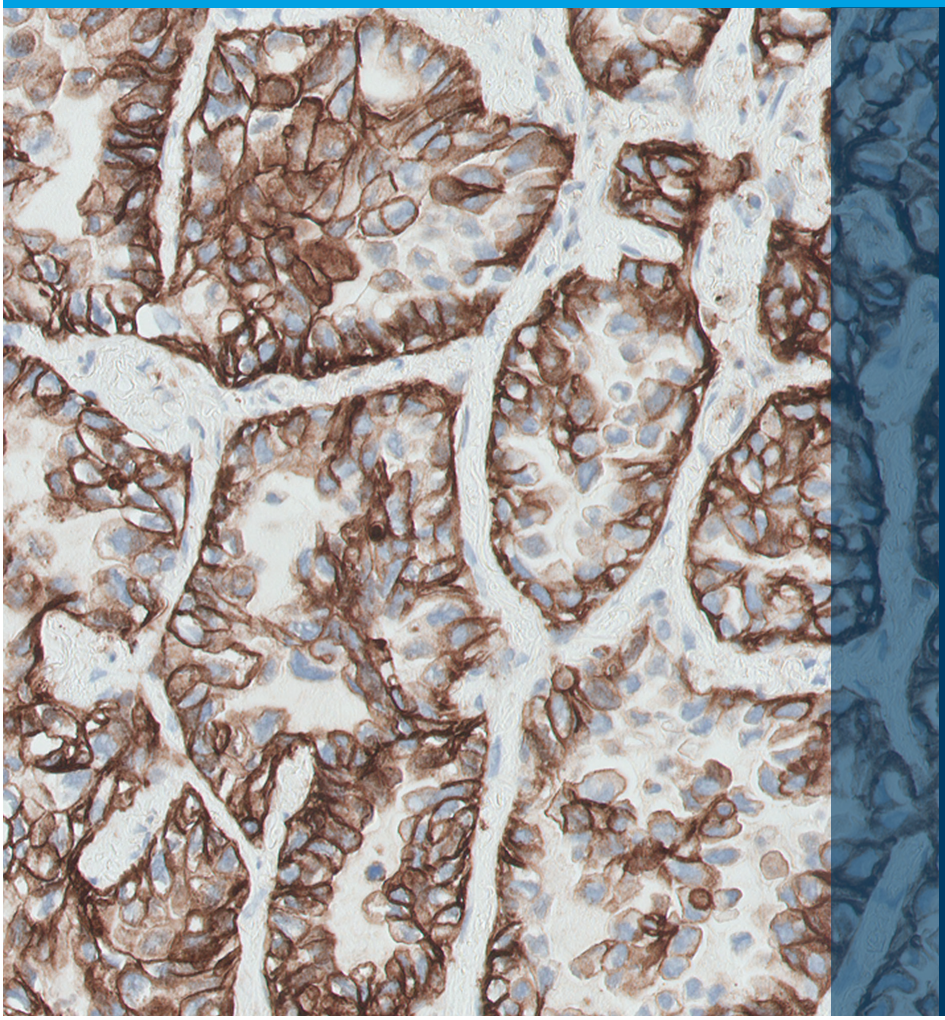
Agilent Dako

# PD-L1 IHC Results You Can Trust

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



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Trusted Answers

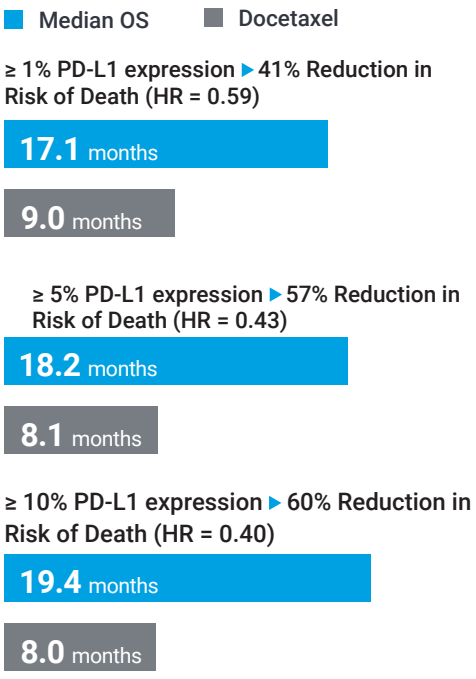
# PD-L1 IHC 28-8 pharmDx is the Only IVD-approved detection of PD-L1 expression for NSCLC patients considering OPDIVO treatment

- PD-L1 IHC 28-8 pharmDx is used to measure the proportion of PD-L1 expression in cancer tissue or cells
- PD-L1 expression (≥ 1% or ≥ 5% or ≥ 10% tumor cell expression) in nsNSCLC and PD-L1 expression (≥ 1% tumor cell expression) in NSCLC

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. Clinical study CheckMate-816 investigated the clinical validity of PD-L1 IHC 28-8 pharmDx for the assessment of PD-L1 expression in NSCLC patients treated with OPDIVO in combination with platinum-doublet chemotherapy. Clinical study CheckMate-227 investigated the clinical validity of PD-L1 IHC 28-8 pharmDx for the assessment of PD-L1 status in NSCLC patients treated with OPDIVO and YERVOY.

## Demonstrated clinical results with PD-L1 IHC 28-8 pharmDx, nsNCLC (CheckMate-057)

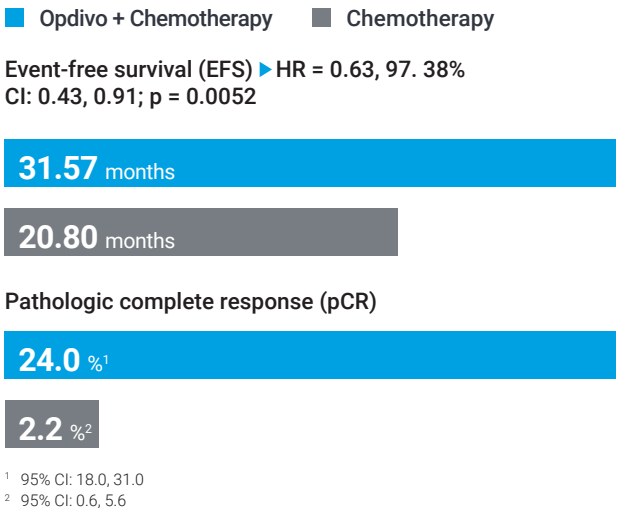
- Patients with PD-L1 expression by the predefined expression levels in the OPDIVO group vs the docetaxel group




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

## Demonstrated clinical results with PD-L1 IHC 28-8 pharmDx, NSCLC (CheckMate-816)

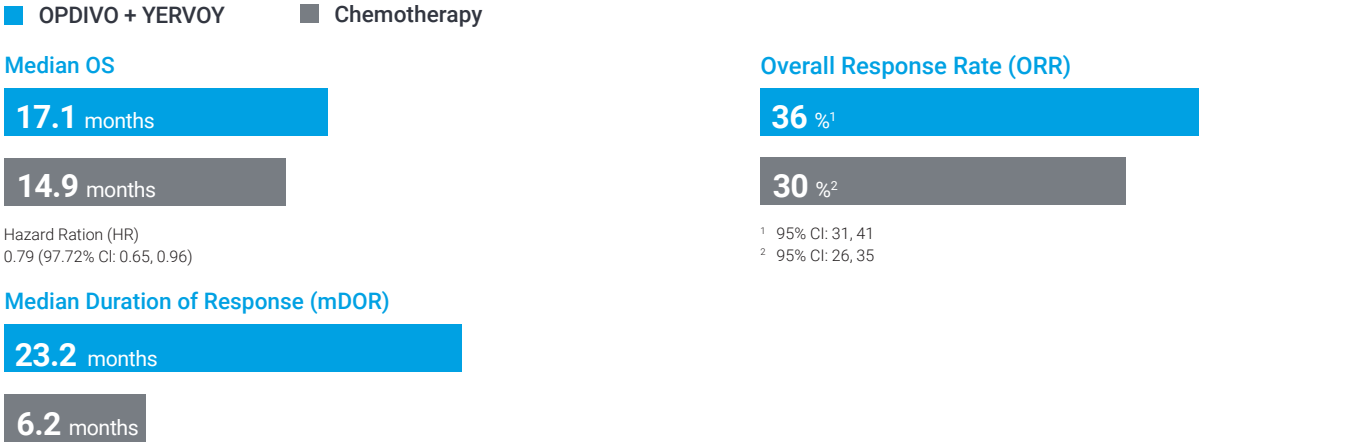
- Patients with PD-L1 expression by predefined expression levels in the OPDIVO combined with platinum-doublet chemotherapy vs Chemotherapy alone




[1] 95% CI: 18.0, 31.0
[2] 95% CI: 0.6, 5.6

## Demonstrated clinical results with PD-L1 IHC 28-8 pharmDx, NSCLC (CheckMate-227)

– Patients with PD-L1 expression by predefined expression level in the OPDIVO + YERVOY vs platinum-doublet chemotherapy alone.




## 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-small cell lung cancer (NSCLC), and 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.

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


## Clinically Validated Scoring Guidelines For Assessing PD-L1 Expression for OPDIVO or OPDIVO Combination Therapy

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.

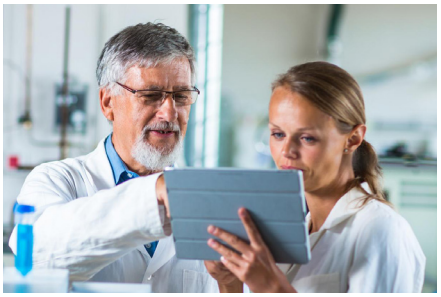
See Interpretation Manual for complete interpretation of PD-L1 IHC 28-8 pharmDx staining results and our eLearning:

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 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<br>EnVision FLEX Hematoxylin, Code K8008 |

## References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3. Borghaei H, Paz-Ares L, Horn L, et al. Nivolumab versus Docetaxel in advanced nonsquamous non-small-cell lung cancer. *New Eng. 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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