EP0259
ePoster Session
Diagnostic parasitology

Molecular diagnosis of toxoplasmosis by Q-Lamp method

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Background: Molecular assays have been of paramount importance for the diagnosis of toxoplasmosis in pregnant women and immunocompromised patients. Today detection of *Toxoplasma gondii* DNA in amniotic fluid (AF) , aqueous humor (AH), cerebrospinal fluid (CSF) and whole blood using real-time PCR assays is a standard approach. The DiaSorin Q-Lamp (loop mediated Isothermal amplification - DiaSorin Saluggia Italy) offers all the benefits of isothermal LAMP technology with the addition of real time fluorescent and multiplexed amplification. Furthermore extraction and Q-Lamp assays are automatized and performed on the Liaison IAM platform. Aim of the study was to evaluate the performance of the Q-Lamp assay (Iam toxo) on clinical sample (AF, CSF, blood) and European quality controls for molecular diagnosis (QCMD – Glasgow UK)

Material/methods: 47 amniotic fluids from pregnant women referred to the Infectious Diseases outpatient clinic for a suspected or confirmed Toxoplasma infection ,2 CSF,1 AH sample and 24 blood samples from immunocompromised patients with suspected toxoplasmic infection/reactivation were store frozen at – 80°C until use. Ten samples of CQMD 2015 were also tested **. Methods** Toxoplasma DNA was extracted with NucliSENS easyMAG (BioMerieux Marcy l'Etoile France). Real time Pcr was run in triplicate using TOXOPLASMA g ELITe MGB Kit (Elitech group SpA Torino Italia) on a 7300 Real-Time PCR System (Applied Biosystems Foster City USA). All the samples were extracted again with Liaison IXT platform after addiction of internal control. Q-Lamp assay was run using Iam Toxo Kit on Liaison IAM instrument. Each test was performed according to the manufacturer's instructions.

Results: All the 47 amniotic fluid gave negative results with the Q-Lamp assay as was recorded with real time PCR . No newborn born from the mothers who underwent amniocentesis resulted infected at the end of one year follow up. The 2 CSF from immunocompromised patients that were positive with real time PCR gave positive results also with Q-Lamp. The patients improved after therapy .The HA sample was negative also with Q-Lamp and the patients was diagnosed a Cytomegalovirus chorioretinis . All the CQMD sample gave the same results with real time PCR and Q-Lamp : 4 of the 5 amniotic fluids samples were positive and 1 negative ,2 of the 5 plasma samples scored negative and 3 positive according with the CQMD due results.

Conclusions: These preliminary data show the good diagnostic accuracy of the new Q-Lamp that seems to be a valid alternative to the classic Real time PCR tests as Q-Lamp is fully automated , less time consuming , less expensive and useful in routine practice with small samples numbers .