Medgenome Labs Ltd
Sy No 94/1C and 94/2, Tower-1, Veerasandra Village,
Attibele Hobli, Electronic City, Phase-1, Bangalore,
Karnataka, 560100.

PD-L1 (22C3 Dako PharmDx) - IHC Test Report

Patient Name	C. Nilmini Thenuwara	Order ID	1042108
Age / Gender	63 Years / Female	Sample ID	8690106
Physician	Dr. Prof Jayantha Balawardana	Collection Date	NA
Customer	MCC18718-Aegle Omics Private Limited	Sample Received Date	04-09-2024 03:30 PM
Report Date	12-09-2024	Report Status	Final

Lab/Biopsy No : MBI-4580-24 **UID :** AOMG011

Clinical Details : Endometrial biopsy - Adenocarcinoma

Specimen received : One block

Gross Examination : One block labelled as IL8568

Sample Adequacy : Adequate tumor cells (≥100 cells) are present : Yes

Test interpretation/Result:

IHC Markers	Microscopy
PD-L1 (22C3)	Tumor cell (TC) staining : 5% of tumor cells show membranous staining of weak to moderate intensity. Immune cells (IC) staining : 10%

Note:No definite CPS threshold cut-off available for Endometrial tumors. Kindly interpret the result with caution and correlate clinically.

Comments:

1. 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) tissue using EnVision FLEX visualization system on Autostainer Link 48.
2. PD-L1 protein expression is determined by using Combined positive score (CPS).
   CPS is the number of PDL1 staining cells (tumor cells, lymphocytes, macrophages) divided by the total number of viable tumor cells, multiplied by 100.
3. PDL1 expression (CPS ≥1) is used to inform patient eligibility for first line therapy with pembrolizumab (KEYTRUDA).
4. Recurrent/ metastatic head and neck squamous cell carcinoma [1]- Specimen should be considered to have PD-L1 expression if CPS ≥1.
5. Gastric or Gastroesophageal Junction (GEJ) Adenocarcinoma [2] : Specimen should be considered to have PD-L1 expression if CPS ≥1.
6. Cervical cancer [3] : The specimen should be considered to have PD-L1 expression if CPS ≥1.
7. Urothelial cancer [4] : The specimen should be considered to have PD-L1 expression if CPS ≥10.

Note:

System level Controls (internal & or external) run with the test are satisfactory. Reagents used are the companion diagnostic assay consisting of primary antibody PDL 1 clone 22C3 using EnVision FLEX visualization system on Autostainer Link 48. This assay has not been validated on decalcified tissue and result should be interpreted with caution given the likelihood of false negativity of decalcified specimen. Specimen should be processed by routine tissue processing method. Inappropriate fixation (nonformalin) and processing may give erroneous result.
The performance characteristics of this assay has been determined by MedGenome.
Performance characteristics refer to the analytical performance of the test.

Please correlate the block# given with that of its HPE report.

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References:

1. Bang, YJ., Kang, YK., Catenacci, D.V. et al. Pembrolizumab alone or in combination with chemotherapy as first-line therapy for patients with advanced gastric or gastroesophageal junction adenocarcinoma: results from the phase II nonrandomized KEYNOTE-059 study. Gastric Cancer 22, 828–837 (2019).
2. Balar AV, et al. First-line pembrolizumab in cisplatin-ineligible patients with locally advanced and unresectable or metastatic urothelial cancer (KEYNOTE-052): a multicentre, single-arm, phase 2 study. Lancet Oncol. 2017 Nov;18(11):1483-1492.
3. Burtness B, et al.Pembrolizumab alone or with chemotherapy versus cetuximab with chemotherapy for recurrent or metastatic squamous cell carcinoma of the head and neck (KEYNOTE-048): a randomised, open-label, phase 3 study. Lancet. 2019 Nov 23;394(10212):1915-1928.
4. Hyun Cheol Chung, et al. Efficacy and Safety of Pembrolizumab in Previously Treated Advanced Cervical Cancer: Results From the Phase II KEYNOTE- 158 Study Journal of Clinical Oncology 2019 37:17, 1470-1478.
5. FDA Approval Summary: Pembrolizumab for Recurrent Locally Advanced or Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma Expressing PDL-1. Lola Fasoyin-Aje et al. The Oncologist January 2019 vol. 24 no. 1 103-109.
6. Zhang T, Liu Q, Zhu Y, Zhang S, Peng Q, Strickland AL, Zheng W, Zhou F. PD-L1 Expression in Endometrial Serous Carcinoma and Its Prognostic Significance. Cancer Manag Res. 2021 Dec 14;13:9157-9165.

Enclosed : One block

Verified By
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*****End of Report*****

CONDITIONS OF LABORATORY TESTING AND REPORTING

Medgenome Labs Ltd, Bangalore, Karnataka, India

- Laboratory results should be used with other clinical information to determine a final diagnosis.
- In case of unexpected test results please contact the laboratory. We will investigate and repeat
- analysis if possible.The medical report must be viewed and reproduced as a whole
- This medical report is not intended for medico-legal purposes.
- The medical report is to be interpreted and used by medical
- personnel onlyAssays are performed and reported in accordance
- with the stated schedule.
- There may be circumstances beyond our control that delay results, e.g., invalid assay run.
- The results of a laboratory test are dependent on the quality of the sample as well as the assay
- procedure.A requested test may not be carried out if:
- Sample is insufficient or
- inappropriateSample quality is
- unsatisfactory
- Request for testing is withdrawn by the ordering doctor or patient

  There is discord between the labelling of the sample container and the name on the test requisition.For any query contact customer support : +91(0)8067154932/33
