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®

More personalized cancer results.
One test makes it possible.

Guidelines[1,2,3] for non-small cell lung cancer (NSCLC) emphasize the importance of PD-L1 testing in identifying appropriate patients for immunotherapy treatment

Agilent Dako

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).

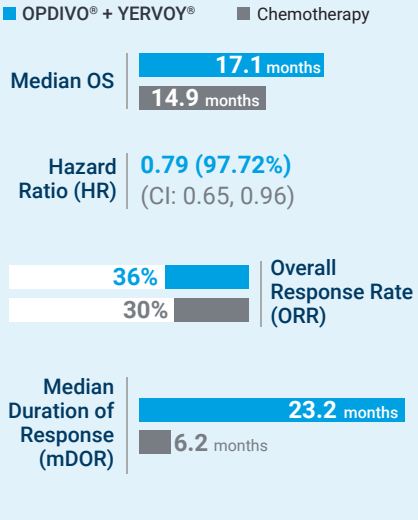
- Lung cancer is the most commonly diagnosed cancer worldwide across both sexes, causing 18.4% of all cancer deaths and with an estimated 2 million new cases reported in 2018[4].
- Results of PD-L1 testing with PD-L1 IHC 28-8 pharmDx in the CHECKMATE-227[5] indicate its use as an aid in identifying NSCLC 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[6].

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).

CHECKMATE-227 was a Phase III, randomized, multi-center, multi-cohort, open-label study in patients with first-line mNSCLC with PD-L1 expression level ≥ 1%, who were previously untreated for advanced disease.

CHECKMATE-227 results highlight overall survival (OS) benefit from OPDIVO® (nivolumab) in combination with YERVOY® (ipilimumab) therapy for NSCLC patients with PD-L1 expression ≥ 1%.

In patients with PD-L1 expression ≥ 1%



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

1. Brahmer JR, Govindan R, Anders RA, et al. The Society for Immunotherapy of Cancer consensus statement on immunotherapy for the treatment of non-small cell lung cancer (NSCLC). J Immunother Cancer. 2018;6(1):75.
2. Hanna N, Johnson D, Temin S, et al. Systemic therapy for stage IV non-small-cell lung cancer: American Society of Clinical Oncology clinical practice guideline update. J Clin Oncol. 2017;35(30):3484-3515.
3. Planchard D, Popat S, Kerr K, et al. Metastatic non-small cell lung cancer: ESMO clinical practice guidelines for diagnosis, treatment and follow-up. Annals of Onc. 2018;29(4):iv192-iv237.
4. Freddie Bray, et al. Global Cancer Statistics 2018: GLOBOCAN Estimates of Incidence and Mortality Worldwide for 36 Cancers in 185 Countries, CA CANCER J CLIN 2018;68:394–424.
5. M.D. Hellmann, et al. Nivolumab plus Ipilimumab in Advanced Non–Small-Cell Lung Cancer, The New England Journal of Medicine, 2019.
6. PD-L1 IHC 28-8 pharmDx Instructions for Use.

Agilent
Trusted Answers

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

Tumor Indication	PD-L1 Expression Clinical Cut-Off	Intended Use
NSCLC	≥ 1% tumor cell expression	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).

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 andits use in NSCLC, please visit:
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.

© Agilent Technologies, Inc. 2020
Published in the USA, May 15, 2020
29377 2020MAY15

Agilent
Trusted Answers