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PATIENT REPORT

Patient Age/Sex: 12 hours Female

Specimen Collected: 13-Mar-24 12:47

PD-L1 22C3 IHC	**|Received: 13-Mar-24 12:47**		**Report/Verified: 13-Mar-24 12:48**
Procedure	**Result**	**Units**	**Reference Interval**
Adequacy of Specimen	Adequate		
PD-L1 Client Block ID	ABC 123		
PDL1 Tissue Source	Tissue		

PD-L1 22C3 Combined Positive Score	**|Received: 13-Mar-24 12:47**		**Report/Verified: 13-Mar-24 12:49**
Procedure	**Result**	**Units**	**Reference Interval**
Adequacy of Specimen	Adequate		
PD-L1 Client Block ID	ABC 123		
PDL1 Tissue Source	Tissue		
Combined Positive Score	11-20		
PDL1 22C3 IHC Result	Expression f1 i1		

PD-L1 22C3 IHC	**|Received: 13-Mar-24 12:47**		**Report/Verified: 13-Mar-24 12:49**
Procedure	**Result**	**Units**	**Reference Interval**
PDL1 Scoring Method	CPS		

Result Footnote

f1: PDL1 22C3 IHC Result

These results have been reviewed and approved by [redacted] Controls performed as expected.

Test Information

i1: PDL1 22C3 IHC Result

INTERPRETIVE INFORMATION: PDL1 22C3 Combined Positive Score

PD-L1 22C3 by IHC with interpretation is an FDA-approved 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) tissue using the EnVision FLEX visualization system on Autostainer Link 48 in gastric, esophageal, or GEJ adenocarcinomas, cervical carcinoma, esophageal squamous cell carcinoma, head and neck squamous cell carcinoma, and triple-negative breast cancer.

PD-L1 protein expression is determined by using combined positive score (CPS), which is the number of PD-L1 staining cells (tumor cells showing partial or complete linear membrane staining greater than or equal to 1+ plus lymphocytes and macrophages within tumor nests and adjacent supporting stroma, showing partial or complete linear membranous staining and/or cytoplasmic staining greater than or equal to 1+) divided by the total number of viable tumor cells, multiplied by 100. The table below summarizes how CPS is used to assess PD-L1 expression in certain tumor types.

Primary Tumor Type:
Gastric/Esophageal/GEJ Adenocarcinoma, Head/Neck Squamous Cell Carcinoma, Cervical Cancer
PD-L1 Expression Cutoff:

Test Information

i1: PDL1 22C3 IHC Result

CPS <1: No PD-L1 expression
CPS >=1: PD-L1 expression

Primary Tumor Type:
Triple-Negative Breast Cancer, Esophageal Squamous Cell Carcinoma
PD-L1 Expression Cutoff:
CPS <10: No PD-L1 expression
CPS >=10: PD-L1 expression

The specimen submitted for testing must contain at least 100 viable, invasive tumor cells to be considered adequate for evaluation. This assay is indicated as an aid in identifying gastric, esophageal, or GEJ adenocarcinoma, cervical carcinoma, esophageal squamous cell carcinoma, head and neck squamous cell carcinoma, and triple-negative breast cancer in patients considered for treatment with pembrolizumab (KEYTRUDA). Please refer to the full prescribing information for tumor-specific indications and PD-L1 expression level cutoff.

Submission of slides that have been oven baked is not recommended as staining may be affected by overbaking or prolonged time between baking and staining. The use of this assay on decalcified tissues has not been validated and is not recommended. Testing on specimens fixed in any fixative other than 10 percent neutral buffered formalin has not been validated and is not recommended.

Controls were run and performed as expected.