

# Quanty TOXO kit performance in the Toxoplasmosis's diagnosis

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## Introduction-Aim.

The survey of *Toxoplasma gondii* DNA occurs through the Polymerase Chain Reaction (PCR) and it makes possible as the diagnosis of congenital Toxoplasmosis and ocular Toxoplasmosis as the diagnosis in immunocompromised patients.

The impact of molecular diagnosis in the immunocompromised patient hasn't been considered yet, differently from congenital Toxoplasmosis diagnosis; therefore, the evaluation of a quantitative kit would be useful for the monitoring of immunocompromised patient undergone to specific therapy with infection/reactivation of the Toxoplasmosis. In this study, We evaluate the analytical performances of quanty-Toxo (Clonit srl, Milan) on amniotic fluid and whole blood samples.

## Materials and Methods.

The new kit quanty TOXO (Clonit srl, Milan) allows the survey and the quantification of the 529-bp repeat genomic region of *T. gondii* through Real Time PCR; this kit is used to analyse 55 amniotic fluid samples, from pregnant with suspected toxoplasmosis, and 59 EDTA blood samples, previously analysed in our lab with TOXOPLASMA g ELITe MGB (ELITechGroup SPA Torino) and proved to be negative for *Toxoplasma gondii* DNA. We made positives the same samples with "1st WHO International Standard for *Toxoplasma gondii* (NIBSC code:10/242)".

DNA is extracted from each samples with EZ1 Advanced XL (QIAGEN), then amplified on Rotor-Gene Q MDX (Qiagen). We analysed also some samples positive for *Leishmaniae spp.* and *Plasmodium spp.* for evaluating possible cross reactions. Comitato di Bioetica of Fondazione IRCCS Policlinico San Matteo in Pavia approved this study.

## Results

Concerning negative samples, the kit quanty TOXO found 54 amniotic fluid samples proved to be negative in 55 with 98.2% of specificity and 58 blood samples in 59 with 98.3% of specificity. Whereas, concerning positive samples, the kit quanty TOXO found 50 amniotic fluids positive in 51, with a sensitivity of 98.1% and all 48 blood samples with a 100% of sensitivity. Moreover, in positive samples we did not find any cross reactions for other pathogens. Using the same reference standards, making positive some negative samples, we can verify the sensitivity of the diagnostic kit, that is able to correctly quantify until at 5 Toxo/ml (corresponding on 5UI/ml).

## Conclusions

The positive control "1st WHO International Standard for *Toxoplasma gondii* (NIBSC code: 10/242)" is used in order to obtain a standardization of the detectable *Toxoplasma* concentrations, as reference material. Furthermore the use of this control permitted to identify the conversion factor between *Toxoplasmas/ml* and IU/ml.

The kit quanty Toxo seems to be an optimal candidate for the monitoring of the immunocompromised patient, considering the obtained outcome; these results show a good sensitivity, sensibility, accuracy and the possibility to quantify the "*parasitic load*".