PRODUCT INFORMATION

PD-L1 IHC 28-8 pharmDx | Squamous Cell Carcinoma of the Head and Neck (SCCHN)

Dako
Agilent Pathology Solutions

FDA approved for SCCHN

More personalized cancer results. One test makes it possible.

Personalized medicine option for patients with squamous cell carcinoma of the head and neck

Head and neck carcinomas are the sixth most common cancer worldwide with approximately 550,000 new cases and 300,000 deaths annually.[1][2][3] 10% of patients present with Stage IV metastatic disease at the time of diagnosis requiring immediate treatment, and approximately 50% develop recurrent or refractory disease.[2] Patients who progress after platinum-based treatment (platinum-refractory or resistant disease) have a poor prognosis, with a median Overall Survival (OS) of approximately 4-6 months.[4]

PD-L1 IHC 28-8 pharmDx: The first **fully validated** and **clinically relevant** test for OPDIVO® (nivolumab) in squamous cell carcinoma of the head and neck

Detection of PD-L1 expressing tumor cells in SCCHN patient specimens may indicate an enhanced survival benefit to OPDIVO (nivolumab) treatment for the patient.[5]

The CHECKMATE-141 study demonstrated a statistically significant improvement in OS for subjects randomized to nivolumab as compared to investigator's choice at a pre-specified interim analysis (78% of the planned number of events for final analysis). The median OS was 7.5 months for nivolumab subjects compared to 5.1 months for investigator's choice subjects with a hazard ratio (HR) of 0.70 (95% CI 0.53, 0.92).

Summary of OS by PD-L1 IHC 28-8 pharmDx expression level and treatment group[5]

Data from a pre-specified exploratory analysis (N=260) of CHECKMATE-141 (N=361).

Tumor PD-L1 Expression	<1%		≥1%	
	Nivolumab	Investigator's Choice	Nivolumab	Investigator's Choice
Median OS	5.7 mos.	5.8 mos.	8.7 mos.	4.6 mos.
Hazard Ratios	0.89 (95% CI: 0.54, 1.45)		0.55 (95% CI: 0.36, 0.83)	

Abbreviations: CI = confidence interval

PD-L1 IHC 28-8 pharmDx Intended 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 (NSCLC), squamous cell carcinoma of the head and neck (SCCHN), urothelial carcinoma (UC), and melanoma tissues using EnVision FLEX visualization system on Autostainer Link 48. PD-L1 protein expression is defined as the percentage of evaluable tumor cells exhibiting partial or complete membrane staining at any intensity. Tumor PD-L1 status is defined by indication specific staining interpretation.

Tumor Indication*	Intended Use	PD-L1 Expression Clinical Cut Off
nsNSCLC	PD-L1 expression as detected by PD-L1 IHC 28-8 pharmDx in non-squamous NSCLC and SCCHN may be associated with enhanced survival from OPDIVO® (nivolumab).	≥1%, ≥5%, ≥10%
SCCHN		≥1%
UC	PD-L1 expression as detected by PD-L1 IHC 28-8 pharmDx in UC may be associated with enhanced response rate from OPDIVO®.	≥1%
Melanoma	Positive PD-L1 status as determined by PD-L1 IHC 28-8 pharmDx in melanoma is correlated with the magnitude of the treatment effect on progression-free survival from OPDIVO®.	≥1%

*For details on staining interpretation, refer to section 13 of the product insert and indication specific PD-L1 IHC 28-8 pharmDx Interpretation Manuals.

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PD-L1 IHC 28-8 pharmDx delivers clinically validated results

Frequency of Tumor PD-L1 Expression in Quantifiable* Samples from SCCHN - CHECKMATE-141

Tumor PD-L1 Expression	Nivolumab (N=161)	Investigator's Choice (N=99)	Total (N=260)
≥1% PD-L1 Expression Subjects	88 (54.7%)	61 (61.6%)	149 (57.3%)
<1% PD-L1 Expression Subjects	73 (45.3%)	38 (38.4%)	111 (42.7%)

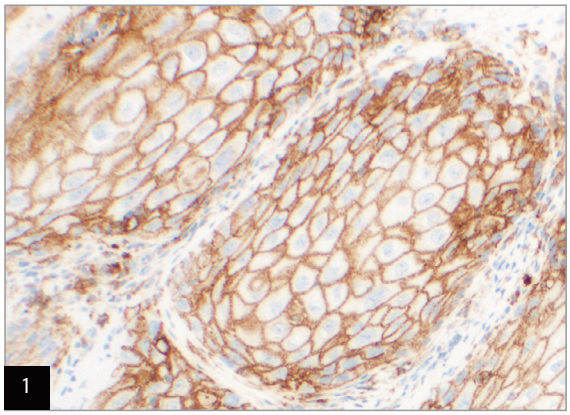
*260 of 327 samples were PD-L1 quantifiable from study CHECKMATE-141.

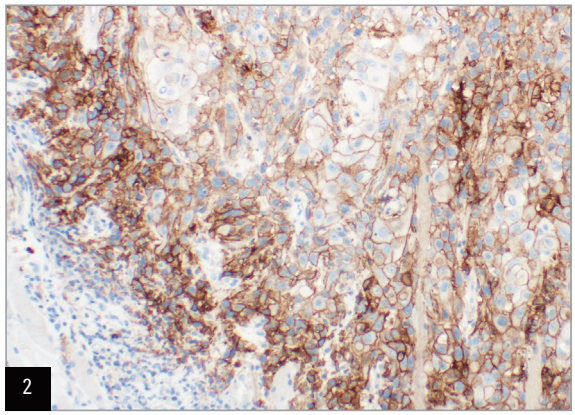
PD-L1 IHC 28-8 pharmDx offers robust performance

PD-L1 IHC 28-8 pharmDx is fully validated for analytical performance, having met stringent acceptance criteria for ultimate quality results.

Selected Analytical validation parameters	Results for SCCHN
Analytical specificity	■ Demonstrated specificity to clone 28-8 for PD-L1 detection ■ PD-L1 primary antibody displays no cross-reactivity for PD-L2 ■ Detection in normal tissues restricted to immune cells and infrequently to cells of epithelial origin
Sensitivity	■ Broad dynamic range of PD-L1 expression (0-95% of positive tumor cells, 0-3 staining intensity) exhibited in study of 236 unique cases of SCCHN FFPE specimen stages I to IV
Repeatability	■ Demonstrated lot-to-lot repeatability ■ 100% overall agreement for ≥1% expression level
External reproducibility	■ ≥96.2% overall agreement for ≥1% expression level ■ Reproducibility testing of day-to-day, site-to-site and observer-to-observer in a blinded study in three certified clinical labs ■ 95% confidence intervals from ≥91.5% to 99.4% agreement for both ANA and APA

ANA= Average Negative Agreement | APA= Average Positive Agreement | OA= Overall Agreement





1. Squamous cell carcinoma of the tonsil stained with PD-L1

2. Squamous cell carcinoma of the tongue stained with PD-L1

Order information:
PD-L1 IHC 28-8 pharmDx – SK005

Include PD-L1 IHC 28-8 pharmDx in your squamous cell carcinoma head and neck cancer panel to provide more personalized cancer results for these patients.

References

(1) Siegel RL, Miller KD, Jemal A. Cancer Statistics 2016. Cancer J Clin 2016; 7-30.
(2) Argiris A, Karamouzis MV, Raben D, et al. Head and neck cancer. Lancet 2008;371:1695-709.
(3) Pignon JP, Bourhis J, Domenge C, et al. Chemotherapy added to locoregional treatment for head and neck squamous-cell carcinoma: three meta-analyses of updated individual data. MACH-NC Collaborative Group. Meta-Analysis of Chemotherapy on Head and Neck Cancer. Lancet 2000;355:949-55.
(4) Colevas AD. Systemic therapy for metastatic or recurrent squamous cell carcinoma of the head and neck. J Natl Compr Canc Netw 2015;13:e37-e48.
(5) PD-L1 IHC 28-8 pharmDx Instructions for Use.

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