

## **R2. ACCURACY OF A DPP SYPHILIS BIO-MANGUINHOS ASSAY FOR SIMULTANEOUS DETECTION OF NONTREPONEMAL AND TREPONEMAL ANTIBODIES IN PATIENTS WITH ACQUIRED SYPHILIS.**

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**INTRODUCTION** Syphilis is a curable infection disease caused by *Treponema pallidum*. WHO estimates that there are 937,000 sexually transmitted syphilis cases per year in Brazil in its sexually active population. Rapid point-of-care (POC) tests for simultaneous detection of nontreponemal and treponemal antibodies can help resolve the issue with regard to treatment decisions.

**OBJECTIVE** To evaluate the accuracy of DPP nontreponemal / treponemal Syphilis Bio-Manguinhos Assay compared to the diagnostic tests currently being used (VDRL and TPHA).

**METHODOLOGY** Sectional study conducted in healthy units where syphilis diagnosis is usually made. The study population was composed by adults stratified in three groups: infected with HIV (N= 174), pregnant women (N=170) and neither pregnant nor HIV infected (N=149). The syphilis status wasn't known before study enrollment. Whole blood, serum and plasma specimens were used for study objective. Reference tests for treponemal and nontreponemal antibody tests were TPHA and VDRL, respectively, following the flowchart of testing from Brazilian Ministry of Health. The sensitivity, specificity, positive and negative predictive values (PPV/NPV) has been calculated separately for each study group and biological specimen. The main outcome was the combined results of nontreponemal and treponemal DPP assays compared with TPHA positive combined with a VDRL with titer of 1:8.

**RESULTS** Considering the reference flowchart and tests, the results for each specimen and group were: people infected with HIV in whole blood - sensitivity

(100%), specificity (93.1%), PPV (7.7%), NPV (100%); people infected with HIV in serum - sensitivity (100%), specificity (91.9%), PPV (6.7%), NPV (100%); people infected with HIV in plasma - sensitivity (100%), specificity (92.5%), PPV (7.1%), NPV (100%); pregnant women in whole blood - sensitivity (100%), specificity (99.4%), PPV (50%), NPV (100%); pregnant women in serum: sensitivity (100%), specificity (99.4%), PPV (50%), NPV (100%); pregnant women in plasma: sensitivity (100%), specificity (98.2%), PPV (25%), NPV (100%); people neither pregnant nor HIV infected in whole blood: sensitivity (80%), specificity (97.2%), PPV (50%), NPV (99.3%); people neither pregnant nor HIV infected in serum: sensitivity (100%), specificity (96.5%), PPV (50%), NPV (100%); People neither pregnant nor HIV infected in plasma - sensitivity (100%), specificity (96.5%), PPV (50%), NPV (100%). Two subjects were in treatment for syphilis during study evaluation and have been removed from the analysis. One study limitation was the observed syphilis prevalence lower than previously estimated, affecting the positive predictive value calculation.

**CONCLUSION** POC DPP Syphilis Bio-Manguinhos evaluated in this study shows good sensitivity and specificity in detecting treponemal and nontreponemal antibodies in whole blood, serum and plasma. Considering the overall study results and the assay simple performance, we conclude that this assay can be considered as an alternative in the diagnosis of syphilis, particularly in resource-limited areas where disease prevalence, and loss to follow-up, are high.

**KEYWORDS** syphilis, diagnostic, point of care, rapid test.