

PD-L1 IHC Results You Can Trust

PD-L1 IHC 28-8 pharmDx for OPDIVO® (nivolumab)
use in non-squamous Non-Small Cell Lung Cancer (nsNSCLC)



PD-L1 IHC 28-8 pharmDx is the Only IVD-approved Test for PD-L1 Expression Associated with Enhanced Survival with OPDIVO for nsNSCLC

- PD-L1 IHC 28-8 pharmDx is used to measure the proportion of PD-L1 expression in cancer tissue or cells
- PD-L1 expression ($\geq 1\%$ or $\geq 5\%$ or $\geq 10\%$ tumor cell expression) in nsNSCLC may be associated with enhanced survival from OPDIVO

Clinical study CheckMate-057 investigated the clinical validity of PD-L1 IHC 28-8 pharmDx for the assessment of PD-L1 status in nsNSCLC patients treated with OPDIVO. The anti-PD-L1 immunotherapeutic OPDIVO treatment effect has been correlated with PD-L1 expression in patients with advanced nsNSCLC.

Demonstrated clinical results with PD-L1 IHC 28-8 pharmDx

- Patients with PD-L1 expression by the predefined expression levels in the OPDIVO group were associated with enhanced survival compared to docetaxel.

■ Median OS ■ Docetaxel

$\geq 1\%$ PD-L1 expression ► 41% Reduction in Risk of Death (HR = 0.59)

17.1 months

9 months

$\geq 5\%$ PD-L1 expression ► 57% Reduction in Risk of Death (HR = 0.43)

18.2 months

8.1 months

$\geq 10\%$ PD-L1 expression ► 60% Reduction in Risk of Death (HR = 0.40)

19.4 months

8 months

- In patients with no PD-L1 expression ($< 1\%$), survival with OPDIVO was similar to docetaxel.

A Complementary Diagnostic for PD-L1 Expression in nsNSCLC

- Pathologists should use PD-L1 IHC 28-8 pharmDx when an oncologist prescribing OPDIVO (nivolumab) for nsNSCLC requests a PD-L1 test
- PD-L1 testing is not required for the use of OPDIVO, but it will provide additional information for physicians and inform patient dialogue
- PD-L1 IHC 28-8 pharmDx provides accurate, reproducible results



PD-L1 IHC 28-8 pharmDx instruction for use

For In Vitro Diagnostic Use

PD-L1 IHC 28-8 pharmDx is a qualitative immunohistochemical assay using Monoclonal Rabbit Anti-PD-L1, Clone 28-8 intended for use in the detection of PD-L1 protein in formalin-fixed, paraffin-embedded (FFPE) non-squamous non-small cell lung cancer (nsNSCLC) tissues using EnVision FLEX visualization system on Autostainer Link 48.

PD-L1 protein expression is defined as the percentage of evaluable tumor cells exhibiting partial or complete membrane staining at any intensity.

When used in accordance with approved therapeutic labeling:

PD-L1 expression ($\geq 1\%$ or $\geq 5\%$ or $\geq 10\%$ tumor cell expression), as detected by PD-L1 IHC 28-8 pharmDx in nsNSCLC may be associated with enhanced survival from OPDIVO®.

See the OPDIVO® product label for specific clinical circumstances guiding PD-L1 testing.

Clinically Validated Scoring Guidelines For Assessing PD-L1 Expression For OPDIVO

To assess the PD-L1 expression level in patient slides stained with PD-L1 IHC 28-8 pharmDx, pathologists should determine the percentage of viable tumor cells exhibiting partial linear or complete circumferential plasma membrane staining at any intensity.

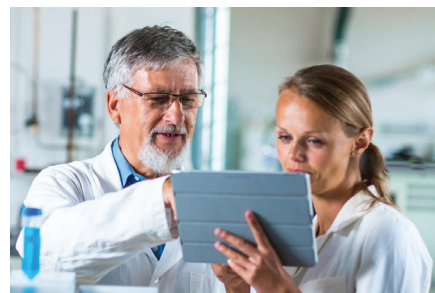
See Interpretation Manual for complete interpretation of PD-L1 IHC 28-8 pharmDx staining results and our eLearning:

Link to eLearning: [PD-L1 IHC 28-8 pharmDx interpretation training | Agilent](#)

Link to eIFU: <https://www.agilent.com/en/library/eifu.html?searchTermRedirect=eifu>

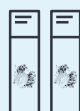
Report confidently using PD-L1 IHC 28-8 pharmDx

- Integrate PD-L1 IHC 28-8 pharmDx into your Dako IHC setup without changing the staining workflow
- Preprogrammed, validated protocol
- Ready-to-use reagents and control slides optimized for Autostainer Link 48
- Comprehensive educational and training resources are available to enable your lab to optimize your workflow and shorten the turnaround time



Benefits of early testing with PD-L1 IHC 28-8 pharmDx

Early PD-L1 testing is not only important for oncologists to guide treatment decisions, but also provides added benefits.



Sample availability

Incorporating PD-L1 IHC 28-8 pharmDx testing in the diagnostic investigation of nsNSCLC patients ensures sample availability at the time of diagnosis.



Patient care

Early testing may ensure availability of results during the initial treatment, planning, and patient dialogue, eliminating the need to wait for testing.



Laboratory efficiency

Can be incorporated during other IHC and molecular testing for patients.

Ordering information

PD-L1 IHC 28-8 pharmDx Kit	Reagents required but not included in kit
SK005	EnVision FLEX Wash Buffer, 20x, Code K8007 EnVision FLEX Hematoxylin, Code K8008

References

1. Topalian SL, Hodi FS, Brahmer JR, et al. Safety, Activity, and Immune Correlates of Anti-PD-1 Antibody in Cancer. *New Eng. J. Med.* **2012**; 366(26):2455-2465.
2. OPDIVO package insert.
3. Borghaei H, Paz-Ares L, Horn L, et al. Nivolumab versus Docetaxel in advanced nonsquamous non-small-cell lung cancer. *N Engl J Med* **2015**; 373(17): 1627-1639.
4. Phillips T, Simmons P, Inzunza HD, et al. Development of an automated PD-L1 immunohistochemistry (IHC) assay for non-small cell lung cancer. *Appl Immuno Molec Morph* **2015**; 23(8):541-9.

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