

Choice of PD-L1 immunohistochemistry assay influences clinical eligibility for gastric cancer immunotherapy

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Key Findings

- **28-8 assay:** higher PD-L1 scores vs the **22C3 assay**.
- **28-8 assay:** higher proportion PD-L1 positivity at various cut offs vs the **22C3 assay**.
- Using **22C3** in lieu of the **28-8** assay to assess nivolumab eligibility could deny patient access to treatment.

Background

Results

- Each immune checkpoint inhibitor (ICI) targeting the PD-1/ PD-L1 pathway in gastric cancer is paired with a different antibody IHC assay to evaluate eligibility for therapy.
 - Pembrolizumab – approved with **22C3** assay for patients with CPS ≥ 1 ^{1,2}
 - Nivolumab – approved with **28-8** assay for patients with CPS ≥ 5 ³
- Prior to the approval of nivolumab, pathology labs performed PD-L1 CPS scoring using the **22C3** assay.
- Understanding the assay interchangeability may be practice defining.

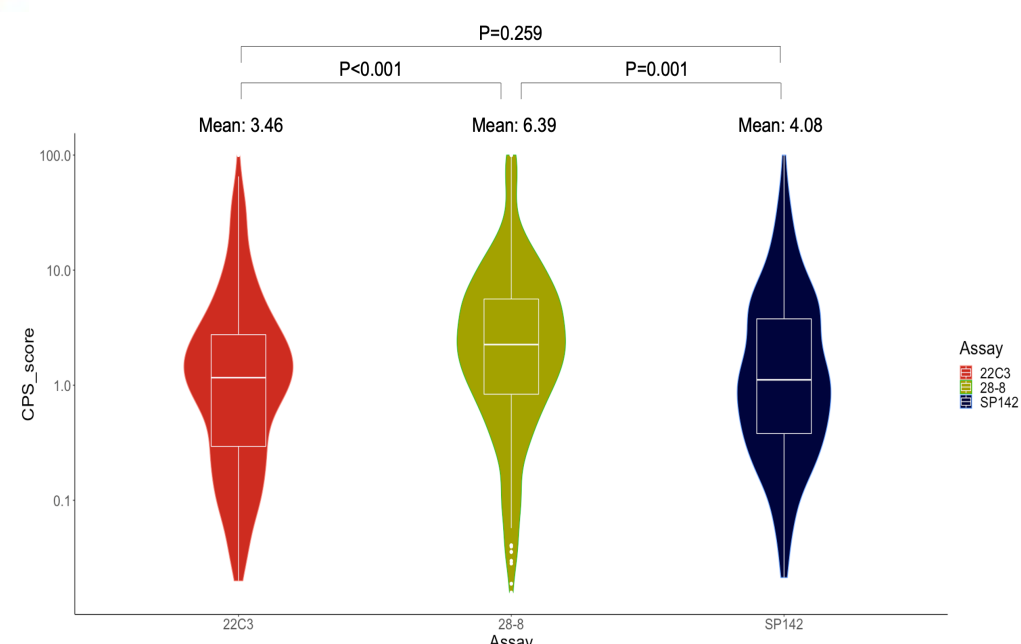
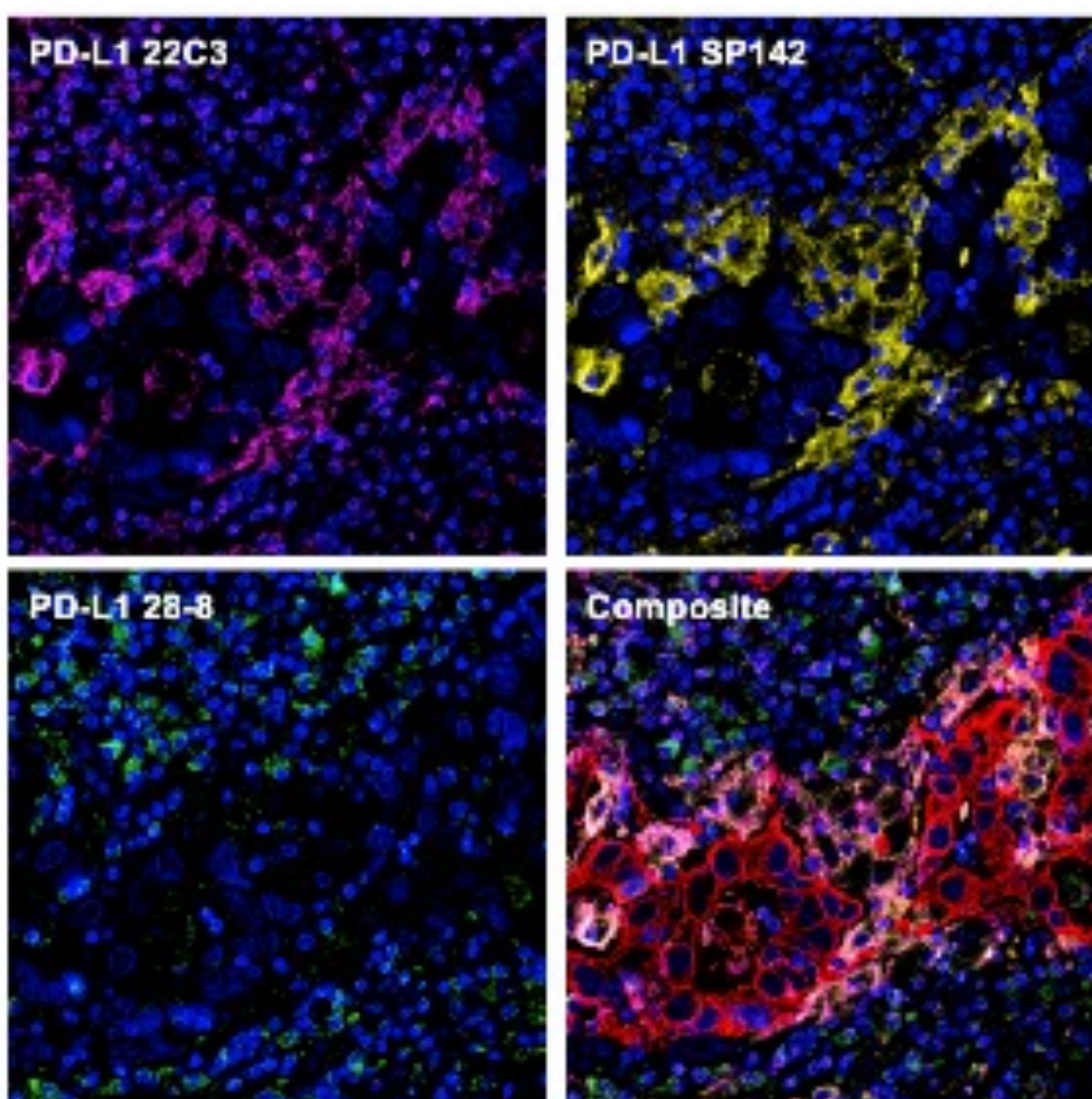
| Assay | CPS ≥ 1 | CPS ≥ 5 | CPS ≥ 10 |
|-------------|----------------|--------------------------------|---------------|
| 22C3 | 170 (49.4%) | 46 (13.4%) | 24 (7.0%) |
| 28-8 | 242 (70.3%) | 100 (29.1%) | 47 (13.7%) |

Methods

- Table 1: Proportion of PD-L1 positivity with different assays, at CPS cut-offs of 1, 5, 10
- The percentage of PD-L1 positive samples at CPS ≥ 1 , ≥ 5 and ≥ 10 (Table 1) assessed with the **28-8** assay were approximately two-fold higher than that of the **22C3** assay

- Samples from **344** patients were obtained via biopsy or resection
- Samples were developed into a tissue microarray
- Each sample scored for PD-L1 expression status, based on the CPS, utilizing the **22C3**, **28-8** and **SP142** assays

Figure 1: Representative images of gastric cancer tissue stained using mIHC [DAPI (Blue), PD-L1 **22C3** (Magenta), PD-L1 **SP142** (Yellow), PD-L1 **28-8** (Green), CK (Red)]. (Magnification, 200X), from one patient.



- Figure 2 : Log-transformed violin plot of CPS Scores on PD-L1 obtained from **22C3**, **28-8** and **SP-142** assays (n=344)
- The mean CPS score obtained from the **28-8 assay** was significantly higher than both the **22C3 assay** (6.39 vs 3.46) and the **SP142 assay** (6.39 vs 4.08)

Acknowledgements

References



Scan this QR to access high resolution images of our multiplex IHC samples