PRODUCT INFORMATION

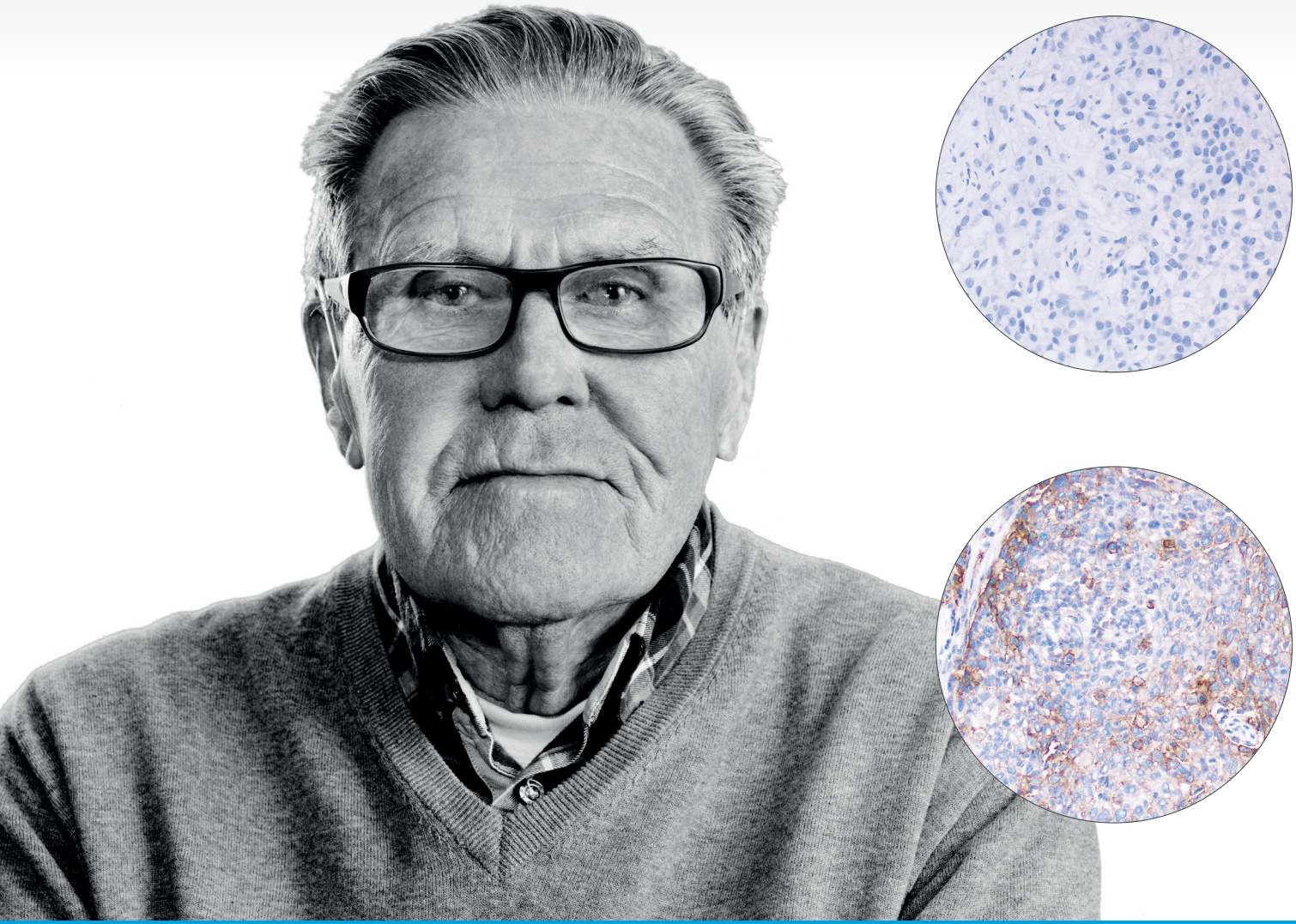
pharmDx | PD-L1 IHC 28-8 pharmDx

Dako

Agilent Pathology Solutions

PD-L1 IHC results you can trust

for OPDIVO® (nivolumab) use in non-squamous NSCLC[1]



Agilent Technologies

PD-L1 expression as detected by PD-L1 IHC 28-8 pharmDx may be associated with enhanced survival from OPDIVO in non-squamous NSCLC[1]

The PD-L1 IHC 28-8 pharmDx is[1]:

- First FDA approved and CE-IVD marked test to assess PD-L1 expression associated with enhanced survival with OPDIVO in non-squamous NSCLC
- The first PD-L1 test with results from a phase III randomized trial based on survival
- Clinical relevant PD-L1 results linked to a clinical outcome in non-squamous NSCLC
- Reliable PD-L1 IHC 28-8 pharmDx kit which meets all acceptance criteria for analytical performance
- Confidence in scoring with a comprehensive PD-L1 Interpretation Manual
- Plug-and-play quality controlled all-inclusive kit, optimized for the Autostainer Link 48

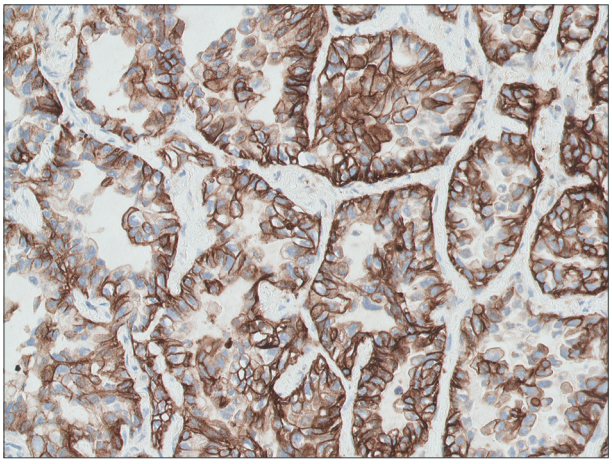


Fig 1. PD-L1 expression ≥ 10%

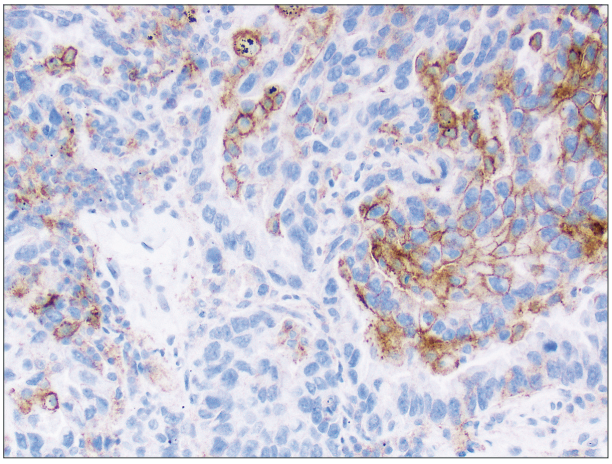


Fig 2. PD-L1 expression ≥ 10%

Experience the easy integration of PD-L1 in your IHC workflow

- Integrate PD-L1 IHC 28-8 pharmDx without changing staining lab workflow
- Ready-to-use reagents and control slides optimized for Autostainer Link 48
- Pre-programmed, validated protocol

Demonstrated clinical results with PD-L1 IHC 28-8 pharmDx

Patients with PD-L1 expression by the predefined expression levels in the OPDIVO group were associated with enhanced survival compared to docetaxel

≥ 1% PD-L1 expression → 41% Reduction in Risk of Death (HR = 0.59) *17.1 months median OS vs. 9 months for docetaxel*
≥ 5% PD-L1 expression → 57% Reduction in Risk of Death (HR = 0.43) *18.2 months median OS vs. 8.1 months for docetaxel*
≥ 10% PD-L1 expression → 60% Reduction in Risk of Death (HR = 0.40) *19.4 months median OS vs. 8 months for docetaxel*

In patients with no PD-L1 expression (< 1%), survival with OPDIVO was similar to docetaxel[1,2]

PD-L1 IHC 28-8 pharmDx, Code SK00**5**

Experience the staining quality of PD-L1 28-8 IHC pharmDx

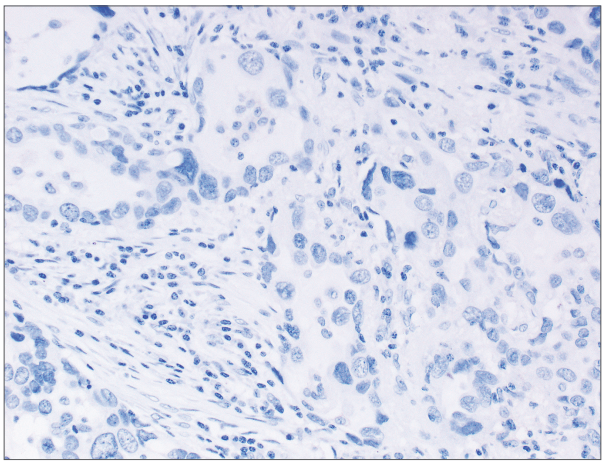


Fig 3. PD-L1 expression < 1% (Non-squamous NSCLC)

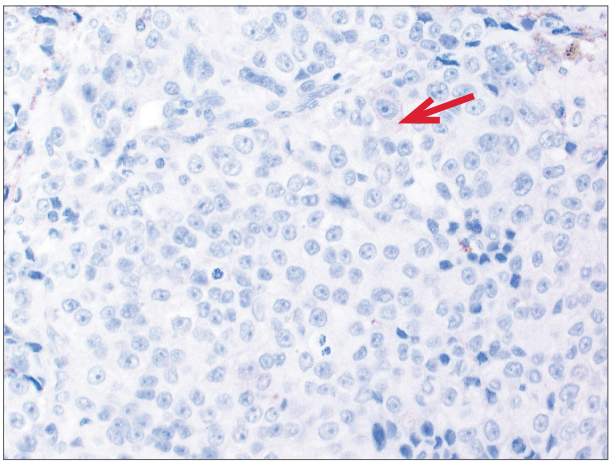


Fig 4. PD-L1 expression ≥ 1% (Non-squamous NSCLC)

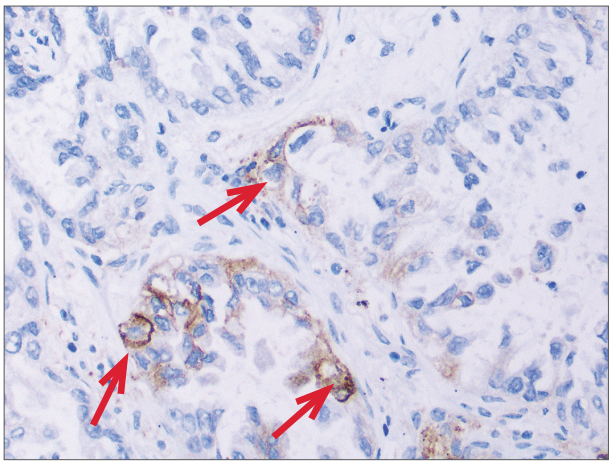


Fig 5. PD-L1 expression ≥ 5% (Non-squamous NSCLC)

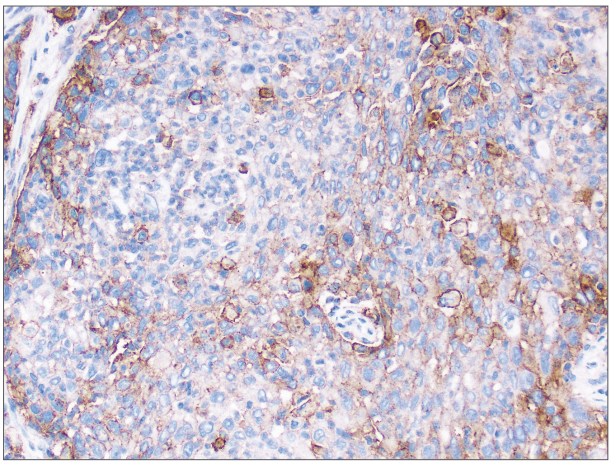
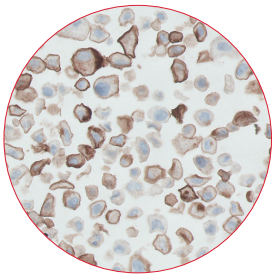


Fig 6. PD-L1 expression ≥ 10% (Non-squamous NSCLC)

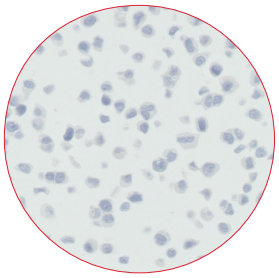
See Dako Interpretation Manual for complete interpretation of PD-L1 IHC 28-8 pharmDx staining results.

Control slides for enhanced confidence in results

Control slides are provided to help validate the staining run. They are not to be used as an interpretation reference.



Positive cell pellet



Negative cell pellet

Confidence in your results

Use the clinically validated scoring guideline for assessing PD-L1 expression in non-squamous NSCLC

To assess the PD-L1 expression level in patient slides stained with PD-L1 IHC 28-8 pharmDx, pathologists should determine the percentage of viable tumor cells exhibiting partial or complete linear circumferential plasma membrane staining at any staining intensity.

Staining pattern	Examples of result reporting
< 1% of the viable tumor cells exhibit complete circumferential or partial linear plasma membrane staining at any intensity	PD-L1 expression < 1%
≥ 1% of the viable tumor cells exhibit complete circumferential or partial linear plasma membrane staining at any intensity.	PD-L1 expression ≥ 1%
≥ 5% of the viable tumor cells exhibit complete circumferential or partial linear plasma membrane staining at any intensity.	PD-L1 expression ≥ 5%
≥ 10% of the viable tumor cells exhibit complete circumferential or partial linear plasma membrane staining at any intensity.	PD-L1 expression ≥ 10%

Table 1: Guidelines for scoring and reporting of PD-L1 IHC 28-8 pharmDx[1,2].

PD-L1 IHC 28-8 pharmDx demonstrate robust performance[1,2]

PD-L1 IHC 28-8 pharmDx is FDA-approved and CE-IVD marked and validated with analytical performance having met all pre-determined acceptance criteria for sensitivity, specificity and precision.

Selected analytical validation parameters	Results for non-squamous NSCLC
Specificity	• Primary antibody: rabbit monoclonal, clone 28-8 • Detects PD-L1 on the plasma membranes of tumor cells, the staining of which can be completely abolished by PD-L1 gene knock-out • Detection in normal tissues is restricted to immune cells and infrequently the cells of epithelial origin • Clone 28-8 exhibits no cross reactivity to PD-L2
Sensitivity	• Broad dynamic range of PD-L1 expression (0-100% tumor cells positive, 0-3 staining intensity) exhibited in study of 112 unique cases of non-squamous NSCLC archival FFPE specimens • In BMS clinical study CA209057 of patients with non-squamous NSCLC, approximately 54% and 40% had PD-L1 expression levels ≥1% and ≥5%, respectively
Precision *- Repeatability*	• Repeatability testing of inter-instrument, inter-operator, inter-day, inter-lot and intra-run performance • ≥ 99% overall agreement for ≥ 1%, ≥ 5% and ≥ 10% expression levels • 95% confidence intervals ranged from 82.4 to 100% for NPA, PPA, and OA*
Precision *- Reproducibility*	• Reproducibility testing of day-to-day, site-to-site and observer-to-observer performance in a blinded study in three certified clinical labs • ≥ 94% overall agreement for ≥ 1% and ≥ 5% expression levels • 95% confidence intervals ranged from 78.5 to 100% for NPA, PPA, and OA*

*Negative Percent Agreement, Positive Percent Agreement, Overall Percent Agreement

Intended Use

For In Vitro Diagnostic Use

PD-L1 IHC 28-8 pharmDx is a qualitative immuno-histochemical 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 (NSCLC) tissue using EnVision FLEX visualization system on Autostainer Link 48.

PD-L1 protein expression is defined as the percentage of tumor cells exhibiting positive membrane staining at any intensity.

PD-L1 expression as detected by PD-L1 IHC 28-8 pharmDx in non-squamous NSCLC may be associated with enhanced survival from OPDIVO (nivolumab).

Confidence in PD-L1 IHC testing with validated Dako pharmDx kits

Kit components

PD-L1 IHC 28-8 pharmDx is a complete kit with reagents sufficient for 50 tests (50 slides incubated with primary antibody to PD-L1 and 50 slides incubated with the corresponding negative control reagent) and 15 Control Slides for use on Autostainer Link 48.

- EnVision FLEX Target Retrieval Solution, Low pH, 50x
- Peroxidase-Blocking Reagent
- Monoclonal Rabbit Anti-PD-L1,Clone 28-8
- Negative Control Reagent
- Anti-Rabbit LINKER
- Visualization Reagent-HRP
- DAB+ Substrate Buffer
- DAB+ Chromogen
- DAB Enhancer
- Control Slides

Fig 7. PD-L1 IHC 28-8 pharmDx Kit, SK005

Order information

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

Use the PD-L1 IHC 28-8 pharmDx

The first and only FDA-approved and CE-IVD marked test for PD-L1 expression associated with enhanced survival with OPDIVO for non-squamous NSCLC[1]

- All-inclusive kit with unique Rabbit Linker only available in PD-L1 IHC 28-8 pharmDx
- Clinically validated PD-L1 IHC 28-8 pharmDx results on the Autostainer Link 48
- High-quality results, meeting all acceptance criteria for robust analytical performance[1]
- Fits within your lab's routine IHC workflow without modifying existing laboratory processes
- Comprehensive Interpretation Manual for non-squamous NSCLC

Trusted Answers. Together.

References

1. PD-L1 IHC 28-8 pharmDx Instructions For Use
2. Clinical Trial: Checkmate 057, CA209057

Dako

Agilent Pathology Solutions

www.dako.com

Represented in more than 100 countries

Australia +61 2 9922 0700
Austria +43 1 408 43 34 0
Belgium +32 (0) 16 38 72 20
Brazil +55 11 50708300
Canada +1 905 335 3256
China +86 21 3612 7091
Denmark +45 44 85 97 56
Finland +358 9 348 73 950
France +33 1 64 53 61 44
Germany +49 40 69 69 470
Ireland +353 1 479 0568
Italy +39 02 58 078 1
Japan +81 3 5232 9970
Korea +82 2 2194 9577
The Netherlands +31 20 42 11 100
Norway +47 23 14 05 40
Poland +48 58 661 1879
Spain +34 93 344 57 77
Sweden +46 8 556 20 600
Switzerland +41 41 760 11 66
United Kingdom +44 (0)1 353 66 99 11
United States of America +1 805 566 6655

29125 2016JUN22 - ROW Version