COLLEGE of AMERICAN PATHOLOGISTS
Laboratory Quality Solutions

Human Papillomavirus Testing in Head and Neck Carcinomas

Statements and Strength of Recommendations

Summary of Recommendations

Guideline Statement		Strength of Recommendation
1.	Pathologists should perform high-risk human papillomavirus (HR-HPV) testing on all patients with newly diagnosed oropharyngeal squamous cell carcinoma (OPSCC), including all histologic subtypes. This testing may be performed on the primary tumor or on a regional lymph node metastasis when the clinical findings are consistent with an oropharyngeal primary.	Strong Recommendation
2.	For oropharyngeal tissue specimens (ie, noncytology), pathologists should perform HR-HPV testing by surrogate marker p16 immunohistochemistry (IHC). Additional HPV-specific testing may be done at the discretion of the pathologist and/or treating clinician, or in the context of a clinical trial.	Recommendation
3.	Pathologists should *not* routinely perform HR-HPV testing on patients with nonsquamous carcinomas of the oropharynx.	Expert Consensus Opinion
4.	Pathologists should *not* routinely perform HR-HPV testing on patients with nonoropharyngeal primary tumors of the head and neck.	Recommendation
5.	Pathologists should routinely perform HR-HPV testing on patients with metastatic squamous cell carcinoma (SCC) of unknown primary in a cervical upper or mid jugular chain lymph node. An explanatory note on the significance of a positive HPV result is recommended.	Recommendation
6.	For tissue specimens (ie, noncytology) from patients presenting with metastatic SCC of unknown primary in a cervical upper or mid jugular chain lymph node, pathologists should perform p16 IHC. Note: Additional HR-HPV testing on p16-positive cases should be performed for tumors located outside of level II or III (nonroutine testing) in the neck and/or for tumors with keratinizing morphology.	Expert Consensus Opinion

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Guideline Statement		Strength of Recommendation
7.	Pathologists should perform HR-HPV testing on head and neck fine needle aspiration (FNA) SCC samples from all patients with known OPSCC not previously tested for HR-HPV, with suspected OPSCC, or with metastatic SCC of unknown primary. Note: No recommendation is made for or against any specific testing methodology for HR-HPV testing in FNA samples. If the result of HR-HPV testing on the FNA sample is negative, testing should be performed on tissue if it becomes available. If pathologists use cytology samples for p16 IHC testing, they should validate the criteria (ie, cutoff) for a positive result.	Expert Consensus Opinion
8.	Pathologists should report p16 IHC positivity as a surrogate for HR-HPV in tissue specimens (i.e., noncytology) when there is at least 70% nuclear and cytoplasmic expression with at least moderate to strong intensity.	Expert Consensus Opinion
9.	Pathologists should *not* routinely perform low-risk HPV testing on patients with head and neck carcinomas.	Expert Consensus Opinion
10.	Pathologists should *not* repeat HPV testing on patients with locally recurrent, regionally recurrent, or persistent tumor if primary tumor HR-HPV status has already been established. If initial HR-HPV status was never assessed or results are unknown, testing is recommended. HPV testing may be performed on a case-by-case basis for diagnostic purposes if there is uncertainty regarding whether the tumor in question is a recurrence or a new primary SCC.	Expert Consensus Opinion
11.	Pathologists should *not* routinely perform HR-HPV testing on patients with distant metastases if primary tumor HR-HPV status has been established. HPV testing may be performed on a case-by-case basis for diagnostic purposes if there is uncertainty regarding whether the tumor in question is a metastasis or a new primary SCC.	Expert Consensus Opinion
12.	Pathologists should report primary OPSCCs that test positive for HR-HPV or its surrogate marker p16 as HPV-positive and/or p16-positive.	Expert Consensus Opinion
13.	Pathologists should *not* provide a tumor grade or differentiation status for HPV-positive/p16-positive OPSCCs.	Expert Consensus Opinion
14.	Pathologists should *not* alter HR-HPV testing strategy based on patient smoking history.	Expert Consensus Opinion

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