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Author: Mario Poljak Boštjan J. Kocjan Anja Oštrbenk Katja

Seme

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ACCEPTED MANUSCRIPT

Commercially available molecular tests for human papillomaviruses (HPV): 2015 update

Mario Poljak*, Boštjan J. Kocjan, Anja Oštrbenk, Katja Seme

Institute of Microbiology and Immunology, Faculty of Medicine, University of Ljubljana, Ljubljana, Slovenia

*Corresponding author: Tel.: +386 1 543 7453; Fax: +386 1 543 7401; E-mail: mario.poljak@mf.uni-

lj.si (M. Poljak)

Highlights

- At least 193 commercial HPV tests and 127 variants of the original tests are available.
- There was a 54% increase in the number of HPV tests in comparison with 2012.
- All but two commercial HPV tests target alpha-HPV types only.
- Only 35% of tests have performance evaluations published in peer-reviewed literature.
- Manufacturers should invest greater effort into evaluating their products.

Abstract

Commercial molecular tests for human papillomaviruses (HPV) are invaluable diagnostic tools in cervical carcinoma screening and management of women with cervical precancerous lesions as well as important research tools for epidemiological studies, vaccine development, and implementation and monitoring of vaccination programs. In this third inventory of commercial HPV tests, we identified 193 distinct commercial HPV tests and at least 127 test variants available on the market in 2015, which represents a 54% and 79% increase in the number of distinct HPV tests and variants, respectively, in comparison to our last inventory performed in 2012. Identified HPV tests were provisionally divided into eight main groups and several subgroups. Among the 193 commercial HPV tests, all but two target alpha-HPV types only. Although the number of commercial HPV tests with at least one published study in peer-reviewed literature has increased significantly in the last three years, several published performance evaluations are still not in line with agreed-upon standards in the HPV community. Manufacturers should invest greater effort into evaluating their products and publishing

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