

# Diagnostic Accuracy and Predictive Value of Latex Agglutination Test, Rapid Cassette Test Compared To ELISA In Diagnosis of *Toxoplasma Gondii* in Pregnant Sudanese Women

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## ABSTRACT

**Background:** There are different procedures for the diagnosis of the pregnant female suspected with toxoplasmosis, however time, cost, and accuracy of the test should meat patients need.

**Material and Method:** Three hundered pregnant female collected from Saad Abualila hospital antenatal care unit, were undergo three different procedures for the diagnosis of *Toxoplasma gondii* infection. Toxolatex. Toxo IgG-IgM rapid test and ELISA were done for all pregnant female. The result described as frequency and percentage of positivity, also specificity and sensitivity of Toxolatex. Toxo IgG-IgM rapid test were assessed according to ELISA results.

**Results:** The sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and diagnostic accuracy for Latex agglutination test to detect *T. gondii* antibodies were: 44.6%, 71.9%, 30.5%, 82.4% and 66. %, while the specificity, sensitivity, PPV, NPV and diagnostic accuracy for rapid cassette test to detect *T. gondii* antibodies were: 29.2%, 88.5%, 41.3%, 81.8% and 75.67%, respectively.

**Conclusion:** Toxo IgG-IgM rapid test (casset) considered as good test for diagnosis of toxoplasmosis and mor specific than Toxolatex with also high diagnostic accuracy.

Keywords: Toxoplasmosis; Pregnancy; Sudan; ELISA; igg; Latex; Rapid test

### INTRODUCTION

Toxoplasma gondii (T. gondii), is an obligate intracellular single-cell parasite that survives only if infects worm blood animals. It is a global health condition that almost infects almost one-third of total world population [1]. In Sudan, scarce data available about T. gondii in total population, however, 34% of the pregnant women were seropositive for Immunoglobin G anti-toxoplasma antibodies [2]. In general, the major route of infection is the oral route by ingestion of sporulated oocysts in contaminated food or drinks [3]. Trans- placental transmission from the pregnant women to the fetus is another possible route of infection [4]. In women who are infected with T. gondii during pregnancy and not treated, the incidence of fetal infection is 25% in the first trimester, 54% in the second trimester and 65% in the third trimester [5]. Pregnant

women infected with *T. gondii* have variable disease outcomes that include miscarriage or stillbirth [6]. Vertical transmission can cause congenital toxoplasmosis, which is characterized by chorioretinitis, hydrocephalus and cerebral calcification [7]. On the other hand, infected pregnant women with *T. gondii* usually asymptomatic and therefore diagnosis can be delayed and adverse outcome may occur [8]. Acute and latent *T. gondii* infections during pregnancy are most commonly diagnosed by detecting the immunoglobulin IgG and IgM in the serum samples of the patients [9]. Thus, early screening and laboratory diagnosis of toxoplasmosis of paramount importance in order to prevent the congenital toxoplasmosis.

Treatment of pregnant women infected with toxoplasmosis reduces the concentration of parasites in the placental tissue and decrease the risk of transmission of infection from mother to fetus [10], and

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if the infection with *T. gondii* is detected in the placenta, it should be accepted that the child is more likely to become infected [11].

Since last century, serological diagnostic method like Enzyme Linked Immunosorbent Assay (ELISA), Immunochromatographic test (ICT) and Latex agglutination test (LAT) were the most common tests for diagnosing toxoplasmosis [12]. However, due to variability of these tests' sensitivity, specificity and diagnostic accuracy, knowledge of which test is superior and cost effective as screening and diagnostic tool of paramount importance for the caregiver. Therefore, this study aimed to report and compares the predictive value of commercially available serological test for *T. gondii* antibodies.

## MATERIAL AND METHOD

A cross-sectional study conducted during the period of November 2016-June 2017 in ante natal care unit of Saad Abualila hospital. The study aimed to assess predictive values and diagnostic accuracy of Toxo-latex test (Linear Chemicals) test and Toxo IgM\IgG rapid test (cassette) in detecting T. gondii antibodies in comparison to ELISA (EUROIMMUN) among pregnant women. After obtaining the informed consent socio-demographic data (age, residency) and obstetrical history (Parity, gestational age, history of miscarriage) were collected by using questionnaire. Also, history related to eating habits of raw or undercooked meat, liver or viscera in addition to contact with cats were collected. Then venous blood samples were collected in plain vacutainers and allowed to clot. Then sera were collected in Eppendorf tubes and Toxo-latex test and Toxo IgM\ IgG rapid test (cassette) were performed immediately according to manufacturer instruction in the hospital lab. The remaining serum stored at -20°C and used for ELISA test after completion of the study period. Very briefly, 50 µl of diluted serum sample loaded to the antigen-coated well without touching the wall. Then incubated for 30 minutes and washed thereafter by using washing buffer. Then 50 µl of horseradish peroxidase-labelled anti-IgG enzyme added to the wells. Coloring solution added and finally the absorbance read at 450 nm using Microtiter Plate Reader. IgM antibodies are highly sensitive marker for acute infection and IgG are Anamnestic antibodies and marker for chronic infection and persist for years and ensure protection against new infection.

#### Statistical analysis

Data were entered into computer using Statistical Package for Social Sciences (SPSS) version 16.0 and doubled check. Sensitivity, specificity, predictive value and diagnostic accuracy were calculated by using Open Source Epidemiologic Statistics for Public Health (Open Epi).

## RESULTS

#### Sociodemographic data

A total of 300 pregnant women were enrolled in this study with mean (SD) age of 30.28(6.4) years. Ninety-one (30.3%), 72(24%), 132(44%) were pregnant in the first, second and third trimester, respectively. Previous miscarriage was reported in 186(62%), 153(51%) have a contact with cats, and 124(41.3%) usually consumed raw meats.

#### Screening results

Out of 300 pregnant women screened for anti *T. gondii* antibodies by using ELISA, 65(21.6%) and 4(1.3%) had seropositive *T. gondii* IgG and IgM, respectively. The screening by Toxo-latex test revealed that 95(31.6%) were tested positive, while, the Toxo IgM\IgG rapid test (cassette) showed that 46(15.3%) have positive result.

Sensitivity, specificity, predictive value Toxo-latex test and Toxo IgM $\IgG$  rapid test (cassette).

ELISA test detects 65(21.6%) women with *T. gondii* IgG, while latex agglutination test detects 95(31.6%), this makes the true positive is 29 and true negative 169. The sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and diagnostic accuracy for Latex agglutination test to detect *T. gondii* antibodies were: 44.6\%, 71.9%, 30.5%, 82.4% and 66. % (Table 1).

Comparing rapid cassette test with ELISA IgG results showed that, only 19 were truly tested positive for *T. gondii* antibodies while 208 tested truly negative. This makes the specificity, sensitivity, PPV, NPV and diagnostic accuracy for rapid cassette test to detect *T. gondii* antibodies were: 29.2%, 88.5%, 41.3%, 81.8% and 75.67%, respectively Table 2.

## DISCUSSION

The presence of toxoplasma antibody in the serum is regarded as the important criterion for the diagnosis of toxoplasmosis. At present, several laboratories utilize different techniques as ELISA, indirect haemoaggutination and latex agglutination [13].

In this study, the Toxo-latex and Toxo IgM\IgG rapid test (cassette) were evaluated. Toxolatex give 44.6%, 71.9% sensativity and speciefity respectively while Toxo IgM\IgG rapid test (cassette) shown 29.2%, 88.5% respectively.

This result was disagreeing with result obtained from Jabbar et al. [14], they found 1 Toxolatex speciefity and sensitivity 80%, 61.5% respectively, while Toxo IgM\IgG rapid test speciefity and

 Table 1: Performance of latex agglutination test relative to ELISA test in diagnosis of toxoplasmosis.

IgG ELISA result					
	Positive	Negative	Total	Accuracy measure (95% CI)	
			Latex agglutin	ation result	
Positive	29	66	95	Sensitivity = 44.6% (33.17 - 56.66)	
Negative	36	169	205	Specificity = 71.9% (65.85 - 77.27)	
Total	65	235	300	Positive predictive value = 30.5% (22.17 - 40.39)	
				Negative predictive value = 82.4% (76.65 - 87.04)	
				Diagnostic accuracy = 66% (60.47-71.13)	

Table 2: Performance of rapid test (ICT) relative to ELISA test in diagnosis of toxoplasmosis.

IgG ELISA result						
	Positive	Negative	Total	Accuracy measure (95% CI)		
Rapid test (ICT) result						
Positive	19	27	46	Sensitivity = 29.2% (19.58 - 41.2)		
Negative	46	208	254	Specificity = 88.5% (83.8 - 91.98)		
Total	65	235	300	Positive predictive value = 41.3% (28.29 - 55.66)		
				Negative predictive value = 81.8% (76.69 - 86.14)		
			_	Diagnostic accuracy = 75.67% (70.51-80.18)		

sensitivity 89.2%, 88% respectively. In comparing the Toxo-latex and Toxo IgM\IgG rapid test (cassette) with ELISA the diagnostic accuracy and positive predictive value was 66%, 75.6%, 30.5%, 41.3% respectively.

This result suggests that there is a fairly agreement of Toxo IgM\ IgG rapid test as accurate and specific, which is commercially available for detection of *T. gondii* antibody. Hence, we conclude and recommend that Toxo IgM\IgG rapid test is useful for diagnosis aimed for epidemiological studies of prevalence of toxoplasmosis more than Toxolatex. Also, in Thailand in dairy cows, the highest sensitivity was achieved with latex (100%) and specificity varied with values of 91.3% for latex and 100% for PCR in a comparison with indirect fluorescent antibody test in diagnosis of toxoplasmosis [15].

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### CONFLICT OF INTEREST

The authors declare that there is no conflict of interests.

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