Test Interpretation and Use

PD-L1 22C3 immunohistochemistry is performed to help identify patients who may exhibit improved response to KEYTRUDA® (pembrolizumab) immunotherapy. PD-L1 22C3 IHC assessment and scoring is in accordance with criteria established for companion diagnostic indications as determined by the manufacturer. Tumor types that have been evaluated in clinical studies and have established scoring systems and expression cut-offs that may help predict response to therapy include Non-Small Cell Lung Cancer (NSCLC), Urothelial Carcinoma (UC), Triple Negative Breast Carcinoma (TNBC), Cervical Carcinoma, Esophageal Squamous Cell Carcinoma (ESCC), Head/Neck Squamous Cell Carcinoma (HNSCC), and Gastric or Gastroesophageal (GEJ) Adenocarcinoma. No established scoring systems or expression level cut-offs have been defined for other tumor types.

Methodology

Testing was performed and interpreted at Peninsula Pathologists Medical Group (PPMG), 383-Suite A E. Grand Ave., South San Francisco, CA 94080, Sourav Ray, M.D., Medical Director, CLIA # 05D1029487. Tissue sections were stained with anti–PD-L1 22C3 mouse monoclonal primary antibody, an FDA approved clone for KEYTRUDA® therapy, on the Leica Bond platform using the recommended visualization system. Validation studies showed a high degree of concordance with an outside reference lab, which performed anti– PD-L1 22C3 primary antibody testing utilizing the Envision FLEX visualization system on a Dako Autostainer Link 48 system. The test was validated with specimens that underwent EDTA decalcification; this assay should be interpreted with caution in specimens that have undergone decalcification with other reagents. This test has not been validated on alcohol-fixed, paraffin-embedded material. The immunoperoxidase stains were developed and their performance characteristics determined by PPMG. Some stains have not been cleared or approved by the USFDA. The FDA has determined that such clearance or approval is not necessary. These stains are used for clinical purposes. They should not be regarded as investigational or for research. Tissue controls perform as expected.

Limitations

PD-L1 22C3 assessment requires a minimum of 100 intact tumor cells for evaluation. Prolonged cold ischemic time (>1 hour), insufficient (<3 hours) or prolonged (>72 hours) formalin fixation, use of previously cut unstained sections stored for >6 months, or FFPE blocks >3 years old may impact analytical performance.