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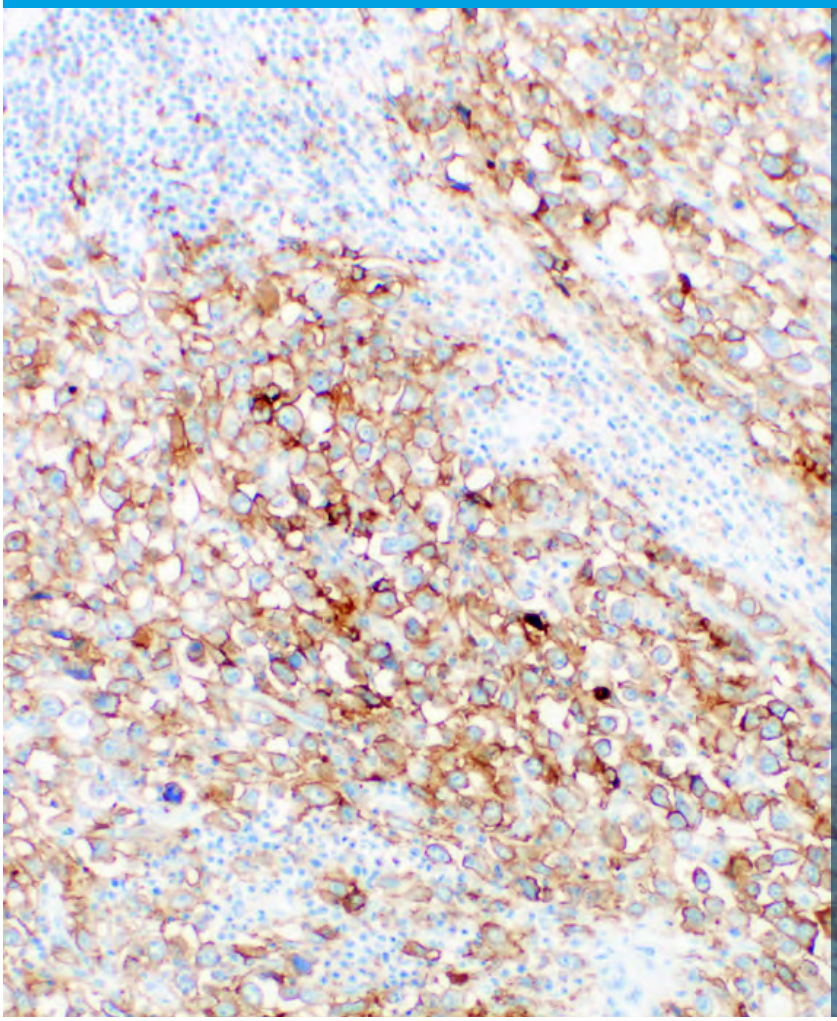
PD-L1 IHC 28-8 pharmDx is an IVD to Identify Melanoma Patients for Treatment with Opdualag™

More personalized cancer results.
One test makes it possible.



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Trusted Answers

There is Increasing Scientific Evidence that Highlights the Role of PD-L1 Expression in the Prognosis of Melanoma.[1, 2, 3]

PD-L1 IHC 28-8 pharmDx is used to measure the proportion of PD-L1 expression in cancer tissue or cells and is indicated as an aid in identifying melanoma patients for treatment with Opdualag (nivolumab and relatlimab).

Melanoma Report 2020[4]

324,635 new cases

estimated **57,043** deaths

Global Rankings[4]

18th in incidence

23rd in mortality

- Results of PD-L1 testing with PD-L1 IHC 28-8 pharmDx in CA224047 study indicate its use as an aid in identifying melanoma patients treated with Opdualag (nivolumab plus relatlimab), versus nivolumab alone.[5]
- 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 IVD diagnostic aid to identify melanoma patients for treatment with Opdualag (nivolumab and relatlimab). Opdualag demonstrated improvement in progression-free survival (PFS), as compared to nivolumab alone.

References:

1. Gadiot J., Hooijkaas A., et al. Overall survival and PD-L1 expression in metastasized malignant melanoma. Cancer. 2011, 117(10), 2017–2238.
2. Mahoney K., Freeman G., and McDermott D. The Next Immune-Checkpoint Inhibitors: PD-1/PD-L1 Blockade in Melanoma. Clin. Ther. 2015, 37(4), 764–782.
3. Yang J., Dong M., et al. A pooled analysis of the prognostic value of PD-L1 in melanoma: evidence from 1062 patients. Cancer. Cell. Int. 2020, 20(96), https://doi.org/10.1186/s12935-020-01187-x.
4. Ferlay J., Ervik M., et al. 2020. Global Cancer Observatory: Cancer Today. Lyon, France: International Agency for Research on Cancer. Available from: https://gco.iarc.fr/today/data/factsheets/populations/900-world-fact-sheets.pdf.
5. Tawbi, H.A.; Schadendorf, D.; Lipson, E.J.; et al. Relatlimab and Nivolumab versus Nivolumab in Untreated Advanced Melanoma. N. Engl. J. Med. 2022, 386(1), 24–34 .
6. PD-L1 IHC 28-8 pharmDx Instructions for Use.

CA224047 is a phase 2/3, global, randomized, double-blind study to compare Opdualag (nivolumab plus relatlimab) versus nivolumab alone in patients with previously untreated advanced (metastatic or unresectable) melanoma.

CA224047 results highlight PFS benefit from Opdualag™ (nivolumab and relatlimab) in all melanoma patients with PD-L1 < 1% tumor cell expression*.

Nivo Nivo + Rela

Median PFS (mo) (95% CI)

PFS data (median in months) for patients with PD-L1 < 1% tumor cell expression (median follow-up of 17.78 months)**

3.0 (2.8, 4.5)

6.7 (4.7, 12.0)

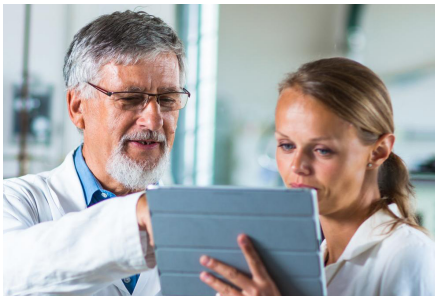
HR#: Nivo + Rela; 95% CI: **0.68** (0.53–0.86)

* Additional subgroup analysis for PD-L1 ≥ 1% is located in the IFU
** PFS: Progression-free Survival | #HR: Hazard Ratio

HR is based on an unstratified Cox proportional hazards model.

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 melanoma 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.

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) melanoma tissues using EnVision FLEX visualization system on Autostainer Link 48.

PD-L1 protein expression in 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.

Companion Diagnostic Indication

Tumor Indication	PD-L1 Expression Clinical Cutoff	Intended Use
Melanoma	< 1% tumor cell expression	PD-L1 IHC 28-8 pharmDx is indicated as an aid in identifying melanoma patients for treatment with Opdualag™ (nivolumab and relatlimab).

Non-Companion Diagnostic Indication

Tumor Indication	PD-L1 Expression Clinical Cutoff	Intended Use
Melanoma	≥ 1%, ≥ 5% tumor cell expression	PD-L1 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 local OPDIVO®, YERVOY®, and Opdualag™ 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 and approved indications.

Check the local OPDIVO, YERVOY and Opdulag product labels for approved indications and expression cutoff values to guide therapy.

D0036118_1.00

Published in Europe, March 7, 2025
29608 2025MAR07

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