Figure 2. Digital Analysis of PD-L1-Stained NSCLC Samples. The 22C3 IVD PD-L1 antibody staining assessment is widely used to predict the efficacy of these interventions in NSCLC. The pathologist assigns a tumor proportion score (TPS) for each sample, with the goal of providing a consistent way to interpret PD-L1 staining intensity and determine patient eligibility for treatment. However, this manual approach is prone to variability due to inter-pathologist differences in scoring criteria and interpretation of staining intensity.

Our virtual central pathology service provides a standardized approach to PD-L1 staining analysis, which eliminates the intra-pathologist and inter-pathologist variability associated with manual scoring. It uses image analysis (IA) to quantify PD-L1 expression within the tumor compartment, ensuring high quality data. Furthermore, IA data yields comparable results to pathologist interpretation, providing a reliable and reproducible method for assessing PD-L1 expression.

Summary

Currently, several factors influence the development of pathologic tools and global implementation strategies for diagnostic and therapeutic decision-making. The immune microenvironment and potential immune infiltration into tumor nests are critical in many diseases, but the assessment of these factors remains challenging due to the variability in interpretation of staining intensity and the subjective nature of scoring.

Our virtual central pathology service addresses these challenges by providing a standardized approach to staining analysis, which eliminates the variability associated with manual scoring. It uses image analysis to quantify expression levels, ensuring high quality data. Furthermore, IA data yields comparable results to pathologist interpretation, providing a reliable and reproducible method for assessing biomarker expression.

Materials & Methods

For this analysis, we identified well-documented outcomes from various studies, including NSCLC (Figure 2: A-C). The 22C3 IVD PD-L1 antibody (Figure 2: A), a validated biomarker, was used to assess PD-L1 expression in NSCLC tissue samples. The pathologist assigns a TPS for each sample, with the goal of providing a consistent way to interpret PD-L1 staining intensity and determine patient eligibility for treatment.

Our virtual central pathology service provides a standardized approach to PD-L1 staining analysis, which eliminates the intra-pathologist and inter-pathologist variability associated with manual scoring. It uses image analysis (IA) to quantify PD-L1 expression within the tumor compartment, ensuring high quality data. Furthermore, IA data yields comparable results to pathologist interpretation, providing a reliable and reproducible method for assessing PD-L1 expression.

Validation of a DKK1 RNA Scope chromogenic in situ hybridization assay

Figure 3 (without and with Macrophage Solution)

<table>
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</table>

Patient Enrollment Based on IA of Samples Stained with DKK1 RNAscope

Utilizing an appropriate IA solution eliminates the error associated with manual slide reads, providing truly reproducible, quantitative results, as evidenced by the high correlation coefficients (r = 0.900, p < 0.00001) and (r = 0.901, p < 0.00001) between IA and manual scoring.

Figure 3: A) DAB-conjugated PD-L1 stained NSCLC tissue (brown) without IA markups. B) The clinically validated PD-L1 (22C3) IA assay detected and quantified PD-L1 cellular expression within the tumor compartment as a pathologist support tool aids in patient selection and can ease the burden of pathologist scoring.

Figure 4: General Immuno-oncology (IO) multiplex panel (CD3, CD8, CD56, CD68, CD163, and PDL1) (Figure 4), Mersin, Turkey.

Phase II to Approval

- Probability of therapeutic successfully approved with and without the use of biomarkers:
  - With biomarkers: 83% to 94%
  - Without biomarkers: 55% to 25.9%

Background

Traditionally, manual immunohistochemistry has been the gold standard for diagnosing tumors based on specific antigen expression. However, this manual approach is prone to variability due to inter-pathologist differences in scoring criteria and interpretation of staining intensity. The introduction of digital pathology and image analysis has provided a standardized approach to staining analysis, which eliminates the variability associated with manual scoring. It uses image analysis to quantify expression levels, ensuring high quality data. Furthermore, IA data yields comparable results to pathologist interpretation, providing a reliable and reproducible method for assessing biomarker expression.

References