#1566. Establishment of Analytical Performance Features of Two Immunohistochemistry Assays for PD-L1 Expression in Lung Cancer

Lei Zhang1, Claire Begot2, Robert McGee3 and Steven Anderson4; Covance Inc., 1Singapore; 2Geneva, Switzerland; 3Indianapolis, IN; 4Durham, NC

**Background**
PD-L1 expression has been demonstrated as a biomarker of immuno-therapy response in a variety of tumor types. Currently there are multiple IHC assays that are used to measure PD-L1 expression in FFPE tissues, with significant variability in primary antibody, assay platform, scoring criteria, and assay cut-offs between assays. This situation creates potential confusion in the application of PD-L1 immunohistochemistry (IHC) assays for the appropriate intended use. In this study we evaluated two assays (Dako pharmDx PD-L1 28-8 assay and Ventana PD-L1 SP263) in terms of its analytical comparability.

**Method**
45 non-small cell lung cancer samples encompassing predominately squamous cell carcinomas (35) and adenocarcinomas (10) were evaluated. These samples were stained and assessed for PD-L1 expression with the Dako pharmDx PD-L1 28-8 and Ventana PD-L1 SP263 assays and scored by trained pathologists. Cutoffs that have been established in clinical studies and are referenced in the respective assay package inserts (>1% positivity percentage of tumor cells for 28-8 assay and >25% positivity percentage of tumor cells for the SP263 assay) were used as the reference standard in data analysis.

**Results**
The correlation of PD-L1 expression measured by the percentage of tumor cell staining positive by two assays achieved a significant concordance ($r^2 = 0.91$). Similar trends in the percentage of positive tumor cells were demonstrated across a broad dynamic range of staining. When these established assay cutoffs were applied, a low-to-medium concordance between two assays was demonstrated ($r^2 = 0.58$). When the same cutoff (1% or 25%) was applied, the correlation between assays improved markedly ($r^2 = 0.73$ or 0.95 respectively). In this sample set the 25% cutoff produced the more consistent data when comparing the two methods.

**Conclusions**
This comparison study showed that the two assays (Dako pharmDx PD-L1 28-8 assay and Ventana PD-L1 SP263) were analytically comparable, when assessed for the percentage of tumor cells staining positive.