



More personalized cancer results.
One test makes it possible.

More options 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.⁽⁴⁾ 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.⁽⁵⁾

PD-L1 IHC 28-8 pharmDx: The first **fully validated** and **clinically relevant** test for OPDIVO[®] in squamous cell carcinoma of the head and neck⁽⁶⁾

Detection of PD-L1 expressing tumor cells in SCCHN patient specimens may indicate an enhanced survival benefit to OPDIVO (nivolumab) treatment for the patient.⁽⁶⁾

The CA209141 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⁽⁶⁾

Data from a pre-specified exploratory analysis (N=260) of CA209141 (N=361).

PD-L1 Expression	<1%		≥1%	
	Nivolumab	Investigator's Choice	Nivolumab	Investigator's Choice
Median OS (95% CI)	5.7 mos. (4.4-12.7)	5.8 mos. (4.0-9.8)	8.7 mos. (5.7-9.1)	4.6 mos. (3.8-5.8)
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), 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, as defined by the specific tumor indication staining interpretation guidelines.

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). 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.

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

Frequency of PD-L1 Expression in Quantifiable* Samples from SCCHN - CA209141

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%)

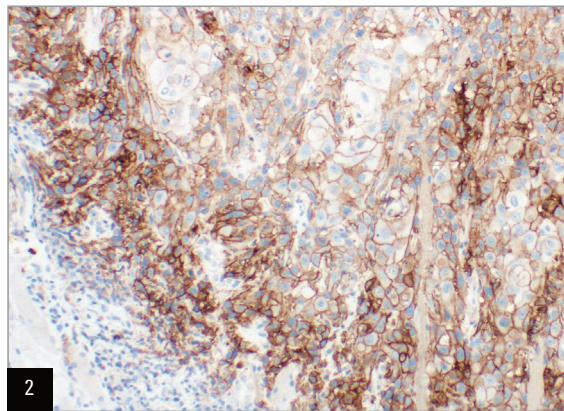
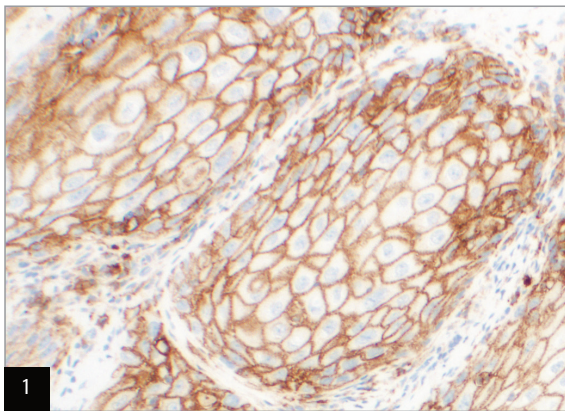
*327 of 361 samples were PD-L1 quantifiable from study CA209141.

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	<ul style="list-style-type: none"> ■ 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	<ul style="list-style-type: none"> ■ 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	<ul style="list-style-type: none"> ■ Demonstrated lot-to-lot repeatability ■ 100% overall agreement for ≥1% expression level
External reproducibility	<ul style="list-style-type: none"> ■ ≥97% 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 88% to 100% agreement for both NPA and PPA

NPA= Negative Percent Agreement | PPA= Positive Percent 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 head and neck cancer panel to provide important information about the latest treatment options 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.
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- [5] 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.
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