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Evaluation of Toxoplasma IgM Detection Methods in 7,607 Patients: A Comparative Study

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Abstract

Toxoplasmosis is a globally relevant infection, and accurate detection of Toxoplasma IgM antibodies is essential for early diagnosis and clinical decision-making. This study assessed the performance of four widely used serological methods in detecting Toxoplasma IgM in a large patient cohort. Between January 1, 2024, and December 31, 2024, a total of 7,607 patients were tested at GeniusLab. Four methods—BKAccess2, ELISA, Roche E801, and Minividas Blu— were used for confirmation. Minividas Blu demonstrated the highest accuracy, confirming 99.5% of positive cases, while ELISA showed a 90% confirmation rate. Roche E801 had the highest rate of false-positive results. These findings highlight variability in detection methods and underscore the importance of selecting reliable diagnostic tools.

Keywords: Toxoplasma Gondii, Toxoplasmosis, IgM Detection, Serological Diagnosis, Comparative Study.

Introduction

Toxoplasmosis, caused by the intracellular parasite Toxoplasma gondii, is a globally prevalent zoonotic infection that can lead to serious complications in immunocompromised individuals and pregnant women [1]. In immunocompetent individuals, the infection is often asymptomatic or mild, but congenital toxoplasmosis can result in miscarriage, stillbirth, or severe neonatal complications. Because of these potential consequences, early and accurate detection of acute infection is critical to guide clinical decision-making and initiate timely interventions [2].

The serological detection of Toxoplasma specific IgM antibodies is considered a primary method for identifying recent infections. However, the reliability of IgM testing can vary significantly depending on the assay used, which may result in false positive or false-negative findings. Several commercial and laboratory-based assays are widely used, including ELISA, chemiluminescent immunoassays, and fluorescence-based methods, each with its advantages and limitations [3-6]. Variability in sensitivity, specificity, and equivocal result rates can complicate diagnosis, highlighting the need for comparative evaluations of diagnostic methods. This study aimed to assess and compare the performance of four commonly used serological methods—BKAccess2, ELISA, Roche E801, and Minividas Blu—in detecting Toxoplasma IgM antibodies in a large cohort of patients [7].

Materials and Methods

A retrospective study was conducted at GeniusLab in Tirana, Albania, analyzing patient data collected between January 1 and December 31, 2024. During this period, 7,607 patients were tested for Toxoplasma IgM antibodies. The patient population included both inpatients and outpatients, ranging in age from 1 to 78 years, who were referred for routine screening, suspected recent infection, or prenatal evaluation. All samples were tested using four different serological methods. The BKAccess2 system, an automated chemiluminescence immunoassay, was employed for its high specificity [8-11]. ELISA, a widely used enzyme linked immunosorbent assay, was applied for its robustness and accessibility in routine clinical laboratories. Roche E801, an electrochemiluminescence immunoassay, was included for comparison due to its widespread use and rapid throughput. Minividas Blu, a fluorescence-based immunoassay, was also evaluated because of its reputation for high sensitivity and accuracy in detecting acute infection [12]. Testing was per-

formed according to the manufacturers' instructions, and results were categorized as positive, negative, or equivocal (gray zone). Confirmatory testing using at least one additional method was carried out for all positive and equivocal cases. Data analysis focused on evaluating the proportion of positive, negative, and equivocal results for each method, as well as determining the overall accuracy, false positive rates, and performance consistency across the cohort. Statistical comparisons were performed using chi-square tests, with significance set at $p<0.05$ [13-15].

Results

Out of the 7,607 patients tested, 453 individuals (5.96%) were found to be positive for Toxoplasma IgM. The performance of the four methods differed notably. Minividas Blu demonstrated the highest overall accuracy, successfully confirming 99.5% of positive cases. This method produced the highest proportion of equivocal results at 2.9%, indicating that while its sensitivity was excellent, borderline cases required careful follow-up [16]. ELISA exhibited strong performance as well, confirming 90% of positive results, with only 0.9% of cases falling into the equivocal range. Although its confirmation rate was slightly lower than Minividas Blu, ELISA had a lower false-positive rate, suggesting a more conservative but reliable detection profile [17-20].

Roche E801 detected a higher proportion of positive cases relative to the total cohort, but this method also generated the most false-positive results, highlighting its tendency to overestimate recent infection. The rate of equivocal results for Roche E801 was 1.8%, which required further testing to avoid misclassification. BKAccess2 showed the lowest proportion of positive cases among the four methods, confirming only 1.1% of the total positives. Notably, it did not produce any equivocal results, which reflects its high specificity, but this came at the cost of reduced sensitivity, potentially missing some true positive cases [21]. These findings underscore the variability of Toxoplasma IgM detection among different serological methods. Minividas Blu and ELISA provided the most reliable results in terms of balancing sensitivity and specificity, whereas Roche E801 and BKAccess2 demonstrated particular limitations in terms of false-positive detection and respectively [22].

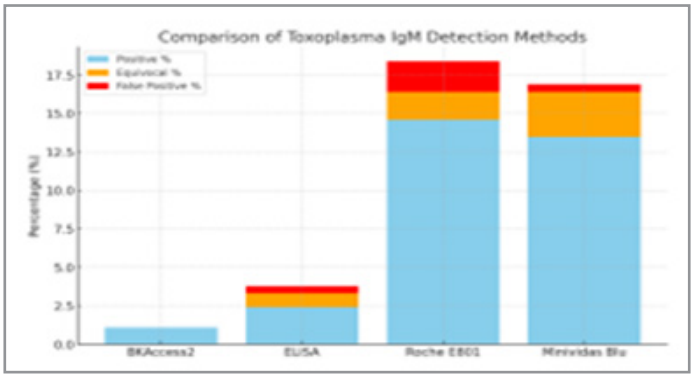

Figure 1: Comparison of Toxoplasma IgM Detection Methods.

Discussion

The comparative analysis of the four serological methods reveals important differences in their diagnostic performance. Minividas Blu's high accuracy and confirmation rate indicate that fluorescence-based immunoassays may be particularly suitable for large-scale screening and high-risk patient populations. Despite its slightly higher proportion of equivocal results, the overall reliability of Minividas Blu suggests that it provides a strong balance between detecting true positives and minimizing false positives [23].

ELISA, while slightly less sensitive, offered robust performance and low rates of false positives, supporting its continued use as a reliable and cost-effective method in routine laboratories. Roche E801, although capable of detecting a larger number of positive cases, exhibited a higher incidence of false positives, which may lead to unnecessary clinical interventions or patient anxiety if results are interpreted without confirmatory testing. BKAccess2's high specificity and absence of equivocal results make it valuable as a confirmatory assay; however, its lower sensitivity limits its utility as a primary screening tool [24].

Accurate detection of Toxoplasma IgM antibodies is particularly crucial in prenatal care, immunocompromised patients, and neonates, where misclassification can have serious consequences. The results of this study emphasize the need for careful selection of diagnostic tools based on clinical context, and they highlight the importance of confirming equivocal or unexpected results with alternative methods. Further research exploring combinations of serological and molecular techniques, such as PCR-based assays, may improve diagnostic accuracy and reduce the risk of misclassification in clinical practice [25-27].

Conclusion

This study demonstrates significant variability among four commonly used serological methods for detecting Toxoplasma IgM in a large patient cohort. Minividas Blu exhibited the highest overall accuracy and reliability, while ELISA provided strong performance with a lower false-positive rate. Roche E801, despite detecting a higher number of positive cases, generated the most false-positive results, and BKAccess2, while highly specific, had reduced sensitivity. These findings underscore the importance of selecting appropriate diagnostic methods and confirmatory testing strategies to improve diagnostic accuracy and optimize patient care.

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