**Abstract**

**Quantitative FFPE VeraTag® Assays**

**PD-L1 VeraTag® Assay**

- Programmed death-ligand 1 (PD-L1)

**PD-L1 VeraTag® Assay Characteristics**

- Background in FFPE cell lines and tumors
- Reproducibility - 19 FFPE SCCHN tumors

**PD-L1 Protein and mRNA Distributions**

- PD-L1 protein expression by VeraTag and mRNA expression from CCLE both show an increase in NSCLC and SCCHN over Breast cancer.

**VeraTag® Assay Workflow**

- VeraTag is compatible with broad array of FFPE protocols.
- Tagging reagents can be competitively added to FFPE slides with or without antigen retrieval.

**PD-L1 IHC compared to VeraTag®**

- PD-L1 IHC utilizing the same primary antibody (EILIN) as the VeraTag assay.
- VeraTag assay provided a wide range of expression in both IHC 1+ and 2+.

**Conclusions**

- We have developed a quantitative and reproducible PD-L1 assay using the VeraTag technology to measure PD-L1 protein expression in FFPE samples.
- The PD-L1 VeraTag assay correlated significantly with mRNA expression in panel FFPE cell lines over an ~30 fold dynamic range.
- The PD-L1 VeraTag assay had good reproducibility within FFPE cell lines (5–15% CV) and between operators with SCCHN tumors (34.7% of the samples within 2.5 SD). The elevated distributions of PD-L1 protein as measured by VeraTag in NSCLC and SCCHN over Breast cancer tumors paralleled the relative distributions of PD-L1 mRNA in FFPE cell lines derived from the FFPE tumor samples.
- The PD-L1 VeraTag assay provided a range of expression within the IHC 1+ and 2+ categories.
- VeraTag measurements of PD-L1 protein expression correlated with HER3-Pi3 kinase complex in both Breast and SCCHN tumors, supportive of a role for the PD3K pathway in the regulation of PD-L1 protein expression.
- Clinical evaluation of PD-L1 protein expression by an objective, quantitative and reproducible VeraTag assay may help identify patients for anti-PD-1 or anti-PD-L1 therapies.