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ALK UltraMAB® Antibody (OT11A4) Outperform D5F3 Antibody, Successfully Demonstrating Higher Sensitivity in NSCLC Immunohistochemistry Diagnostics

Recent Studies Validate High performance and Accurate Results for UltraMAB® OT11A4 as an Effective Screening Tool for ALK Translocation in Non-Small Cell Lung Cancer patients

Rockville, MD – April 14, 2016. A pair of recently published studies shed light on the highly interesting area on detection of ALK expression among NSCLC patients by IHC. One study was conducted by NordiQC (Aalborg, Denmark), the other by a group of Germany scientists and was published in the Journal of Thoracic Oncology. Both studies compared the performance of OT11A4 antibody from OriGene (Rockville, MD) and the D5F3 antibody from Ventana (Tucson, AZ) in a large set of lung cancer specimens with known ALK status identified by FISH assay. The Germany group, Dr. Gruber et al, used the conventional immunohistochemistry staining procedures without signal enhancement. They revealed that the OT11A4 ALK antibody clone identified all 20 ALK-rearranged tumors, indicating 100% sensitivity, and correctly characterized 196 of 198 negative cases (99.1% specificity). The study revealed that the performance of the OT11A4 antibody exceeded the performance of the leading market alternative, the D5F3 antibody clone from Ventana. This result highly correlates with the performance of the anti-ALK OT114 antibody clone in a recent NordiQC assessment lu-ALK run 45 2015, which concluded that the clone is “recommendable for demonstration of EML4-ALK translocation in lung adenocarcinoma.” The conclusions from two highly respectable and independent scientific evaluators suggest that the clone OT11A4 antibody is a reliable reagent for evaluating lung tumors for the presence of ALK rearrangements.

Another independent study published in the Journal of Lung Cancer applied the ALK antibodies to screen ALK-positive Chinese patients with lung adenocarcinoma. Once again the study revealed that the OT11A4 clone outperformed the frequently recognized D5F3 antibody. Results indicate in a study of 595 lung adenocarcinoma cases that the OT11A4 antibody yielded a markedly higher sensitivity on ALK rearrangement and detection. The authors concluded “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.”

The OT11A4 antibody clone used in both studies was developed from OriGene’s proprietary UltraMAB® antibody development platform and has been verified to an unprecedented level of “mono-specificity”, ensuring superior performance in tissue evaluations and in antibody dependent applications such as immunohistochemistry.

“We are thrilled to see multiple leading research groups independently validated the superior performance of OriGene’s ALK antibody (OT11A4). IHC detection of ALK in lung carcinoma is a challenging task and its feasibility relies on the quality of the ALK antibody. We are glad that our UltraMAB® clone OT11A4 was recognized as a better ALK antibody than Vantana’s D5F3 clone”, commented Dr. Donghui Ma, Senior Vice President and Head

of Antibody Development at OriGene Technologies. “We firmly believe that our unique UltraMAB® technology will bring forth many more high quality antibodies into the IHC diagnostic market.”

UltraMAB® Antibody Overview:

Initiated in 2010, OriGene’s UltraMAB® antibody development and validation program has successfully released more than 150 “Ultra-Specific” antibodies, each validated against OriGene’s proprietary high density protein microarray chip technology. Through this unique validation approach, each UltraMAB® Antibody is performance tested and specificity-verified to possess no discernable cross-reactivity with unrelated proteins.

Created mostly from full-length human protein antigens and through the screening of hundreds of mouse hybridomas to identify the best performing clones, UltraMAB® Antibodies are also extensively validated through different applications on a large number of clinical samples to ensure superior performance. For a comprehensive review of each study listed and for a complete overview of the UltraMAB® program please visit www.origene.com/ultramab.

Referenced Scientific Studies:

- **Antibody 1A4 with routine immunohistochemistry demonstrates high sensitivity for ALK rearrangement screening of Chinese lung adenocarcinoma patients: A single-center large-scale study,** [Lung Cancer Feb 2016](#)

- **NordiQC Immunohistochemistry Quality Control Run 45 2015 on Lung Anaplastic Lymphoma Kinase (Lu-ALK),** Nordi QC Team, [NordiQC assessment Run 45 on ALK](#)

- **A Novel, Highly Sensitive ALK Antibody 1A4 Facilitates Effective Screening for ALK Rearrangements in Lung Adenocarcinomas by Standard Immunohistochemistry,** [J Thorac Oncol. 2015 Apr;10\(4\):713-6](#)

About OriGene Technologies

OriGene Technologies, Inc. is a gene centric life sciences company dedicated to support academic, diagnostic, pharmaceutical and biotech companies in their research of gene functions and drug discovery. OriGene's novel product line includes the world's largest cDNA and shRNA clone collections, over 12,000 purified human proteins produced from mammalian (HEK293) cells, over 50,000 high quality primary antibodies including TrueMAB™ mouse monoclonal antibodies and polyclonal antibodies made against full-length proteins for the conservation of native epitopes, validated “mono-specific” monoclonal antibodies called UltraMAB® which offer a unique solution to the critical issue of antibody specificity, >140,000 highly validated human tissues, and protein microarray products and services. For more information, visit www.origene.com.

For inquiries please contact:

Mark Watson, MBA, MS

OriGene Technologies, Inc.

Tel: (301) 340-3188

Email: businessdev@origene.com