FOUNDATION MEDICINE®

Patient Name		Report Date
Date of Birth	Medical Facility	
Sex	Ordering Physician	
FMI Case #	Additional Recipient	Specimen Received
Medical Record #		Date of Collection
Specimen ID	Medical Facility #	Specimen Type
	Pathologist	

PD-L1 IMMUNOHISTOCHEMISTRY (IHC) ANALYSIS (Dako 22C3 pharmDx™)

TUMOR RESULT

- Combined Positive Score (CPS)

Results Criteria

- **PD-L1 EXPRESSION** (CPS ≥1)
- **NO PD-L1 EXPRESSION** (CPS <1)
- **INDETERMINATE** (test reliability compromised)

Electronically signed by: _____ Date: _____

PD-L1 Test Description

PD-L1 IHC 22C3 pharmDx™ is a qualitative immunohistochemical assay using Monoclonal Mouse Anti-PD-L1, Clone 22C3 intended for use in the detection of PD-L1 protein in formalin-fixed, paraffin-embedded (FFPE) non-small cell lung cancer (NSCLC), gastric or gastroesophageal junction (GEJ) adenocarcinoma, and cervical cancer tissues using EnVision FLEX visualization system on Autostainer Link 48. PD-L1 protein expression in gastric or GEJ adenocarcinoma and cervical cancer is determined by using Combined Positive Score (CPS), which is the number of PD-L1 staining cells (tumor cells, lymphocytes, macrophages) divided by the total number of viable tumor cells, multiplied by 100. PD-L1 IHC 22C3 pharmDx™ is indicated as an aid in identifying NSCLC, gastric or GEJ adenocarcinoma, and cervical cancer patients for treatment with KEYTRUDA® (pembrolizumab). For additional information, refer to the PD-L1 IHC 22C3 pharmDx™ Package Insert.

Clinical Significance of PD-L1 Protein Expression

Programmed death-ligand 1 (PD-L1), expressed on tumor cells and tumor-infiltrating immunocytes, mediates an immune checkpoint by binding to its receptors, programmed death 1 (PD-1) and B7-1, on activated T cells[1–4]. This checkpoint represses T-cell function and can therefore lead to evasion of anti-tumor immunity. On the basis of extensive clinical evidence in various tumor types, PD-L1-positive tumors are more likely to respond to PD-1/PD-L1 checkpoint inhibitors; however, patients with PD-L1-negative tumors may also derive benefit from these agents[4-14]. Checkpoint inhibitors such as the PD-1 antibodies nivolumab and pembrolizumab and the PD-L1 antibodies atezolizumab, avelumab, and durvalumab are FDA approved to treat various tumor types.

Note

Foundation Medicine, Inc. established performance characteristics for this assay per the requirements of the Clinical Laboratory Improvement Amendments (CLIA '88) and in accordance with College of American Pathologists (CAP) checklist requirements and guidance[15].

General Limitations

- Immunohistochemical analysis is dependent on the handling and processing of tissue prior to staining; false negative or inconsistent results may be a consequence of pre-analytic variations.
- As with any immunohistochemistry test, a negative result means that the antigen was not detected, not that the antigen was absent in the cells or tissue assayed.
- For additional information and comprehensive list of limitations, refer to the PD-L1 IHC 22C3 pharmDx™ Package Insert.

References

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