Histogenomics

Specimen information

PRF#: PRF50XXXX

Specimen ID: XXX

Specimen site: XXX

TRF Diagnosis: XXX

Selected Disease Ontology: XXX

% Tumor nucleated Cells: XXX %

PD-L1 Immunohistochemistry (IHC) analysis (Ventana SP142)

Tumor cell (TC) result: XXX

- TC Score (%): XXX

Tumor-infiltrating immune cell (IC) result: XXX

- IC Score (%): XXX

Results Criteria

- High positive (≥50% proportion of positive staining of at least 1+ intensity)
- Moderate positive (25-49% proportion of positive staining of at least 1+ intensity)
- Low positiv (1-24% proportion of positive staining of at least 1+ intensity)
- Negativ (<1% proportion of positive staining of at least 1+ intensity, or no staining)
- Indeterminate (test reliability compromised)

Electronically signed by: XXX

Date: XXX

AT/ONCO/1219/0025

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PD-L1 Test Description
VENTANA PD-L1 (SP142) Assay is a qualitative immunohistochemical assay using rabbit monoclonal anti-PD-L1 clone SP142 intended for use in the assessment of the PD-L1 protein in formalin-fxed, paraffn embedded (FFPE) urothelial carcinoma and nonsmall cell lung cancer (NSCLC) tissue stained with OptiView DAB IHC Detection Kit and OptiView Amplifcation Kit on a VENTANA BenchMark ULTRA instrument. Determination of PD-L1 status is indication-specifc, and evaluation is based on either the proportion of tumor area occupied by PD-L1 expressing tumor-infltrating immune cells (% IC) of any intensity or the percentage of PD-L1 expressing tumor cells (% TC) of any intensity.
Non-Small Cell Lung Carcinoma (NSCLC)
PD-L1 expression in ≥ 50% TC or ≥ 10% IC determined by VENTANA PD-L1 (SP142) Assay in NSCLC tissue may be associated with enhanced overall survival from TECENTRIQ® (atezolizumab).
Urothelial Carcinoma
PD-L1 expression in ≥ 5% IC determined by VENTANA PD-L1 (SP142) Assay in urothelial carcinoma tissue is associated with increased objective response rate (ORR) in a non-randomized study of TECENTRIQ® (atezolizumab).

This product is intended for in vitro diagnostic (IVD) use. For additional information, including information on other approved indications, refer to the VENTANA PD-L1 (SP142) Assay package insert.

Clinical Signifcance of PD-L1 Protein Expression
Programmed death-ligand 1 (PD-L1), expressed on tumor cells and tumor-infltrating 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[4–10]; however, patients with PD-L1-negative tumors may also derive beneft from these agents[11]. 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[12].

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, including information on other approved indications, refer to the VENTANA PD-L1 (SP142) Assay package insert.

References
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