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Antibody 1A4 with routine immunohistochemistry demonstrates high sensitivity for ALK rearrangement screening of Chinese lung adenocarcinoma patients: A single-center large-scale study

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Objectives: The rearrangement of echinoderm microtubule-associated protein-like 4-anaplastic lymphoma kinase (EML4-ALK) in non-small cell lung cancer (NSCLC) cells might be a promising therapeutic target. However, the low positive rate seeks a reliable and cost-effective method for ALK rearrangement prescreening. This study aimed to evaluate the application of a novel primary antibody 1A4 for routine ALK immunohistochemistry (IHC) test.

Materials & Methods: Primary antibody 1A4 and D5F3 were used for the screening of 595 formalin-fixed, paraffin-embedded tissues of consecutive patients with lung adenocarcinoma for ALK-positive candidates. Ventana detection system and fluorescence in situ hybridization (FISH) were used as reference methods.

Results: Among 595 cases, the protein expression statuses of 1A4 were 3+ (18), 2+ (50), 1+ (153), and 0+ (374) and those of D5F3 were 3+ (17), 2+ (18), 1+ (20) and 0+ (540). Ventana detection system and FISH test results were successfully obtained from 482 cases. A total of 298 specimens with 1A4 (-) showed 100% concordance with standard FISH results. All 58 FISH (+) cases were identified by antibody 1A4. Meanwhile, 14 and 5 were missed by antibody D5F3 with routine IHC and Ventana system, respectively. 1A4 with routine IHC had better sensitivity (100%, 75.9% and 91.4%, respectively) but lower specificity (70.3%, 99.8% and 100%, respectively), than D5F3 with routine IHC and Ventana system.

Conclusion: The novel antibody 1A4 used as a prescreening method may help to reduce the false-negative rearranged ALK status if FISH or reverse transcription polymerase chain reaction results were used for validation.

Biography

Qiushi Wang is currently a Research Assistant from the Department of Pathology at Daping Hospital, Third Military Medical University, China. He is the Head of the Molecular Pathology Group and the Administrator of the Clinical Biobank of Daping Hospital (CBDH). He has been working on tumor (Especially for NSCLC) molecular diagnosis, target therapies and clinical biobank construction. He has published 8 papers in some of the reputed journals.

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