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O0679 Evaluation of three point-of-care (POC) tests for detection of Toxoplasma-IgG and IgM in the United States: proof of concept and pitfalls

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Background: Congenital toxoplasmosis (CT) is a preventable disease, but most pregnant women worldwide are not routinely screened and treated. The cost and validation of serological testing is a major limitation for universal adoption of maternal screening. Point-of-Care (POC) technology may constitute a cost-effective approach. However, there are published data for only one POC for patients in the U.S. and no comparisons of performance of various kits. We compare the diagnostic accuracy of three *Toxoplasma*-POC tests utilizing reference-gold-standard methods.

Materials/methods: Three POC-tests were included: ***Biopanda*** *Toxo IgG/IgM Rapid-test* (Biopanda Reagents, Belfast, UK); ***Onsite*** *Toxo IgG/IgM Combo Rapid-test* (CTK-Biotech, San Diego, USA) and ***LDBIO*** *Toxoplasma-ICT IgG/IgM* (LDBIO Diagnostics, Lyon, France). Samples were selected from the Palo Alto Medical Foundation Toxoplasma Serology Laboratory (PAMF-TSL) (n=150) and the CDC Toxoplasma 1998 Human Serum Panel (n=100). All samples were previously tested at PAMF-TSL for *Toxoplasma*-IgG and IgM detection using the Sabin-Feldman IgG Dye test and IgM-ELISA, respectively. Samples representing acute toxoplasmosis (IgG+/IgM+,n=85), chronic *Toxoplasma* infection (IgG+/IgM-,n=85) and *Toxoplasma*-seronegative sera (IgG-/IgM-,n=80) were tested. Additionally, sera with false-positive *Toxoplasma*-IgM (n=60) were also tested. POC testing was performed following manufacturer's instructions and in duplicate by two independent investigators; final readings were ascertained by two additional investigators, all were blinded to PAMF-TSL's and CDC's results (Figure 1). Sensitivity and specificity were calculated against PAMF-TSL results.

Results: Sensitivity for detection of *Toxoplasma*-IgG was 100% (95%CI,97.8-100%;170/170) for all three POC-tests. Specificity for *Toxoplasma*-IgG POC-tests was comparable: 96.3%(95%CI,89.4-99.2%;3/80), 97.5%(95%CI,97.8-100%;2/80) and 98.8%(95%CI,93.2-99.9%;1/80), for Biopanda, Onsite and LDBIO, respectively. However, sensitivity for detection of *Toxoplasma*-IgM significantly varied across POC-tests: **Biopanda: 62.2%**(95%CI,50.8-72.7%;51/82); **Onsite: 28%**(95%CI,18.7-39.0%;23/82) **and LDBIO: IgG/IgM combined: 100%**(95%CI,97.8-100%;82/82) with comparable IgM specificity between all 3-POC-tests. Sixty sera without IgG seroconversion and with non-specific IgM showed negative IgM results (0 positives/60) with all POC-tests.

Conclusions: POC-tests exhibited optimal sensitivity for *Toxoplasma*-IgG antibodies in the setting of acute and chronic *Toxoplasma* infection. The LDBIO POC-test showed 100% sensitivity for the combined detection of IgG/IgM in acute and chronic *Toxoplasma* infection. Biopanda and Onsite POC-tests showed poor sensitivity for *Toxoplasma*-IgM detection. *Toxoplasma*-POC kits should be evaluated for sensitivity and specificity for both IgG and IgM detection.

Figure 1. *Toxoplasma* Point-of-Care (POC) Tests for Detection of *Toxoplasma* IgG and IgM. **Left:** *Biopanda Toxo IgG/IgM Rapid test* (Biopanda Reagents, Belfast, UK) cassette showing 2 separate strips for *T. gondii* IgG and IgM detection, each one with a control band (C)(sample #24: positive IgG, positive IgM). **Center:** *Onsite Toxo IgG/IgM Combo Rapid test* (CTK Biotech, San Diego, CA, USA) cassette showing one single testing strip with 3 separated testing bands for Control(C), *T. gondii* IgG (G) and IgM (M) antibodies (from top to bottom) (sample #78: positive IgG, negative IgM). **Right:** *LDBIO Toxoplasma® ICT IgG and IgM* (LDBIO Diagnostics, Lyon, France) cassette showing one testing strip with 2 bands for simultaneous detection of *T. gondii* IgG/IgM antibodies (T band) and a control band (C band) (sample #20: positive combined IgG/IgM).