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Clinical validation of a new assay for detection of Toxoplasma gondii DNA by real-time PCR

Francesca Genco*[1], Silvia Mason[2], Claudia Savio[3], Martina Prestia[4], Valeria M.V. Meroni[5]

[1]*San Matteo Hospital Foundation; Microbiology and Virology Unit, Laboratory of Parasitology*

[2]*Ab Analitica Srl*

[3]*Ab Analitica*

[4]*University of Pavia*

[5]*University of Pavia; Medicina Interna e Terapia Medica Sez Malattie Infettive*

Background: Today detection of *Toxoplasma gondii* DNA in amniotic fluid (AF), aqueous an vitreous humor (AH), cerebrospinal fluid (CSF) using Real time PCR assays is a standard approach for the diagnosis of congenital toxoplasmosis, toxoplasmic coroidoretinitis and opportunistic infection in immunocompromised patients. Aim of this study was the external evaluation of clinical performances of the diagnostic device REALQUALITY RQ-TOXO (AB ANALITICA Srl) for detection of *T. gondii*. in Real time PCR, targeting a gene fragment repeated 200 to 300-fold in the pathogen genome (529 bp repeat element).

Material/methods: A group of 103 amniotic fluid and 102 whole blood samples, already resulted negative with TOXOPLASMA g. ELITe MGB® Kit (ELITechGroup SPA), were tested with REALQUALITY RQ-TOXO at the laboratory of Parasitology of IRCCS Policlinic San Matteo Foundation.The same samples have been spiked with different concentrations of 1st WHO International Standard for *Toxoplasma gondii* (NIBSC code:10/242) and analyzed with the new device.
The DNA was extracted from 500 µL (obtained by centrifugation of 10 mL) and 200 µL of amniotic fluid and whole blood respectively by using NucliSENS easyMag (BioMerieux).
Real time PCR was carried out on 7500 Fast Dx Real-Time PCR System (Applied Biosystems).
The assay was tested also with real positive samples of vitreous and aqueous humor, CSF, whole blood and amniotic fluid and with QCMD 2016 *Toxoplasma gondii* DNA EQA Programme.

Possible cross-reactivity of the assay was verified with samples positive for potentially cross-reactive bacterial pathogens (*Staphilococcus hominis, Escherichia coli, Streptococcus pneumoniae, Leishmania spp,Plasmodium spp*).
The study had been approved by the Ethics Committee of IRCCS Policlinic San Matteo Foundation in Pavia (Italy).

Results: All negative samples gave negative results also with REALQUALITY RQ-TOXO device. Among positive samples, 1 of 114 resulted negative. It was an aqueous humor specimen presenting a delayed Ct also with the reference method. None potentially cross-reactive pathogen gave a positive result.

Conclusions: The REALQUALITY RQ-TOXO test showed good sensitivity and specificity also at a low parasitic concentration. It is a reliable method with good reproducibility and easy to perform due to the ready to use reagents format. It can be considered a suitable test for the routinely diagnosis of *Toxoplasma* infections in pregnant women, immunocompromised patients and patients with ocular problems.