

IVD_06 - Establishing proof-of-concept for multiplex lateral flow assay to congenital and perinatal infections

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Introduction: Congenital and perinatal infections represent a serious global public health problem. Although there are efficient tests to detect antibodies for these diseases, they are laborious and require significant sample volume. The lateral flow assay (LFA) is an alternative platform with low development and production costs, easy to perform, rapid and portable detection of congenital disorders..

Objectives: This work aims to obtain proof-of-concept (PoC) of a qualitative multiplex lateral flow assay (mLFA) which has been able to detect IgG antibodies against four congenital and perinatal infections. The PoC is an initial stage of testing characteristic of new product or process development. These initial tests should provide relevant result with a good correlation with a reference standard methodology.

Methodology: The development of the mLFA was performed by testing a combination of membranes and different concentrations of the proteins of interest. The prototype obtained was evaluated with twenty-one serum samples, characterized by MBBA (multiplex bead binding assay) to detect IgG antibodies against four congenital and perinatal infections (Toxoplasmosis, Syphilis, Rubella, Cytomegalovirus) and the results were displayed within 15 min. Therefore, a positive result is indicated by a visible signal in the test line, while negative result is the lack of a visible signal. Diagnostic performance (clinical sensitivity and specificity) was evaluated.

Results: The mLFA was specific to four congenital infections and provided a positive agreement percentage of 95% (20/21) compared with MBBA. Only one syphilis positive sample showed false negative in the mLFA. Preliminary clinical sensitivity and specificity were calculated by comparing the mLFA to MBBA (CMV 100%,100%; Syphilis 90%, 100%; Rubella virus 100%, 100%; Toxoplasmosis 100%, 100%) respectively.

Conclusion: In conclusion, PoC data suggest that mLFA could be a valuable diagnostic tool for rapid and efficient detection of IgG antibodies from congenital and perinatal infections presenting satisfactory sensitivity and specificity levels.

Keywords: mLFA; MBBA; Proof-of-Concept