Non-Small Cell Lung Cancer (NSCLC)

HISTOPLUS™: LUNG CANCER ASSAY

HistoPlus™: Lung Cancer Assay

An increasing number of clinical studies have shown the importance of establishing the histologic subtype of non-small cell lung cancer (NSCLC) to guide the use of appropriate subtype-specific therapies for patients.

- Patients with tumors classified as squamous cell carcinoma may have adverse effects from treatment with bevacizumab or pemetrexed.\(^1\)
- The NCCN® Guidelines include additional molecular tests (EGFR mutation analysis, ALK gene rearrangements, ROS1 gene rearrangements) for selecting specific targeted therapies (erlotinib, crizotinib) for tumors classified as adenocarcinoma.\(^2\)

What is HistoPlus™: Lung Cancer Assay?

- HistoPlus: Lung Cancer assay is a gene expression assay using quantitative real-time PCR (qRT-PCR) for 57 genes expressed in NSCLC subtypes. This test can be used to distinguish adenocarcinoma from squamous cell cancer subtypes.
- An interobserver reproducibility study for NSCLC diagnosis found that there was only moderate agreement (kappa value = 0.55) among pathologists in standard H&E diagnosis of squamous cell carcinoma versus adenocarcinoma. Higher agreement was associated with differentiated tumors and pathology experience and expertise.\(^3\)
- In an internal comparative study of HistoPlus: Lung Cancer assay results versus standard H&E morphologic classification (performed at a CLIA certified reference laboratory), an agreement of 90.5% was observed between a consensus pathology diagnosis and subtype determination by gene expression, in differentiating squamous cell carcinoma from adenocarcinoma.\(^4\)

Clinical Dilemma

- In current practice many lung tumor samples submitted for pathology evaluation are too small for ancillary IHC testing to determine the NSCLC subtypes.
- Standard morphologic classification (H&E) can produce disagreement between pathologists in providing a specific diagnosis of adenocarcinoma versus squamous cell carcinoma as determined in the VOILA study.\(^3\)
- Per the NCCN® guidelines, it is important to maintain adequate tissue for molecular testing. Therefore, pathology evaluation should limit the use of IHC studies in small tissue samples to preserve critical tissue.\(^2\)

Clinical Application of HistoPlus™: Lung Cancer Assay

What can be done with problematic cases that cannot be histologically evaluated by standard H&E, with limited tissue to test by IHC, or samples with low tumor content?

- HistoPlus: Lung Cancer assay is a molecular test that aids in differentiating squamous cell carcinoma from adenocarcinoma in NSCLC.\(^5,6\)
- HistoPlus: Lung Cancer assay, in conjunction with morphological studies, helps further stratify neuroendocrine pulmonary neoplasms.\(^6\)
- HistoPlus: Lung Cancer assay complements standard histopathology and can be particularly useful in poorly differentiated tumors or tumors with limited cellularity.
Methodology

Quantitative real-time PCR (qRT-PCR)

Specimen Requirement Options

- Formalin-fixed, paraffin-embedded tissue block (preferred) or
- Four unstained slides at 10 μM and one matching H&E slide (Air dry. Do not oven dry.)

CPT Code(s): 81479

REFERENCES

4. Data sourced from studies at LabCorp’s Center for Molecular Biology and Pathology.