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Researchers find two new methods to determine ALK status

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The implementation of personalized health care in cancer relies on the identification and characterization of cancer biomarkers and the availability of accurate detection systems and therapies for those biomarkers. Anaplastic lymphoma kinase (ALK), a tyrosine kinase, is a more recently characterized cancer biomarker in non–small-cell lung cancer (NSCLC). To identify NSCLC patients with ALK gene rearrangement in clinical trials, researchers have used the methods known as fluorescence in situ hybridization (FISH) or immunohistochemistry (IHC). While IHC is a less complex and less costly technology than FISH, both methods present challenges.

Now research published in the August issue of the *Journal of Thoracic Oncology* (*JTO*), describes the development and evaluation of two new methodologies.

To improve IHC assay sensitivity, the researchers incorporated the novel, nonendogenous hapten 3-hydroxy-2-quinoxaline and tyramide amplification into a diaminobenzidine and horseradish peroxidase–based assay. The new detection system proved to be very useful for detecting low levels of ALK protein expression in NSCLC.

They also developed a brightfield IHC–in situ hybridization combination assay (gene–protein assay) for the concurrent visualization of ALK protein and ALK gene arrangement. This allows the concurrent visualization of ALK gene and ALK protein status in single cells, allowing more accurate ALK status determination even in heterogeneous

specimens.

The authors say, "this tool for simultaneously assessing both ALK protein expression (IHC) and ALK gene rearrangement (ISH) in NSCLC will be valuable for research on the mechanisms driving ALK-dependent malignancies and as a model of new diagnostic approach for identifying patients who might benefit from ALK-targeted therapies. More generally, it also provides proof of concept for the development of new methodologies for the simultaneous assessment of gene structure and protein-expression status in a single cell.

Provided by International Association for the Study of Lung Cancer

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