**TITLE**: COMPARISON OF THE LINEAR ARRAY $^{\otimes}$  HPV GENOTYPING TEST AND COBAS $^{\otimes}$  HPV TEST FOR GENOTYPING OF HUMAN PAPILLOMAVIRUS (HPV) INFECTION IN IMMUNOCOMPETENT WOMEN

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## **ABSTRACT:**

A total of 40 genotypes of human papillomavirus (HPV) that infect the anogenital region have already been described. They can be classified as high-risk or low-risk according to their potential to cause high-grade intraepithelial lesions and invasive cervical carcinomas. This highlights the importance of using accurate methods for HPV detection and genotyping in order to determine the group of women at increased risk for HPV-induced lesions. The Linear Array HPV Genotyping® (Roche Molecular Systems, Pleasanton, CA) (LA) is mostly used in scientific researches and detects 37 genotypes of HPV, whereas the Cobas® HPV Test (Roche Molecular Systems, Pleasanton, CA) (CO) only detects 14 high-risk HPV genotypes and it is mainly used for diagnostic routine. Thus, the aim of this study was to compare the prevalence of HPV genotypes in immunocompetent women using LA and CO tests. A total of 91 women that participate of the cohort "Prevalência da coinfecção e fatores associados ao HPV em mulheres em idade reprodutiva atendidas em Programa de Prevenção do Colo Uterino", held in Botucatu, SP, Brazil, were included this study. Detection and genotyping of HPV were performed in cervical samples obtained using the SurePath® (BD Diagnostics, Sparks Glencoe, MD) by LA and CO methods. The agreement of the two methods was determined by kappa index. Of the 91 samples analyzed, 55 were HPV positive in LA and 28 in CO. From 27 samples with discordant results, 17 were low-risk HPV, thus not expected to be detected by CO. The remaining 10 samples, resulted in high-risk HPV in LA, but were not detected by CO. The overall positivity for high-risk HPV was 37 (40.6%) using LA and 27 (29.7%) using CO resulting in a kappa value of 0.74. Among HPV-positive samples, 16 HPV was the most prevalent genotype using both methods, LA (n= 11, 20.0%) and CO (n= 9, 32.1%), resulting in a kappa value of 0.89. In conclusion, the results of this study show a good agreement between the LA and CO, but below of those described in the literature.

**Keywords:** Human papillomavirus, HPV genotyping, HPV testing comparison

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