PD-L1 IHC 28-8 pharmDx is CE-IVD Marked to Identify Gastric Adenocarcinoma, Gastroesophageal Junction Adenocarcinoma, and Esophageal Adenocarcinoma Patients for Treatment with OPDIVO®

More personalized cancer results.
One test makes it possible.

There is increasing scientific evidence that highlights the role of PD-L1 expression in the prognosis of gastric adenocarcinoma, gastroesophageal junction (GEJ) adenocarcinoma, and esophageal adenocarcinoma[1, 2, 3].

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PD-L1 IHC 28-8 pharmDx is the only clinically validated test which aids in identifying appropriate advanced or metastatic gastric, GEJ, and esophageal adenocarcinoma with HER2-negative patients whose tumors express PD-L1 with CPS ≥ 5 for the first-line treatment with OPDIVO (nivolumab) in combination with fluoropyrimidine and platinum-based chemotherapy.

- Gastric cancer is the fifth most common cancer and the fourth leading cause of death from cancer worldwide causing 7.7% of all cancer deaths and with an estimated over one million new cases reported in 2020[4].
- Esophageal cancer is the seventh most common cancer and the sixth leading cause of death from cancer worldwide causing 5.5% of all cancer deaths and with an estimated 604,100 new cases reported in 2020[4].
- Results of PD-L1 testing with PD-L1 IHC 28-8 pharmDx in the CheckMate-649[5] study indicate its use as an aid in identifying gastric, GEJ, and esophageal adenocarcinoma patients whose tumors express PD-L1 with a Combined Positive Score (CPS) ≥ 5, for first-line treatment with nivolumab in combination with fluoropyrimidine and platinum-based chemotherapy.
- PD-L1 IHC 28-8 pharmDx has been analytically validated for specificity, sensitivity, and reproducibility, and shows high clinical utility across various indications.[6]

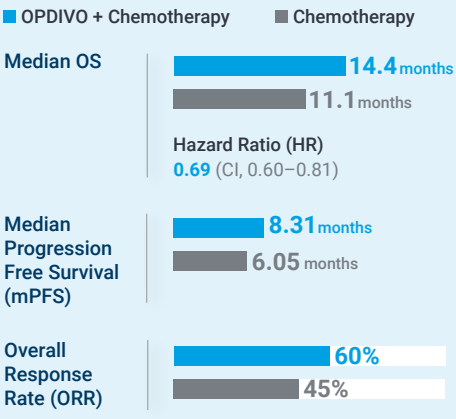
PD-L1 IHC 28-8 pharmDx is the only CE-IVD marked diagnostic aid to identify gastric, GEJ, and esophageal adenocarcinoma patients for the first and the only first-line treatment with OPDIVO (nivolumab) in combination with fluoropyrimidine and platinum-based chemotherapy, that demonstrated superior overall survival vs chemotherapy.

CheckMate-649 is a phase 3, randomized, multi-center, open-label study in patients who were previously untreated with HER2-negative, advanced or metastatic gastric, GEJ, and esophageal adenocarcinoma whose tumors express PD-L1 with a Combined Positive Score (CPS) ≥ 5.

CheckMate-649 results highlight overall survival (OS) benefit from OPDIVO (nivolumab) in combination with fluoropyrimidine and platinum-based chemotherapy for gastric, GEJ, and esophageal adenocarcinoma patients whose tumors express PD-L1 with a Combined Positive Score (CPS) ≥ 5.

The prevalence of PD-L1 CPS ≥ 5 in CheckMate-649 was 60%

In patients with Combined Positive Score (CPS) ≥ 5



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5. Janjigian Y. Y., Shitara K., et al. First-line nivolumab plus chemotherapy versus chemotherapy alone for advanced gastric, gastro-esophageal junction, and esophageal adenocarcinoma (CheckMate 649): a randomised, open-label, phase 3 trial. *The Lancet*. 2021, 398, 27-40.
6. PD-L1 IHC 28-8 pharmDx Instructions for Use.

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Trusted Answers

Report confidently using the PD-L1 IHC 28-8 pharmDx assay

- Integrate PD-L1 IHC 28-8 pharmDx assay into 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 gastric, GEJ, and esophageal adenocarcinoma patients ensures sample availability at the time of diagnosis.

Patient care

Early testing may ensure the 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.

PD-L1 IHC 28-8 pharmDx 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-squamous non-small cell lung cancer (nsNSCLC), squamous cell carcinoma of the head and neck (SCCHN), urothelial carcinoma (UC), melanoma, gastric adenocarcinoma, gastroesophageal junction (GEJ) adenocarcinoma, and esophageal adenocarcinoma tissues using EnVision FLEX visualization system on Autostainer Link 48.

PD-L1 protein expression in nsNSCLC, SCCHN, UC, and melanoma is determined by using % tumor cell expression, which is the percentage of evaluable tumor cells exhibiting partial or complete membrane staining at any intensity.

PD-L1 protein expression in gastric adenocarcinoma, GEJ adenocarcinoma, and esophageal adenocarcinoma is determined by using Combined Positive Score (CPS), which is the number of PD-L1 staining cells (tumor cells, lymphocytes, macrophages) divided by the total number of viable tumor cells, multiplied by 100.

Companion Diagnostic Indications

Tumor Indication	PD-L1 Expression Clinical Cut-off	Intended Use
Gastric, GEJ, or Esophageal Adenocarcinoma	CPS ≥ 5	PD-L1 IHC 28-8 pharmDx is indicated as an aid in identifying gastric, gastroesophageal junction, or esophageal adenocarcinoma patients for treatment with OPDIVO® (nivolumab) in combination with fluoropyrimidine and platinum-based chemotherapy.

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

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® (nivolumab).

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

PD-L1 expression (≥ 1% or ≥ 5% tumor cell expression) as detected by PD-L1 IHC 28-8 pharmDx in melanoma may be used as an aid in the assessment of patients for whom OPDIVO® (nivolumab) and YERVOY® (ipilimumab) combination treatment is being considered.

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

Please go to **www.agilent.com/library/eifu** and find the correct IFU version for your Kit Lot Number.

Check the local OPDIVO product label for approved indications and expression cut-off values to guide therapy.

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