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 (≥ 1% or ≥ 5% or ≥ 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**
  - ≥ 1% PD-L1 expression ➤ 41% Reduction in Risk of Death (HR = 0.59)
    - 17.1 months
    - 9 months
  - ≥ 5% PD-L1 expression ➤ 57% Reduction in Risk of Death (HR = 0.43)
    - 18.2 months
    - 8.1 months
  - ≥ 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 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 (≥ 1% or ≥ 5% or ≥ 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

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.

<table>
<thead>
<tr>
<th>Sample availability</th>
<th>Patient care</th>
<th>Laboratory efficiency</th>
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<tbody>
<tr>
<td>Incorporating PD-L1 IHC 28-8 pharmDx testing in the diagnostic investigation of nsNSCLC patients ensures sample availability at the time of diagnosis.</td>
<td>Early testing may ensure availability of results during the initial treatment, planning, and patient dialogue, eliminating the need to wait for testing.</td>
<td>Can be incorporated during other IHC and molecular testing for patients.</td>
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Ordering information

<table>
<thead>
<tr>
<th>PD-L1 IHC 28-8 pharmDx Kit</th>
<th>Reagents required but not included in kit</th>
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<tbody>
<tr>
<td>SK005</td>
<td>EnVision FLEX Wash Buffer, 20x, Code K8007</td>
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<td></td>
<td>EnVision FLEX Hematoxylin, Code K8008</td>
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References

2. OPDIVO package insert.