

# Get Started With PD-L1 IHC 22C3 pharmDx, Code GE006

For use with Dako Omnis family of instruments.  
IVDR-certified for NSCLC and HNSCC.



## PD-L1 IHC 22C3 pharmDx, Code GE006, is now available on the Dako Omnis family of instruments



- Combines the clinical relevance of PD-L1 22C3 pharmDx with the flexibility and choice of Dako Omnis to provide a fully automated PD-L1 diagnostic service integrated into the core of your laboratory workflow
- Identify non-small cell lung cancer (NSCLC) and head and neck squamous cell carcinoma (HNSCC) patients eligible for treatment with KEYTRUDA® (pembrolizumab)\* monotherapy using a fully validated and IVDR-certified PD-L1 assay reconfigured for the Dako Omnis family of instruments by Agilent<sup>1,2</sup>
- Extensive clinical validation on NSCLC and HNSCC through concordance<sup>1</sup> with PD-L1 IHC 22C3 pharmDx, Code SK006, enables laboratories to implement PD-L1 testing on Dako Omnis quickly and simply, with diagnostic confidence



Contact your Agilent Sales Representative today to get started with PD-L1 IHC 22C3 pharmDx, Code GE006, on the Dako Omnis family of instruments in your laboratory.

### Tumor Proportion Score (TPS) Indication

	TPS < 1%	TPS ≥ 50%
<b>Non-small Cell Lung Cancer (NSCLC)</b> TPS ≥ 1% TPS ≥ 50%		

\* KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA. Please refer to the KEYTRUDA product label for PD-L1 expression cutoff values and specific clinical circumstances guiding therapy.

### Combined Positive Score (CPS) Indication

	CPS < 1	CPS ≥ 1
<b>Head and Neck Squamous Cell Carcinoma (HNSCC)</b> CPS ≥ 1		

## Workflow-optimized PD-L1 testing for modern pathology labs

Reconfiguration of PD-L1 IHC 22C3 pharmDx, Code GE006, for Dako Omnis family of instruments offers “walk away” full automation

- Saves staff hands-on time and enables PD-L1 slides to be delivered on the same platform as your routine IHC and in the context of your routine lung and HNSCC IHC panel for an efficient and LEAN workflow
- Controlled on-board environment with a fully optimized, standardized and validated assay protocol ensures consistent results every time. Enables you to provide a clinically proven, high-quality PD-L1 diagnostic service
- Continuous case delivery gives pathologists new options to manage their workload, allowing them to score patient PD-L1 slides throughout the day, accelerating turnaround time and providing timely reports to oncologists



### Dako Omnis

The Dako Omnis solution for automated IHC, double staining, IF, ICC, and ISH staining includes staining instruments, reagents, accessories, and software. It is designed to meet the needs and challenges faced by lab managers, lab technicians, and pathologists. This solution helps pathology labs efficiently and cost-effectively manage increasing test demands while ensuring reliable and reproducible staining results.

## PD-L1 IHC 22C3 pharmDx, Code GE006, ordering information

Product Name	Part no.	Size
PD-L1 IHC 22C3 pharmDx, Code GE006 (includes Negative Control Reagent)	GE00621-2	60 Tests
EnVision FLEX DAB Enhancer (Dako Omnis)	GC80611-2	60 Tests
PD-L1 Control Slides	T139130-2	5 Slides



This product is intended for in vitro diagnostic use and has a modular format. Additional Dako Omnis reagents are required to run the test<sup>1</sup>

## Intended use

### For in vitro diagnostic use.

PD-L1 IHC 22C3 pharmDx, Code GE006, is a qualitative immunohistochemical assay using Monoclonal Mouse Anti-PD-L1, Clone 22C3 intended for use in the detection of PD-L1 protein in formalin-fixed, paraffin-embedded (FFPE) non-small cell lung cancer (NSCLC) and head and neck squamous cell carcinoma (HNSCC) tissues, using EnVision FLEX visualization system on the Dako Omnis family of instruments.

PD-L1 protein expression in NSCLC is determined by using Tumor Proportion Score (TPS), which is the percentage of viable tumor cells showing partial or complete membrane staining at any intensity.

PD-L1 protein expression in HNSCC 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 Indication

Tumor Indication	PD-L1 Expression Clinical Cut-Off	Intended Use
NSCLC	TPS $\geq$ 1% TPS $\geq$ 50%	PD-L1 IHC 22C3 pharmDx, Code GE006, is indicated as an aid in identifying NSCLC patients for treatment with KEYTRUDA® (pembrolizumab)*
HNSCC	CPS $\geq$ 1	PD-L1 IHC 22C3 pharmDx, Code GE006, is indicated as an aid in identifying HNSCC patients for treatment with KEYTRUDA® (pembrolizumab)*

\* See the local KEYTRUDA® (pembrolizumab) product label for PD-L1 expression cutoff values and specific clinical circumstances guiding PD-L1 testing<sup>2</sup>.

## References

1. PD-L1 IHC 22C3 pharmDx [Instructions for Use]. Santa Clara, CA: Agilent Technologies, Inc.; 2026.
2. KEYTRUDA (pembrolizumab) [package insert]. Rahway, NJ: Merck Sharp & Dohme LLC; 2026

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This information is subject to change without notice.

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