ANALYTICAL COMPARISON OF A PD-L1 22C3 ANTIBODY LABORATORY-DEVELOPED TEST PROTOCOL ON THE BENCHMARK XT AND PD-L1 IHC 22C3 PHARMDX: PAN-TUMOR AND TRIPLE-NEGATIVE BREAST CANCER SAMPLES

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Background PD-L1 IHC 22C3 pharmDx is an FDA-approved companion diagnostic for pembrolizumab across multiple tumor types designed for use on the Autostainer Link 48 (AL48). Many pathology laboratories do not have access to the AL48 and therefore do not use PD-L1 IHC 22C3 pharmDx but instead assess PD-L1 using laboratory-developed tests (LDTs) on the Ventana BenchMark platform. We compared our PD-L1 22C3 antibody-based LDT on the BenchMark XT platform with PD-L1 IHC 22C3 pharmDx using cervical cancer (CC), head and neck squamous cell carcinoma (HNSCC), urothelial carcinoma (UC), esophageal SCC (ESCC), and triple-negative breast cancer (TNBC) samples.

Methods Tumor specimens from patients with CC, HNSCC, UC, ESCC, and TNBC were stained with the 22C3 antibody, scored using the LDT on the BenchMark XT as previously described,¹ and compared with PD-L1 IHC 22C3 pharmDx scored by a trained pathologist, who measured PD-L1 with the use of combined positive score (CPS) and standard cutoffs (HNSCC and CC, ≥ 1 ; UC, ESCC, and TNBC, ≥ 10). Agreement in PD-L1 CPS as determined using the LDT and the PD-L1 IHC 22C3 pharmDx was evaluated.

Results 423 samples with CC (n = 77), HNSCC (n = 126), UC (n = 121), ESCC (n = 80), and TNBC (n = 19) were evaluated in this study. The pan-tumor (CC, HNSCC, UC, and ESCC) intraclass correlation coefficient (ICC) of PD-L1 CPS as a continuous variable was 0.95 (95% CI, 0.94–0.96%); Spearman correlations were 0.95. ICC (95% CI) was 0.92 (0.88–0.95) for CC, 0.97 (0.96–0.98) for HNSCC, 0.95 (0.92–0.97) for UC, and 0.92 (0.88–0.95) for ESCC; Spearman correlation was 0.93, 0.96, 0.92, and 0.89, respectively. The overall percentage agreement at the respective CPS cutoff was 96% (CC), 96% (HNSCC), 96% (UC), and 90% (ESCC). Staining patterns by 22C3 LDT and PD-L1 IHC 22C3 pharmDx were also very similar in our TNBC pilot study; however, correlation was not calculated because of the small sample numbers.

Conclusions The PD-L1 22C3 antibody-based LDT on the BenchMark XT demonstrated high concordance with PD-L1 IHC 22C3 pharmDx. These findings suggest the comparability of PD-L1 IHC 22C3 pharmDx with an LDT based on the 22C3 antibody across several tumor types. Further validation for TNBC is ongoing to confirm the data from the pilot run.

REFERENCE

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