the execution and interpretation of the tests, the biomedical professional must possess the ability to correlate Laboratory findings in conjunction with the patient's clinical history, identifying borderline results and ensuring the analytical reliability necessary for medical decision-making.

Given the problematic nature of the main challenges in interpreting the tests and how the Laboratory performance influences maternal and infant prognosis; the present study aimed to... To analyze the diagnostic strategies for congenital toxoplasmosis and describe their implications. laboratory studies and compile the biomedical scientist's contribution to the accuracy of analytical results.

2 METHODOLOGY

This study consisted of an integrative literature review, conducted in The search for articles was conducted between September 2025 and June 2026. Electronic databases: PubMed *(National Library of Medicine),* SciELO *(Scientific Electronic Library Online),* LILACS *(Latin American and Caribbean Literature in Science) (Health),* ScienceDirect and *Google Scholar.* There were no restrictions on languages, which allowed for the inclusion of articles in Portuguese, English, and Spanish. A choice was made for w

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a five-year time frame, from 2021 to 2026, focusing on the most recent evidence regarding... topic, although technical manuals and seminal institutional guidelines were consulted. for the theoretical foundation.

The Health Sciences Descriptors (DeCS) and their corresponding terms were used. in English *(Medical Subject Headings - MeSH):* Congenital Toxoplasmosis *(Toxoplasmosis, Congenital), Clinical* Laboratory Diagnosis , Serology Molecular Diagnostic Techniques, Analytical Precision *(Analytical Precision)* and Biomedicine *(Biomedical Science).* These descriptors were combined using the Boolean operators *AND* and *OR* to formulate the strategies of search.

The inclusion criteria adopted for the selection of studies were: published articles between 2021 and 2026; complete studies with free or institutional access, available at digital format; works that addressed diagnostic approaches to toxoplasmosis. gestational and congenital, including clinical trials, comparative studies and reviews; and articles which dealt with the accuracy of serological tests (such as the IgG avidity test) and molecular tests (PCR), as well as the role of the laboratory professional in quality control. As criteria For exclusion purposes, the following were considered: articles that addressed toxoplasmosis exclusively in immunocompromised patients or in animal models, with no correlation to transmission. vertical gestational age; works without full texts available; and duplicate publications or studies that did not present original data to complement the evidence already selected.

3 RESULTS

Based on a structured search conducted in the PubMed, SciELO, and LILACS databases, ScienceDirect and Google Scholar identified an initial 480 studies. After removal From duplicates, 210 articles remained for the selection stage. Through reading titles and abstracts and the application of exclusion criteria, which included deviation from the topic (such as studies on isolated ocular manifestations or other infections), the approach to populations inappropriate outside the context of vertical transmission (immunocompromised patients or (animal models) and the unavailability of access to the full text, 200 studies were excluded. Thus, 10 articles that best answered the research question were selected. to compose the final analysis corpus, as detailed in the flowchart below (Figure 1).

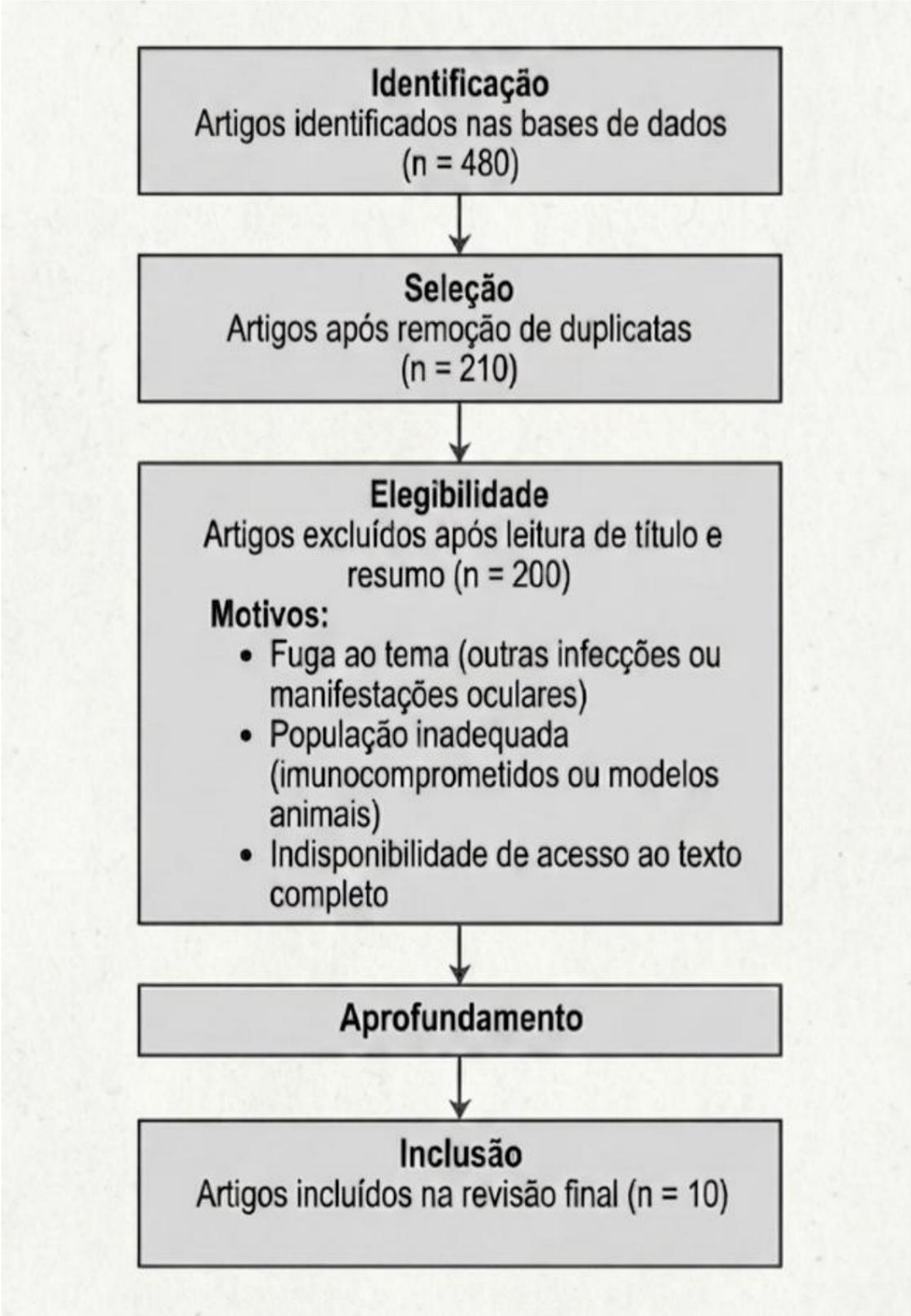
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Figure 1 – Article selection flowchart, 2026.



(Source: Prepared by the author, 2026)

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Among the 10 articles selected for review, the main laboratory diagnostic approaches and their contribution were analyzed.
Analytical precision for the prevention of congenital toxoplasmosis. The main assays and markers investigated and identified as determinants.
Clinical tests included the IgG Avidity Test and Polymerase Chain Reaction (PCR) targeting the REP-529 repetitive element. Regarding...
In terms of laboratory management, the evidence pointed to rigorous prenatal screening, associated with the clinical-epidemiological correlation performed by the professional.
biomedical, such as the protocols with the highest efficacy and safety for the patient. Details of the evaluated articles are presented below (Table
1).

Table 1 – Characteristics of the selected scientific articles, according to title, authors, year of publication, objective and results, 2026.

Title	Authors:	Year	Objectives	Results
routine diagnosis of congenital gestational toxoplasmosis: a literature review laboratory and	GAZOLA, AL et al.	2021	To discuss the main laboratory techniques used in screening of pregnant women.	Combining immunoenzymatic techniques with avidity tests is the best strategy for timely diagnosis.
Diagnostic accuracy of serological tests for congenital toxoplasmosis: a systematic review and meta-analysis. Analyzing the overall accuracy of commercial serological tests for detection in 2021.	MURATA, FHA et al.		of the infection.	Conventional tests exhibit variations in sensitivity, requiring confirmatory methods to avoid false-positive results.
Evaluation of a new commercial IgG 2021: Validating the accuracy of a new avidity test for Toxoplasma gondii.	ROBERT GANGNEU X, F. et al.		commercial for determining the avidity of IgG antibodies.	High-avidity tests early in pregnancy identify pre-existing chronic infection and eliminate the risk of inappropriate interventions.
Molecular diagnosis of Toxoplasma gondii: a systematic review of target genes	ROSTAMI, A. et al.	2021	Systematically review the main molecular target genes used in the diagnosis of infection.	PCR targeting repetitive sequences (such as REP529 and the B1 gene) surpasses single-copy gene assays in sensitivity.
Surveillance Protocol of Toxoplasmosis in Pregnancy and Congenital	BRAZIL. Ministry of Health	2022	Standardize monitoring actions, serological screening, and therapeutic procedures nationwide.	Early prenatal screening drastically reduces the rate of vertical transmission and the impact of fetal sequelae.
Evaluation of PCR assay targeting the REP529 sequence for the diagnosis of congenital	POMARES, C. et al.	2022	Evaluate the analytical effectiveness of the PCR technique using the target sequence. highly repetitive REP529.	The REP529 molecular target provides extremely sensitive and rapid fetal diagnosis from amniotic fluid.

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toxoplasmosis				
The role of PCR in the diagnosis of congenital toxoplasmosis: an update	VILLARD, O. et al.	2022	Update the scientific evidence on the practical role of PCR in the prenatal diagnosis of vertical transmission.	PCR has become the gold standard in prenatal care, reducing the need for repeated invasive procedures.
Performance of IgA and IgM for congenital toxoplasmosis: systematic study the	LIMA, MS et al.	2023	Evaluate the diagnostic performance of IgA and IgM antibodies in detecting congenital infection.	The combined testing of IgA and IgM increases diagnostic sensitivity in neonatal screening when compared to the use of IgM alone.
The contribution of laboratory teams and the role of the biomedical scientist in the analytical accuracy of prenatal tests.	VALDANH A, GT et al..	2023	Analyze the impact of the biomedical professional's role in mitigating errors in analytical phases.	Rigorous management by biomedical professionals in quality control ensures accuracy and the issuance of highly reliable clinical reports.
Congenital toxoplasmosis: Challenges in laboratory diagnosis and interpretation of tests.	SANTOS, L. F.; SILVA, MR	2024	Investigate the main challenges and difficulties of interpretation in routine immunological laboratory work.	The persistence of IgM antibodies generates ambiguities that demand critical analysis and robust epidemiological correlation.

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4. DISCUSSION

The historical and technological evolution applied to the diagnosis of toxoplasmosis. It has reconfigured the clinical management of pregnant women and newborns from a medical perspective. preventive. The transition from methodologies purely based on serological screening to High-avidity confirmatory assays and molecular biology tools have consolidated the accuracy. Analytical analysis is the main clinical differentiator in determining fetal prognosis. As the The gestational immune system presents a complex and fluctuating dynamic; research Laboratory analysis requires that findings not be interpreted in isolation, but rather through a broader context. an integrated reasoning that correlates analytical data with epidemiological history and the patient's gestational age. (ROSTAMI, A. et al., 2021)

4.1 Challenges of Conventional Serology and the Innovation of the Test IgG avidity.

In routine prenatal screening, the isolated detection of IgG and IgM class antibodies... It often poses complex and dangerous interpretative challenges to the healthcare team. Although the appearance of the IgM antibody theoretically signals an acute phase of the infection, the occurrence of so-called "residual IgM" (which has the property of remaining detectable) for months or even years after initial contact with the parasite) severely compromises the accuracy of immunological dating. This scenario establishes a diagnostic "gray area" in What is the misinterpretation of a chronic infection as acute that leads to treatments premature and unnecessary use of highly toxic drugs, in addition to triggering serious conditions. of anxiety and psychological stress in pregnant women. (ROBERT-GANGNEUX et al., 2021)

As a direct response to this methodological limitation, the IgG Avidity Test It has established itself as a highly specific tool for the chronological elucidation of infection. This assay is based on measuring the strength of protein binding between the antibodies produced by the host and antigens of the parasite, an affinity that matures and increases progressively over time. Identifying a high avidity index, When performed strictly within the first 16 weeks of gestation, it certifies in a way... unequivocal evidence that the infection occurred in the past (at least four months ago), ruling out primary gestational infection and protecting the patient from iatrogenic therapeutic interventions. unnecessary. (VILLARD et al., 2022)

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4.2 Molecular Diagnosis by PCR and Confirmation of Fetal Transmission

In critical scenarios where maternal serology confirms or strongly suggests
In cases of recent acute infection, laboratory investigation should shift to direct monitoring of the
fetal compartment. Polymerase chain reaction (PCR) performed using the fluid.
Amniotic fluid, obtained through safe amniocentesis after the 16th week of gestation,
It revolutionized prenatal diagnosis by allowing the direct detection of *Toxoplasma* DNA.
gondii. This genetic engineering methodology has superseded older inoculation methods.
animal and cell culture methods, which were time-consuming, dangerous, and biologically unfeasible in routine practice.
hospital, establishing a standard of very high diagnostic specificity. (POMARES et
(al., 2022)

The optimization and analytical reliability of the PCR technique are intrinsically linked.
associated with the rigorous selection of genetic targets used in the amplification assay
molecular. The use of the repeating element REP-529, which is replicated between 200 and 300 times.
times in the parasite's genome, it demonstrated considerably superior analytical sensitivity.
when compared to the traditional single-copy B1 gene. This methodological choice, carried out
In a laboratory setting, it increases the assay's ability to detect the pathogen even in
situations of incipient parasitic load, guaranteeing the necessary safety for the medical staff.
to institute combined therapy and mitigate the progression of neurological sequelae or
permanent ocular problems in newborns (LIMA et al., 2023).

4.3 The Biomedical Scientist's Technical Responsibility for Reliability ANALYTICAL

The inclusion of biomedical professionals in the scope of toxoplasmosis diagnosis.
Congenital malformation constitutes the main pillar of patient safety in all phases of the process.
laboratory. In the pre-analytical phase, rigorous control of collection, centrifugation and
Serum storage prevents biological interference and operational errors from compromising the product.
The sensitivity of immunoassays. It is the biomedical professional's responsibility to supervise these technical processes and
Rigorously calibrate automated equipment, mitigating the occurrence of adverse results.
false-positives or false-negatives that would compromise clinical conduct (SANTOS; SILVA,
2024).

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Furthermore, in the analytical and post-analytical phases, the contribution of this professional is evident- whether in its scientific capacity to correlate discordant immunological profiles with the picture The biomedical professional's role is not limited to releasing mechanical and automated data; It also works in risk management and in the validation of complementary tests (such as the (monitoring of IgA antibodies in newborns). This technical expertise ensures that the report The issued document should be a tool of very high analytical fidelity, providing the necessary support. so that the medical team can adopt quick and assertive treatments to protect the integrity of the maternal and child health (VALDANHA et al., 2023).

FINAL CONSIDERATIONS

This integrative review concluded that analytical precision in diagnosis Controlling congenital toxoplasmosis is the fundamental pillar for ensuring maternal clinical safety. infantile. It became evident that the immunological complexity of gestational infection requires the overcoming the limitations of conventional serology (IgG and IgM), with systematic incorporation confirmatory tests, such as the IgG Avidity Test and the Polymerase Chain Reaction. (PCR) in amniotic fluid, the most effective strategy for the precise chronological elucidation of infection and for reliable confirmation of vertical transmission.

The study achieved its objective by demonstrating that the choice of molecular targets of High sensitivity, such as the REP-529 repeating element, drastically reduces margins of laboratory errors, providing the necessary scientific support for the medical team to adopt Immediate therapeutic interventions and mitigate the development of neurological sequelae and severe eye problems in the fetus.

Finally, it is worth highlighting that the technical and scientific contribution of the biomedical professional transcends... The mere automated execution of tests. This professional acts as the main person responsible. for quality and patient safety in the pre-analytical, analytical and post-analytical phases. Their critical ability to correlate discordant or ambiguous immunological profiles with the The pregnant woman's epidemiological history ensures the issuance of highly accurate reports. analytical. Given this, the assertive performance of the biomedical professional is consolidated as a link. indispensable in public health, transforming laboratory data into sound clinical decisions. and effective for preserving lives.

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