WHO's announcement on adopting the fulfilment of Meijer's 2009 criteria in independent evaluations as WHO's prequalification independent performance evaluation component for HPV nucleic acid tests

The prequalification assessment process for in vitro diagnostics consists of the following components:

1. review of a product dossier;
2. performance evaluation, including operational characteristics;
3. inspection of a manufacturing site against all applicable requirements of ISO 13485:2016; and
4. labelling review.

WHO's prequalification builds on a risk-based approach whereby considerations such as the risk class of the product, the novelty of the technology, the manufacturer's experience level with the type of product and specific public health concerns are considered. The need to undertake a prequalification independent evaluation also follows risk-based principles.

Testing for human papillomavirus (HPV) using nucleic acid-based methods are used as an alternative for cytology-based cervical cancer screening. These tests must offer an optimal balance between clinical sensitivity (i.e. capacity to detect HPV infections that are associated or will develop into cervical cancer) and clinical specificity to minimize unnecessary follow-up procedures. An international team of experts defined in 2009 a set of criteria (often called the Meijer's criteria) that are considered for the validation of HPV tests (1). These criteria are based on the cross-sectional evaluation of the relative clinical accuracy of HPV tests compared with comparator tests that were shown to be superior to cytology in large prospective screening trials, as well as intra- and inter-laboratory reproducibility. The latest list of HPV tests suitable for primary cervical cancer screening based on these criteria included 11 tests (2).

In this context and as part of a broader effort to streamline assessment processes, WHO has taken the decision to adopt the fulfilment of Meijer's criteria in independent evaluations as the prequalification independent performance evaluation component for HPV nucleic acid tests. For these products, the prequalification assessment will include the review of a product dossier, a site inspection and labelling review. For products which have already fulfilled Meijer's criteria in independent evaluations, such data will be used by WHO to inform the prequalification decision. Manufacturers of HPV nucleic acid tests submitted for WHO's prequalification assessment for which Meijer's criteria in independent evaluations have not yet been fulfilled must take the necessary steps to ensure their compliance with such criteria as a condition for WHO's prequalification listing. Fulfilment of Meijer's criteria in independent evaluations will be assessed by external experts based on scientific publications or studies provided by the manufacturer. Studies designed to meet Meijer's criteria may not address all requirements for studies establishing diagnostic sensitivity and specificity for the product dossier, as described in TSS-4. A product dossier containing all information as per document PQDx_018 – *Instructions for compilation of a product dossier* must be submitted for review by WHO.

This measure is applicable with immediate effect. Applications already submitted for WHO's prequalification assessment and accepted by WHO for assessment are subject to the provisions described above.

1. *Meijer CJLM, Castle PE, Hesselink AT, Franco EL, Ronco, Arbyn M, et al. Guidelines for human papillomavirus DNA test requirements for primary cervical cancer screening in women 30 years and older. Int J Cancer 2009; 124:516e20.*
2. *Arbyn M, Simon M, Peeters E, Xu L, Meijer CJLM, Berkhof J, Cuschieri K et al. 2020 list of human papillomavirus assyas suitable for primary cervical cancer screening. Clin Microbiol Infect. 2021 Aug;27(8):1083-1095*