Medgenome Labs Ltd
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Karnataka, 560100.

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

Patient Name	Pubudu Kodithuwakku	Order ID	1649979
Age / Gender	33 Years / Female	Sample ID	9785548
Physician	Dr. Mahendra Perera	Collection Date	NA
Customer	MCC18718-Aegle Omics Private Limited	Sample Received Date	21-02-2026 11:30 PM
Report Date	02-03-2026 07:05 PM	Report Status	Final

Lab/Biopsy No : MBI-850-26 **UID :** AOM324

Clinical Details : Case of Triple Negative Breast Cancer

Specimen received : One block

Gross Examination : One block labelled asBS-765-A3

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

Test interpretation/Result:

IHC Markers	Microscopy	CPS raw score	Combined Positive Score (CPS) cut-off
PD-L1 (22C3)	Predominantly immune cell staining seen adjacent to tumor. No definite tumor cell staining seen.	35	≥ 10

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).
3. CPS is the number of PDL1 staining cells (tumor cells, lymphocytes, macrophages) divided by the total number of viable tumor cells, multiplied by 100.
4. PDL1 expression (CPS ≥ 1) is used to inform patient eligibility for first line therapy with pembrolizumab (KEYTRUDA).
5. Recurrent/ metastatic head and neck squamous cell carcinoma [1]- Specimen should be considered to have PD-L1 expression if CPS ≥ 1.
6. Breast TNBC [2] : The specimen should be considered to have PD-L1 expression if CPS ≥ 10.
7. Oesophageal cancer [3] : The specimen should be considered to have PD-L1 expression if CPS ≥ 10.
8. Gastric or Gastroesophageal Junction (GEJ) Adenocarcinoma [4,5] : Specimen should be considered to have PD-L1 expression if CPS ≥ 1.
9. Urothelial cancer [6] : The specimen should be considered to have PD-L1 expression if CPS ≥ 10.
10. Cervical cancer [7] : The specimen should be considered to have PD-L1 expression if CPS ≥ 1.

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. 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.
2. Cortes J, Rugo H S, Cescon D W, et al. Pembrolizumab plus chemotherapy in advanced triple-negative breast cancer. New England Journal of Medicine. 2022; 387(3), 217–226.
3. Sun, Jong-Mu et al. Pembrolizumab plus chemotherapy versus chemotherapy alone for first-line treatment of advanced oesophageal cancer (KEYNOTE-590): a randomised, placebo-controlled, phase 3 study. The Lancet. 2021; 398: 759 - 771
4. 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.
5. 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).
6. 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.
7. 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.

Enclosed : One block

Verified By

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Approved 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 only
- Assays 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 inappropriate
- Sample 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