

V14 Development and validation of multiplex test for measurement of antibodies against heptavalent vaccine componentes

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Introduction: Multiplex is a liquid microarray assay that is replacing the immunoenzymatic assays (ELISA) in assessing the immunogenicity of multicomponent vaccines in pre-clinical and clinical trials. This technology utilizes fluorescent distinct microspheres as carriers for different molecules, allowing the simultaneous detection of multiple reactions in a small amount of samples and reagents with high reproducibility and sensitivity. The aim of this study is to develop and validate a multiplex assay for quantitation of antibodies against vaccine antigens present in current pentavalent vaccine (Difteric toxin, Tetanic toxin, H. influenzae type B (Hib) polysaccharide (PRRP), *B. pertussis* and Hepatitis B virus) besides the antigens intended to be used in na heptavalent formulation (N. Meningitidis type C conjugated and Poliovirus). During the upcoming introduction of the heptavalent vaccine in the National Immunization Program, this test might reduce the number of reactions to be performed during pre-clinical and clinical studies, generating working time optimization and lower costs for the National Health System of Brazil.

Objective: The aim of our study is to develop and validate a multiplex assay to quantify IgG against all antigens present in heptavalent vaccine formulation.

Methodology: For this purpose, we have constructed standard curves utilizing diphtheria toxin (Dtx), tetanus toxin (Ttx), capsular polysaccharide of Hib (fosforibosilribitol phosphate – PRRP) and pertussis toxin (Ptx). In addition, 10 serum samples were dosed in monoplex and multiplex assays.

Results: The results demonstrated a good performance of all those curves when comparing monoplex assay and multiplex assay. We have demonstrated that there is a high correlation between monoplex assay, multiplex assay and ELISA tests.

Conclusion: These results show the feasibility and applicability of this approach for clinical studies of combined vaccines.

Palavras-Chave: Multiplex, Heptavalent Vaccine