

# PD-L1 CTC Test

---

## Test Report

## Patient Information

|                      |   |
|----------------------|---|
| Requisition Number   |   |
| Patient Name         |   |
| ID Number            |   |
| Date of Birth        |   |
| Gender               | <input type="checkbox"/> M <input type="checkbox"/> F |
| Patient Phone Number |   |
| Patient E-mail       |   |
| Name of Lab          |   |
| Lab Phone Number     |   |
| Name of Physician    |   |
| Disease              |   |
| Date of Collection   |   |
| Date of Report       |   |

# Test Report

Name:

Date of Birth:

ID:

## Patient Test Result

|                                   |     |
|-----------------------------------|-----|
| CTCs Detected (Count)             | 4   |
| PD-L1 Positive CTCs (Count)       | 2   |
| Percentage of PD-L1 Positive CTCs | 50% |

## Comments

50% PD-L1 positive CTCs has been correlated with  $\geq 50\%$  PD-L1 expression by immunohistochemistry on tissue.

## Electronic Signatures

This test was developed and its performance characteristics determined by CellMax. Clinical decisions regarding care and treatment of patients should not be solely based on this test. Not all disease will be accurately detected. How this information is used to guide patient care is the responsibility of the physician.

Lab Supervisor Leon Chen \_\_\_\_\_

Date \_\_\_\_\_

Pathologist Manana Kvezereli-Javey, MD, PhD \_\_\_\_\_

Date \_\_\_\_\_

Copyright CellMax Life, 2016. All Rights Reserved

### About The Test

The CellMax PD-L1 CTC test is a non-invasive blood test specifically designed for the determination of cancer immunotherapy regimen eligibility. The CellMax Life PD-L1 CTC test is a cell-based liquid biopsy assay, conducted on the proprietary CMx biomimetic biochip platform® that sensitively captures circulating tumor cells (CTCs). The captured CTCs are gently eluted by a patented release agent for subsequent immunofluorescent staining with markers for CTC enumeration and quantification of PD-L1-expressing CTC fraction.

Test Limitations : PD-L1 CTC test is designed to detect CTCs of epithelial origin. The test utilizes tissue specific markers to determine the tissue(s) of origin. CTC counts can be affected by various types of treatment regimens including chemotherapy and radiation. CellMax PD-L1 CTC test requires at least 2 CTC counts for PD-L1 expression evaluation. Fewer than 2 CTC count yields inconclusive results or warrants repeated testing.

### Indications For Ordering

The PD-L1 CTC test is appropriate for patients who have been diagnosed with lung cancer. The test is intended to be used at the time of diagnosis and during the disease course.

### Important Notice

Utilization of the information provided is the sole responsibility of the treating physician. The test is not intended to replace any standard of care testing modalities, but rather to aid them for a better assessment of a patient's cancer during the disease course.

## Disclaimer

This test was developed and its performance characteristics determined by CellMax Life, a clinical laboratory accredited by the College of American Pathologists (CAP) to perform testing. Clinical decisions regarding care and treatment of patients should not be solely based on this test. How this information is used to guide patient care is the responsibility of the physician. This test is used for clinical purposes, and should not be regarded as investigational or for research.

The CellMax Life test is designed to assist health care practitioners in providing additional clinical information. The information therein should not be relied upon as being complete or accurate, nor should it be considered as inclusive of all proper treatments or methods of care or as a statement of the standard of care. Medical knowledge develops rapidly and new evidence may emerge between the time information is developed to when it is published or read.

CellMax Life provides this information on an "as is" basis, and makes no warranty, express or implied, regarding the information. CellMax specifically disclaims any warranties of merchantability or fitness for a particular use or purpose. CellMax Life assumes no responsibility for any injury or damage to persons or property arising out of or related to any use of this information or for any errors or omissions.

The information herein is not continually updated and may not reflect the most recent evidence. The information addresses only the topics specifically identified therein and is not applicable to other interventions, diseases, or stages of diseases. This information does not mandate any particular course of medical care. Further, the information is not intended to substitute for the independent professional judgment of the treating physician, as the information does not account for individual variation among customers. CellMax Life provides this information on an "as is" basis, and makes no warranty, express or implied, regarding the information. CellMax Life specifically disclaims any warranties of merchantability or fitness for a particular use or purpose. CellMax Life assumes no responsibility for any injury or damage to persons or property arising out of or related to any use of this information or for any errors or omissions.

## References

1. Anantharaman, A., Friedlander, T., Lu, D., Krupa, R., Premasekharan, G., Hough, J., Edwards, M., Paz, R., Lindquist, K., Graf, R., Jendrisak, A., Louw, J., Dugan, L., Baird, S., Wang, Y., Dittamore, R. and Paris, P.L., 2016. Programmed death-ligand 1 (PD-L1) characterization of circulating tumor cells (CTCs) in muscle invasive and metastatic bladder cancer patients. *BMC Cancer*. 16, 744.
2. Ilić, M., Szafer-Glusman, E., Hofman, V., Chamorey, E., Lalvée, S., Selva, E., Leroy, S., Marquette, C.H., Kowanetz, M., Hedge, P., Punnoose, E. and Hofman, P., 2017. Detection of PD-L1 in circulating tumor cells and white blood cells from patients with advanced non-small-cell lung cancer. *Annals of Oncology*. mdx636-mdx636.
3. Mazel, M., Jacot, W., Pantel, K., Bartkowiak, K., Topart, D., Cayrefourcq, L., Rossille, D., Maudelonde, T., Fest, T. and Alix-Panabières, C., 2015. Frequent expression of PD-L1 on circulating breast cancer cells. *Molecular Oncology*. 9, 1773-1782.
4. Nicolazzo, C., Raimondi, C., Mancini, M., Caponnetto, S., Gradilone, A., Gandini, O., Mastromartino, M., del Bene, G., Prete, A., Longo, F., Cortesi, E. and Gazzaniga, P., 2016. Monitoring PD-L1 positive circulating tumor cells in non-small cell lung cancer patients treated with the PD-1 inhibitor Nivolumab. *Scientific Reports*. 6, 31726.
5. Oliveira-Costa, J.P., de Carvalho, A.F., da Silveira, G.G., Amaya, P., Wu, Y., Park, K.-J.J., Gigliola, M.P., Lustberg, M., Buim, M.E.C., Ferreira, E.N., Kowalski, L.P., Chalmers, J.J., Soares, F.A., Carraro, D.M. and Ribeiro-Silva, A., 2015. Gene expression patterns through oral squamous cell carcinoma development: PD-L1 expression in primary tumor and circulating tumor cells. *Oncotarget*. 6, 20902-20920.
6. Satelli, A., Bath, I.S., Brownlee, Z., Rojas, C., Meng, Q.H., Kopetz, S. and Li, S., 2016. Potential role of nuclear PD-L1 expression in cell-surface vimentin positive circulating tumor cells as a prognostic marker in cancer patients. *Sci Rep*. 6, 28910.
7. Zeng, Z., Shi, F., Zhou, L., Zhang, M.-N., Chen, Y., Chang, X.-J., Lu, Y.-Y., Bai, W.-L., Qu, J.-H., Wang, C.-P., Wang, H., Lou, M., Wang, F.-S., Lv, J.-Y. and Yang, Y.-P., 2011. Upregulation of Circulating PD-L1/PD-1 Is Associated with Poor Post-Cryoablation Prognosis in Patients with HBV-Related Hepatocellular Carcinoma. *PLOS ONE*. 6, e23621.

Simple Blood Test. Real Time Protection.



CellMax Life (USA)  
1271 Oakmead Parkway  
Sunnyvale, CA 94085  
USA



CellMax Life (ASIA)  
18F.-1, No.3, Park St.  
Nangang Dist., Taipei City 11503,  
Taiwan (R.O.C.)



[www.cellmaxlife.com](http://www.cellmaxlife.com)  
[info@cellmaxlife.com](mailto:info@cellmaxlife.com)