2020 ESGO LIST OF HPV ASSAYS THAT CAN USED FOR CERVICAL CANCER SCREENING

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Clear evidence is Today available indicating that human papillomavirus (HPV)-based primary screening is more effective to prevent cervical cancer than screening with cytology[1,2]. Therefor more and more countries have switched or are in the process of switching towards virological testing. Currently there is a multitude of HPV assays on the market but only a small minority of them have been clinically validated against internationally agreed criteria[3]. The international criteria concern high-risk HPV DNA tests on cervical specimen (Meijer, Int J Cancer, 2009) [4]. Two HPV assays (Hybrid Capture-2 [Qiagen] and GP5+/6+ PCR [Diassay, Rijkswijk, the Netherlands]) are considered in the Meijer guidelines as standard comparator tests since they were used in the pivotal randomized trials that demonstrated the superior efficacy of screening with HPV tests. Experts agree that it is not needed to repeat large, expensive and long lasting trials to accept other HPV assays. It is sufficient to demonstrate non-inferior sensitivity and specificity for detecting CIN2+ compared to one of the standard comparator tests and to show good intra- and extra-reproducibility[4].

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Besides, the two standard comparator assays (HC2 and and GP5+/6+ PCR), eight other assays can be considered as usable in cervical cancer screening (in alphabetic order):

- Alinity m HR HPV Assay [Abbott, Wiesbaden, Germany]
- Anyplex II HPV HR Detection [Seegene, Seoul, South Korea]
- Cobas 4800 HPV Test [Roche Molecular System, Pleasanton, CF, USA]
- HPV-Risk Assay [Self-Screen BV, Amsterdam, The Netherlands]
- Onclarity HPV Assay [BD Diagnostics, Sparks, MD, USA]
- PapilloCheck HPV-Screening Test [Greiner Bio-One, Frickenhausen, Germany]
- RealTi*m*e High Risk HPV Test [Abbott, Wiesbaden, Germany]
- Xpert HPV [Cepheid, Sunnyvale, CA, USA].

The cobas 6800 [Roche] also fulfilled all the three validation criteria but its clinical accuracy has been compared with cobas 4800 which is not a standard comparator, but it might be accepted as an alternative comparator test in the future.
Certain other assays fulfilled certain but not all of the criteria are were therefore classified as *partially* validated[5].
Currently, the validation criteria of Meijer are under review and this process is also supported by ESGO. The new criteria will include guidance on HPV on self-samples, HPV genotyping, extension of the list of standard comparator tests and the development of longitudinal validation criteria for non HPV DNA HPV assays such HPV RNA assays. Together with the experts preparing the new criteria, ESGO will inform its members on new validated assays and the updated validation criteria. It is important that clinicians send the cervical specimens of their patients to laboratories that use clinically validated HPV assays.

References

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