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Performance evaluation of Papilloplex™ HR-HPV kit: A novel multiplexing assay for genotyping all 14 HR HPV types in a single closed tube real-time PCR reaction

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Multiplex Probe Amplification (MPA) technology dramatically expands multiplexing ability of a real-time PCR reaction. It was used to develop a quick, easy-to-use, sensitive and affordable genotyping assay that detects all 14 HR-HPV types in a single reaction Papilloplex™ HR-HPV test. In the present study, we carried out a comparative analysis of the performance of Papilloplex™ HR-HPV test with four well established assays on a panel of liquid based cytology (LBC) samples. Analytical specificity of the assay was also interrogated using the WHO HPV LabNet proficiency panel (2015). The Papilloplex™ HR-HPV test was used to test 500 diseases enriched cervical LBC samples obtained from the Scottish HPV Archive, Edinburgh with known concurrent pathology results. Samples were also tested by the Abbott rT HPV assay, the Qiagen Hybrid Capture 2 Assay, the Diamex Optiplex HPV Genotyping kit and Roche Linear Array HPV Genotyping test. Concordance between the comparator assays vs. Papilloplex™ was performed using binomial test and McNemars test of proportions. As the samples were enriched for CIN2+ the applicability of clinical performance measures to screening settings are limited however these were assessed in terms of sensitivity and specificity for underlying CIN2+. These data indicate that the analytical performance of Papilloplex™ HR-HPV assay is comparable to established HPV assays at the level of generic HR-HPV detection and at the type specific level. The assay shows potential promise for both disease management and epidemiological applications. Further data on the clinical performance of the assay will be presented.

Biography

Guoliang Fu has completed his PhD from Moscow State University in 1995 and is a Chief Scientist and Founder of GeneFirst Limited, UK. He has held several research positions within Cambridge University, Imperial College London, Oxford University and Oxitec Limited. He is also a Founder for 360 Genomics Limited (acquired by EFK Diagnostics in 2012). He has invented several patented technologies relating to the application of qPCR in medical diagnostics. His technologies allow detection of multiple targets in single closed tube and his interests are to develop further applications while collaborating with industry and academia.

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