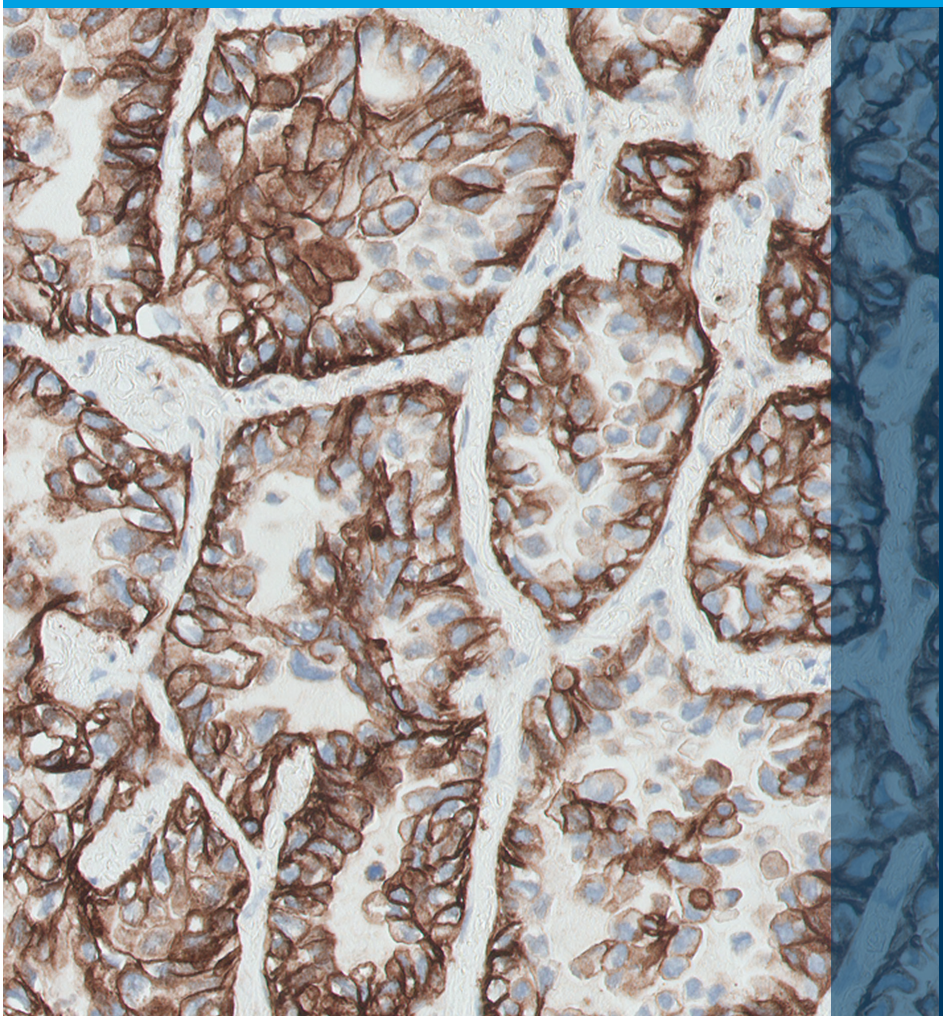
Agilent
Dako

PD-L1 IHC Results You Can Trust

PD-L1 IHC 28-8 pharmDx is an FDA-approved CDx IVD used to Identify Esophageal Squamous Cell Carcinoma (ESCC), Gastric, Gastroesophageal Junction (GEJ), and Esophageal Adenocarcinoma Patients for Treatment with OPDIVO® or OPDIVO QVANTIG® for US



Agilent
Trusted Answers

PD-L1 IHC 28-8 pharmDx is an FDA-Approved Diagnostic Aid

Detecting PD-L1 expression in gastric adenocarcinoma, gastroesophageal junction (GEJ) adenocarcinoma, esophageal adenocarcinoma, and esophageal squamous cell carcinoma (ESCC) in patients considering OPDIVO® or OPDIVO QVANTIG® 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 in the aforementioned indications 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.

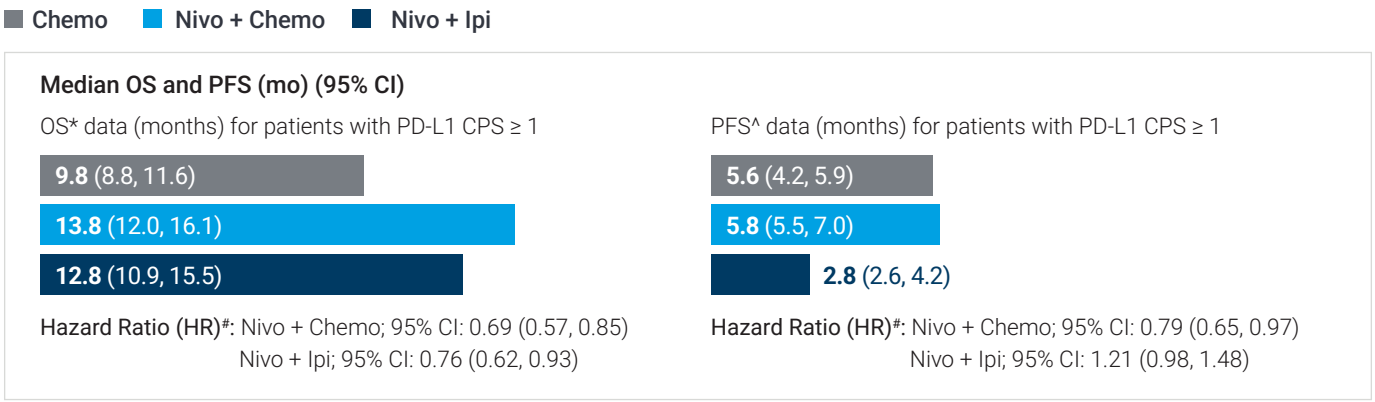
PD-L1 IHC 28-8 pharmDx is an FDA-approved diagnostic aid to assess:

ESCC (CHECKMATE-648) patients for treatment with OPDIVO® (nivolumab) or OPDIVO QVANTIG® (nivolumab and hyaluronidase-nvhy) in combination with fluoropyrimidine and platinum-based chemotherapy.

Gastric, GEJ and esophageal adenocarcinoma (CHECKMATE-649) patients for treatment with OPDIVO® (nivolumab) or OPDIVO QVANTIG® (nivolumab and hyaluronidase-nvhy) in combination with fluoropyrimidine and platinum-based chemotherapy.

Demonstrated clinical results with PD-L1 IHC 28-8 pharmDx (CHECKMATE-648 and CHECKMATE-649)

CHECKMATE-648: Results from the retrospective exploratory analysis highlight overall survival (OS) and progression-free survival (PFS) benefit from OPDIVO® (nivolumab) + fluoropyrimidine and platinum-based chemotherapy and OS benefit from OPDIVO® (nivolumab) + YERVOY® (ipilimumab) in all ESCC patients with PD-L1 CPS ≥ 1.



*OS: Overall survival | ^PFS: Progression-free survival | #HR is based on stratified cox proportional hazards model.

CHECKMATE-649 results highlight OS and PFS benefit from OPDIVO® (nivolumab) in combination with fluoropyrimidine and platinum-based chemotherapy in gastric, GEJ, and esophageal adenocarcinoma patients whose tumors express PD-L1 with a CPS ≥ 1.

■ Chemo ■ OPDIVO® + Chemo

Median OS and PFS (mo) (95% CI)

OS* data (months) for patients with PD-L1 CPS ≥ 1

11.3 (10.6, 12.3)

14.0 (12.6, 15.0)

Hazard Ratio (HR)# (95% CI): 0.77 (0.68, 0.88)

PFS^ data (months) for patients with PD-L1 CPS ≥ 1

6.9 (6.1, 7.0)

7.5 (7.0, 8.4)

Hazard Ratio (HR)# (95% CI): 0.74 (0.65, 0.85)

*OS: Overall survival | ^PFS: Progression-free survival | #HR is based on a stratified Cox proportional hazards model.

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) gastric adenocarcinoma, GEJ adenocarcinoma, and esophageal carcinoma tissues using the EnVision FLEX visualization system on the Agilent Autostainer Link 48.

Tumor Indication	PD-L1 Expression Level	Therapy
ESCC	CPS ≥ 1	OPDIVO® (nivolumab) or OPDIVO QVANTIG® (nivolumab and hyaluronidase-nvhy)
Gastric, GEJ, or Esophageal Adenocarcinoma	CPS ≥ 1	

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

Clinically validated scoring guidelines for assessing PD-L1 expression for OPDIVO® or OPDIVO QVANTIG® therapy

To assess the PD-L1 expression level in patient slides stained with PD-L1 IHC 28-8 pharmDx, pathologists should determine the 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.

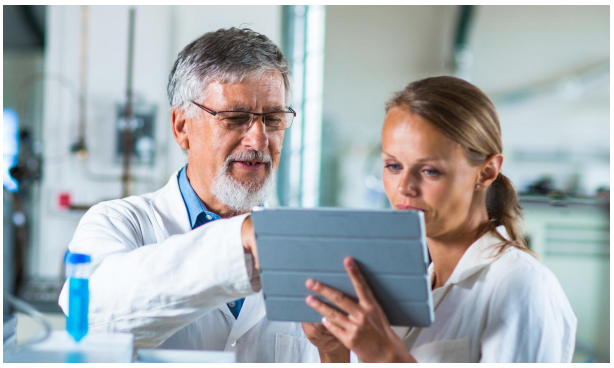
See **Interpretation Manuals** for complete interpretation of PD-L1 IHC 28-8 pharmDx staining results and our eLearning:

Link to CDx Digital Education Portal including eLearning: **pathology-education.agilent.com/**

Link to eIFU: **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

Product	Code	Reagents required but not included in kit
PD-L1 IHC 28-8 pharmDx	SK005	EnVision FLEX Wash Buffer, 20x, Code K8007 EnVision FLEX Hematoxylin, Code K8008

References

1. Topalian, S.L.; Drake, C.G.; Pardoll, D.M. Targeting the PD-1/B7-H1 (PD-L1) Pathway to Activate Anti-tumor Immunity. *Curr. Opin. Immunol.* **2012**, *24* (2), 207–212. DOI: 10.1016/j.coi.2011.12.009.
2. Wang, C.; Thudium, K.B.; Han, M.; et al. In Vitro Characterization of the Anti-PD-1 Antibody Nivolumab, BMS-936558, and In Vivo Toxicology in Non-human Primates. *Cancer Immunol. Res.* **2014**, *2* (9), 846–856. DOI: 10.1158/2326-6066.CIR-14-0040.
3. OPDIVO® package insert.
4. Doki, Y.; Ajani, J.A.; Kato, K.; et al. Nivolumab Combination Therapy in Advanced Esophageal Squamous-Cell Carcinoma. *N. Engl. J. Med.* **2022**, *386* (5), 449–462. DOI: 10.1056/NEJMoa2111380.
5. Janjigian Y.Y.; Shitara K.; Moehler, M.; et. al. First-line Nivolumab plus Chemotherapy versus Chemotherapy Alone for Advanced Gastric, Gastro-oesophageal Junction, and Oesophageal Adenocarcinoma (CHECKMATE 649): A Randomised, Open-label, Phase 3 Trial. *Lancet* **2021**, *398* (10294): 27–40. DOI: 10.1016/S0140-6736(21)00797-2.

D0146575_1.00

Published in the USA, August 19, 2026
29708 2026AUG19

Agilent
Trusted Answers