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GeneXpert for HighRisk HPV Detection in FFPE Cervical Tissues: Diagnostic Value and Methodological Considerations

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[1] Magaji SJ, Aminu M, Doko MH, Oguntayo AO, Yaro JD. Characterization of High-Risk Human Papillomavirus Genotypes in Formalin-Fixed Paraffin-Embedded Cervical Tissues Using... [2] Molina MA, Carosi Diatricch L, Castany Quintana M, Melchers WJ, Andralojc KM. Cervical cancer risk profiling: molecular biomarkers predicting the... [3] Srinivasan M, Sedmak D, Jewell S. Effect of fixatives and tissue processing on the content and integrity of... [4] Kelly H, Jaafar I, Chung M, Michelow P, Greene S, Strickler H, et al. Diagnostic accuracy of cervical cancer screening strategies for high-grade cervical intraepithelial neoplasia... [5] Einstein MH, Smith KM, Davis TE, Schmeler KM, Ferris DG, Savage AH, et al. Clinical evaluation of the cartridge-based GeneXpert human papillomavirus assay in...

Dear Editor,

We read with great interest the article by Magaji et al. entitled “Characterization of HighRisk Human Papillomavirus Genotypes in FormalinFixedParaffinEmbedded Cervical Tissues Using GeneXpert,” published in Infection Epidemiology and Microbiology [1]. Investigation of highrisk human papillomavirus (hrHPV) in archived cervical tissues is of considerable clinical and epidemiological importance because persistent hrHPV infection is recognized as a necessary cause of cervical cancer worldwide [2]. Molecular characterization of HPV genotypes in formalinfixed paraffinembedded (FFPE) tissues may therefore provide valuable information for retrospective studies and for understanding genotype distribution in cervical neoplasia.

In the present study, the authors analyzed 200 FFPE cervical tissue samples using the cartridgebased GeneXpert/Xpert HPV assay. According to the abstract, 47 samples (23.5%) were positive for hrHPV, 96 samples (48%) were negative, and 57 samples (28.5%) yielded invalid results.

HPV16 was reported as the most frequently detected genotype. The use of a rapid and automated PCRbased platform represents

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an important step toward expanding molecular HPV diagnostics beyond conventional cytologybased samples.

Nevertheless, several methodological aspects merit further discussion.

First, the proportion of invalid results reported in the study appears relatively high. Out of 200 analyzed specimens, 57 samples (28.5%) were classified as invalid. Such a rate may substantially affect the feasibility of implementing this assay in routine diagnostic settings. DNA extracted from FFPE tissues is known to be susceptible to fragmentation and crosslinking due to formalin fixation and longterm storage, which may impair amplification efficiency in PCRbased assays [3]. Providing additional information regarding tissue processing conditions, fixation duration, storage time, or DNA quality assessment would help clarify potential sources of assay failure and guide future optimization strategies.

Second, the study indicates that the assay demonstrated low sensitivity for CIN1 lesions**,** while the positive predictive value for preinvasive diseases was described as poor. From a clinical perspective, accurate detection of early cervical lesions is crucial because screening and preventive strategies aim to identify disease before progression to invasive cancer. Previous validation studies have shown that clinically useful hrHPV assays should demonstrate high sensitivity for detecting CIN2+ lesions to ensure reliable screening performance [4]. Therefore, the relatively limited sensitivity observed in early lesions warrants further discussion regarding the potential diagnostic role of this assay in FFPE tissue samples.

Third, the authors report comparatively better specificity and negative predictive value, including a notably high negative predictive value for CIN2. These findings may suggest that the assay could have greater utility as a ruleout test rather than as a confirmatory diagnostic tool in certain pathological contexts. Clarifying this potential application would help laboratories better interpret negative results when using GeneXpert on archival tissue specimens.

Finally, it should be noted that the GeneXpert/Xpert HPV assay was originally designed and clinically validated primarily for cervical cytology samples rather than for FFPE tissue sections [5]. While adapting such platforms for archival tissue analysis is a promising approach, differences in specimen preparation and DNA integrity may influence assay performance. Further validation studies comparing FFPEbased results with those obtained from cytology or fresh tissue specimens could provide additional insight into the reliability of this method.

In conclusion, the study provides valuable preliminary data on the feasibility of applying GeneXpert technology for hrHPV detection in FFPE cervical tissues. However, the relatively high invalid rate, limited sensitivity in lowgrade lesions, and the need for clearer methodological reporting highlight important areas for further optimization. Addressing these issues in future investigations may improve the diagnostic reliability of molecular HPV testing in archival pathology specimens.

Conflicts of Interest: None

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