

Expand Your ALK Testing Menu With New ALK FLEX RTU Antibody

High-performing¹ clone OT11A4 for ALK
is now available in FLEX RTU format
for Dako Omnis



Is one testing technique sufficient for ALK testing?

ALK (anaplastic lymphoma kinase) is an important biomarker in lung cancer² but it is also a challenging biomarker to detect and inconclusive results are sometimes observed². More than one testing technique may be needed to diagnose these difficult cases.

The Dako Omnis ALK RTU antibody is based on the OT11A4 clone and can be implemented as an additional IHC technique for ALK testing in non-squamous cell lung cancer. The OT11A4 clone shows high performance when compared head-to-head with other clones in peer-reviewed studies³⁻⁵ and EQA schemes, see Table 1.

Table 1. NordiQC run 57 2019, Lung ALK

Concentrated Antibodies	Pass rate	Number of users
Clone OT11A4	92%	25
Clone D5F3	89%	28
Clone 5A4	81%	32

Staining with ALK FLEX RTU GA785 clone OT11A4 on low-expressor tissue (appendix), and three clinical tissues (lung adenocarcinomas with EML4-ALK rearrangement)

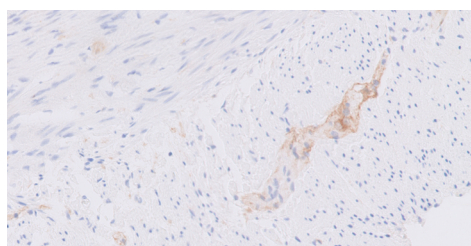


Figure 1. The ganglion cells and axons of the myenteric plexus show a weak to moderate, distinct cytoplasmic staining reaction.

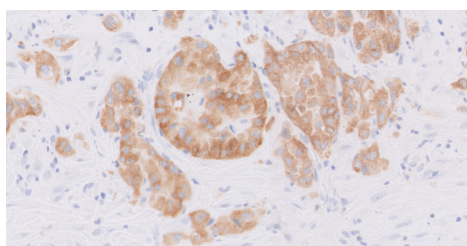


Figure 2. Weak to strong cytoplasmic staining of tumor cells containing the EML4-ALK rearrangement.

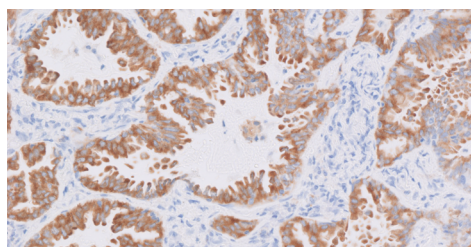


Figure 3. Weak to strong cytoplasmic staining of tumor cells containing the EML4-ALK rearrangement.

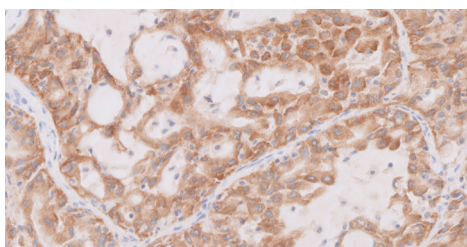


Figure 4. Weak to strong cytoplasmic staining of tumor cells containing the EML4-ALK rearrangement.

Agilent
Dako

ALK Testing

We have additional testing modalities for ALK testing. Reach out to your Agilent representative for more information on our other ALK testing options.

Incorporate ALK RTU into your Dako Omnis workflow

The standardized FLEX RTU concept and the Dako Omnis workflow capabilities work together to enable your lab to run the required tests for your patients efficiently, minimizing hands-on time related to sorting and re-assembly of cases, and accelerating time to diagnosis⁶.



Workflow benefits

The FLEX RTU concept provides a simple, efficient workflow:

- Fully calibrated antibodies that ensure easy and straightforward implementation
- Appropriate plug-and-play protocols to ensure that the antigen is correctly demonstrated in both high and low tissue expression structures
- Precise control recommendations support monitoring of staining results and efficient QC

This supports your lab in achieving reliable and reproducible diagnostic results.

Table 2. Ordering details

Target	Product	Package Size	Part No.
ALK	FLEX Monoclonal Mouse Anti-Human CD246, ALK Protein, Clone OTI1A4, Ready-to-Use (Dako Omnis)	12 mL, 60 tests	GA78561-2

Integrated quality control

Dako Omnis is designed with a host of integrated quality control features to ensure accurate staining results:

- A double check of reagent vials helps avoid dispensing problems and ensures that the necessary volumes are dispensed onto the slides
- The Dynamic Gap Staining process provides full and even reagent coverage of the slide to deliver consistent staining slide after slide
- A temperature-controlled reagent environment maintains reagent integrity, and a stable temperature (32 °C) throughout the staining process
- Full traceability of patient cases

References

1. Data from NordiQC assessment run 57 2019, (ALK, lung). https://www.nordiqc.org/downloads/assessments/122_14.pdf. Last accessed 30 July, 2021.
2. Kalemkerian G., et al. Molecular Testing Guideline for the selection of Patients With Lung Cancer for Treatment With Targeted Tyrosine Kinase Inhibitors. J Clin Oncol 2018; 36:911-919.
3. Gruber K., et al. A Novel, Highly Sensitive ALK antibody 1A4 Facilitates Effective Screening for ALK Rearrangements in Lung Adenocarcinomas by Standard Immunohistochemistry; J Thorac Oncol. 2015;10: 713-716.
4. Shen Q., et al. Comparing Four Different ALK Antibodies with Manual Immunohistochemistry (IHC) to Screen for ALK-rearranged Non-Small Cell Lung Cancer (NSCLC); Lung Cancer 2015;90 492-498
5. Wang Q., et al. 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 95 (2016) 39-43.
6. Agilent Case Study: Dako Omnis Workflow. Lab Achieves 74% Increase in Same-Day Patient Case Completion. Available at https://www.agilent.com/cs/library/casestudies/public/29295_case_study_dako_omnis_dutch_experience.pdf. Last accessed 30 July, 2021.