More personalized cancer results.
One test makes it possible.

PD-L1 IHC 28-8 pharmDx is FDA-approved for Expanded Use to Identify NSCLC Patients for First-line Therapy with OPDIVO® in Combination with YERVOY®

Guidelines for non-small cell lung cancer (NSCLC) emphasize the importance of PD-L1 testing in identifying appropriate patients for immunotherapy treatment

PD-L1 IHC 28-8 pharmDx is the only clinically validated test which aids in identifying appropriate NSCLC patients for first-line treatment with OPDIVO® (nivolumab) in combination with YERVOY® (ipilimumab).

- Lung cancer is the most commonly diagnosed cancer worldwide across both sexes, causing 18.4% of all cancer deaths and with an estimated 2 million new cases reported in 2018.

- Results of PD-L1 testing with PD-L1 IHC 28-8 pharmDx in the CHECKMATE-227 study indicate its use as an aid in identifying NSCLC patients with PD-L1 expression ≥ 1%, for first-line treatment with nivolumab in combination with ipilimumab.

- PD-L1 IHC 28-8 pharmDx has been analytically validated for specificity, sensitivity, and reproducibility, and shows high clinical utility across various indications.

PD-L1 IHC 28-8 pharmDx is the only FDA-approved companion diagnostic to identify NSCLC patients for treatment with OPDIVO® (nivolumab) in combination with YERVOY® (ipilimumab).

OPDIVO® and YERVOY® are registered trademarks of Bristol-Myers Squibb Company.

6. PD-L1 IHC 28-8 pharmDx Instructions for Use.
Report confidently using the PD-L1 IHC 28-8 pharmDx assay

- Integrate PD-L1 IHC 28-8 pharmDx assay to your Dako IHC setup without changing the staining workflow
- Ready-to-use reagents and control slides
- 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 a NSCLC patient 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.

Intended 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), squamous cell carcinoma of the head and neck (SCCHN), and urothelial carcinoma (UC) 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.

### Companion Diagnostic Indication

<table>
<thead>
<tr>
<th>Tumor Indication</th>
<th>PD-L1 Expression Clinical Cut-Off</th>
<th>Intended Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>NSCLC</td>
<td>≥ 1% tumor cell expression</td>
<td>PD-L1 IHC 28-8 pharmDx is indicated as an aid in identifying NSCLC patients for treatment with OPDIVO® (nivolumab) in combination with YERVOY® (ipilimumab).</td>
</tr>
</tbody>
</table>

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

PD-L1 expression (≥ 1% tumor cell expression), as detected by PD-L1 IHC 28-8 pharmDx in SCCHN may be associated with enhanced survival from OPDIVO®.

PD-L1 expression (≥ 1% tumor cell expression), as detected by PD-L1 IHC 28-8 pharmDx in UC may be associated with enhanced response rate from OPDIVO®.

See the OPDIVO® and YERVOY® product labels for specific clinical circumstances guiding PD-L1 testing.

For more information about PD-L1 IHC 28-8 pharmDx and its use in NSCLC, please visit:

[www.agilent.com/chem/PDL128-8pharmDx](http://www.agilent.com/chem/PDL128-8pharmDx)

For countries outside of the United States, see the local OPDIVO and YERVOY product labels for approved indications and expression cut-off values to guide therapy.

This information is subject to change without notice.