The **ONE** companion diagnostic FDA-approved in gastric or GEJ adenocarcinoma to aid in the identification of patients for treatment with KEYTRUDA® (pembrolizumab)\(^1\)\(^2\)

**PD-L1 IHC 22C3 pharmDx can help identify gastric or GEJ adenocarcinoma patients for treatment with KEYTRUDA\(^1\)**

**PD-L1 is a proven biomarker for patient response to KEYTRUDA\(^1\)\(^2\)**

- Despite decreasing incidence and an increasing number of treatment options, gastric cancer continues to be a leading cause of cancer-related mortality worldwide\(^3\)\(^4\)
- IHC testing for PD-L1 expression levels enables identification of patients most likely to benefit from PD-1 checkpoint inhibitors\(^1\)\(^2\)—in KEYNOTE-059, a KEYTRUDA clinical trial, 58% of patients with gastric or GEJ adenocarcinoma had tumors that exhibited PD-L1 expression\(^1\)

**PD-L1 testing should be an integral part of patient care from day **\textbf{ONE}\)

**Because patients with gastric cancer have poor prognosis, it is critical to assess their PD-L1 expression status upon diagnosis**

- Most gastric cancer patients present at an advanced stage and are treated with upfront, systemic chemotherapy\(^4\). Patients may initially respond to treatment, but many of them relapse over time,\(^4\) with durations of response being as short as a few months\(^5\)
- Therefore, it is important to test for PD-L1 upon diagnosis to better inform long-term patient management and treatment

KEYTRUDA is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.
Trust the ONE PD-L1 test FDA-approved to determine PD-L1 expression in patients with gastric and GEJ adenocarcinoma¹

Proven in KEYNOTE-059, a KEYTRUDA® (pembrolizumab) clinical trial, for PD-L1 results in gastric or GEJ adenocarcinoma that you can rely on¹²

- PD-L1 IHC 22C3 pharmDx was used to assess PD-L1 expression in patients treated with KEYTRUDA in the KEYNOTE-059 trial
  - Fifty-eight percent of patients had tumors that expressed PD-L1 with a Combined Positive Score (CPS)² of greater than or equal to 1¹
- Gastric or GEJ adenocarcinoma patients with PD-L1 expression and microsatellite stable tumor status (or unknown) demonstrated an overall response rate of 13.3%¹

<table>
<thead>
<tr>
<th>PD-L1 Expression</th>
<th>CPS &lt; 1</th>
<th>CPS ≥ 1</th>
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<tr>
<td>Prevalence (n)</td>
<td>42.0% (109)</td>
<td>58.0% (148)</td>
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* Note: For more information on CPS assessment, review the Gastric or GEJ Adenocarcinoma PD-L1 IHC 22C3 pharmDx Interpretation Manual or the eLearning Program at agilent.com/chem/PDL122C3.

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) and gastric or gastroesophageal junction (GEJ) adenocarcinoma tissues 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% and high PD-L1 expression if TPS ≥ 50%.

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 expression cutoff values guiding therapy in specific clinical circumstances.

Gastric or Gastroesophageal Junction (GEJ) Adenocarcinoma

PD-L1 protein expression in gastric or GEJ adenocarcinoma 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. The specimen should be considered to have PD-L1 expression if CPS ≥ 1.

PD-L1 IHC 22C3 pharmDx is indicated as an aid in identifying gastric or GEJ adenocarcinoma patients for treatment with KEYTRUDA® (pembrolizumab).

For clinically relevant PD-L1 results in gastric or GEJ adenocarcinoma, use trial-proven PD-L1 IHC 22C3 pharmDx