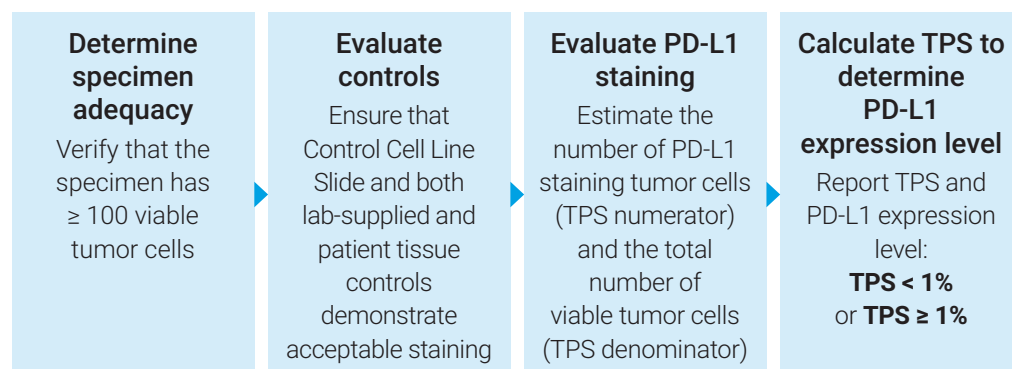


Your Guide for Accurate Scoring in NSCLC Using PD-L1 IHC 22C3 pharmDx (SK006)

Use this quick scoring guide as a reference when evaluating NSCLC specimens for PD-L1 expression using PD-L1 IHC 22C3 pharmDx when treatment with KEYTRUDA® (pembrolizumab) is being considered.

For more information on Tumor Proportion Score (TPS) assessment, review the NSCLC Interpretation Manual.

Steps for scoring



Note: PD-L1 expression level TPS ≥ 50% may be of interest to treating physician but does not determine eligibility for KEYTRUDA monotherapy.

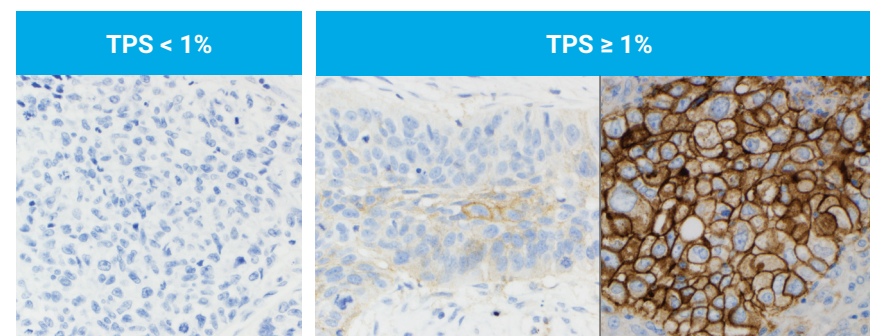
Definition of TPS and PD-L1 staining cells

TPS is the percentage of viable tumor cells showing partial or complete membrane staining at any intensity (≥ 1+) relative to all viable tumor cells present in the sample.

$$\text{TPS (\%)} = \frac{\text{\# PD-L1 staining cells (tumor cells)}}{\text{Total \# of viable tumor cells}} \times 100$$

Note: TPS is reported as a percent.

PD-L1 staining in NSCLC is defined as perceptible and convincing membrane staining of tumor cells (partial or complete) at any intensity (≥ 1+) that is perceived distinct from cytoplasmic staining. All staining of tumor-associated immune cells should be excluded from scoring.



Intended Use

For in vitro diagnostic use.

PD-L1 IHC 22C3 pharmDx 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) tissue using EnVision FLEX visualization system on Autostainer Link 48.

Non-Small Cell Lung Cancer (NSCLC)

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. The specimen should be considered to have PD-L1 expression if TPS ≥ 1%.

PD-L1 IHC 22C3 pharmDx is indicated as an aid in identifying NSCLC patients for treatment with KEYTRUDA® (pembrolizumab). See the KEYTRUDA® product label for specific clinical circumstances guiding PD-L1 testing.

For descriptions of the intended use in other indications, please refer to the current version of the Instructions for Use (IFU) for PD-L1 IHC 22C3 pharmDx, Code SK006.

Tissue Elements	Included in TPS Scoring for NSCLC	Excluded from TPS Scoring for NSCLC
Tumor Cells	Convincing partial or complete cell membrane staining (at any intensity) of viable tumor cells	Exclude any cytoplasmic staining
Immune Cells	Not included	Exclude any staining of immune cells, such as: <ul style="list-style-type: none"> – Mononuclear inflammatory cells (large lymphocytes, monocytes, pulmonary macrophages) – Plasma cells – Neutrophils
Other Cells	Not included	Exclude any staining of: <ul style="list-style-type: none"> – Normal cells adjacent to tumor cells – Stromal cells (fibroblasts) – Necrotic cells and/or cellular debris – Anthracotic pigment

Case examples

TPS 0–10% case example*

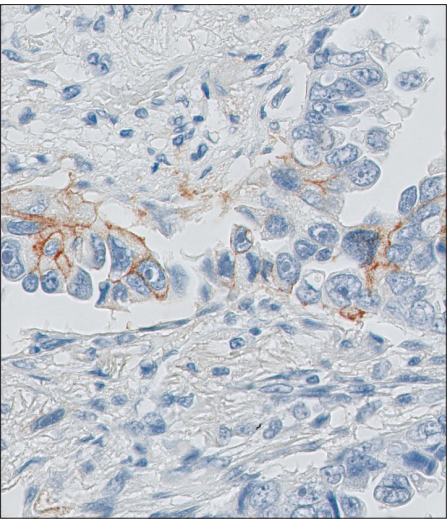
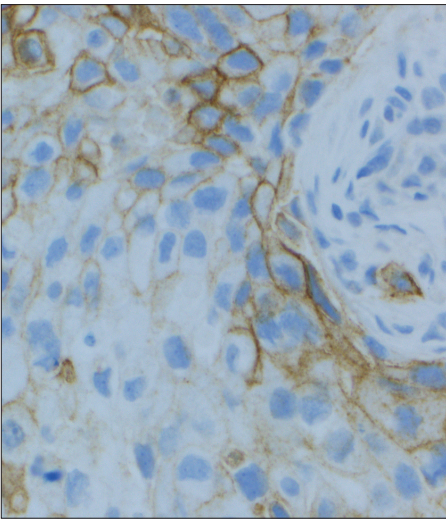


Figure 1–2: Patients with NSCLC are indicated for treatment with KEYTRUDA® (pembrolizumab) monotherapy if **TPS ≥ 1%**.

* Image shown represents one field of view. TPS is derived from scoring the entire slide

TPS 40–60% case example*



PD-L1 staining characteristics in NSCLC

Weak but perceptible and convincing membrane staining

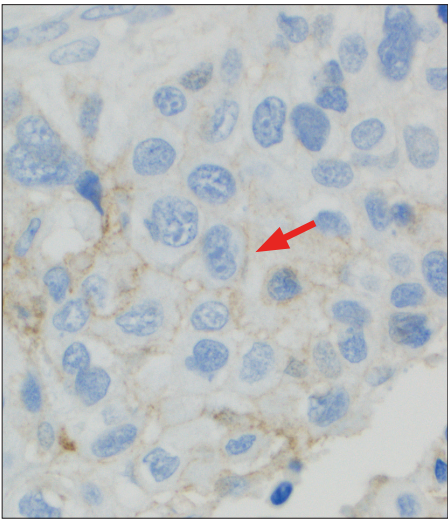


Figure 3: All weak but perceptible and convincing membrane staining of tumor cells (arrow) should be **included** in the TPS.

Tumor cells vs. tumor-associated immune cells (TAIC)

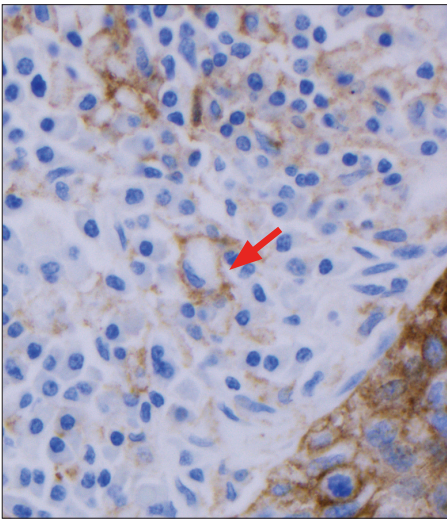


Figure 4: All staining of TAIC (arrow) should be **excluded** from the TPS.

For countries outside of the United States, see the local KEYTRUDA product label for approved indications and expression cutoff values to guide therapy.

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This information is subject to change without notice.

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