Evaluation of the PD-L1 22C3 clone using the Leica Bond-III stainer to effectively identify lung cancer patients who may be eligible for anti-PD-L1 immunotherapy

***Thembelihle Mayeza*[1], *Sharlene Naidoo*[1], *Deepna Govind Lakhoo*[1,2]**

[1] *Pathology Division, National Institute for Occupational Health, National Health Laboratory Service, Johannesburg, South Africa*

[2] *Department of Anatomical Pathology, School of Pathology, Faculty of Health Sciences, University of the Witwatersrand, Parktown, South Africa*

Correspondence**:** *lihlemayeza19@gmail.com*

Abstract:

Introduction

The PD-L1 IHC 22C3 pharmDx test is the only clinical trial companion diagnostic test approved for the identification of patients with non-small cell lung cancer (NSCLC) for treatment with Keytruda (pembrolizumab). PD-L1 IHC 22C3 has been optimized for use with the Envision FLEX visualization system on the Dako Auto stainer Link 48 (ASL48) IHC platform. A constraint faced by South African public sector laboratories using this test is the restricted availability of the Dako ASL48 platform and the high cost of the PD-L1 22C3 pharmDx kit.

Objective

To evaluate a laboratory developed test (LDT) for PD-L1 22C3 expression in NSCLC formalin-fixed paraffin-embedded (FFPE) biopsies by comparing the results obtained on the Bond-III Leica Biosystems and the gold standard ASL48 platforms.

Methods

The study comprised 26 FFPE samples from patients diagnosed in 2022 with NSCLC at the Department of Pathology, NIOH. Sample selection criteria included tissue samples that contained at least 100 viable tumour cells on examination of the Haematoxylin and eosin sections. PD-L1 immunohistochemistry was performed on the ASL48 and Leica Bond III platforms. PD-L1 expression was evaluated using the tumour proportion score (TPS) by two pathologists. Data was analysed using STATA version 16 (Stata Corp, College, TX, USA).

Results and Discussion

The Bond II stainer showed an average sensitivity and specificity of 81.3% and 100% and negative predictive and positive predictive values of 92% and 100% respectively. Whilst the staining intensity of the LDT appeared weaker, the results remained reliable and consistent to the Dako ASL48 platform.

Conclusion

The Bond-III platform provides a comparable and cost effective alternative for analysing PD-L1 expression with the PD-L1 22C3 pharmDx test. The study presents opportunities to develop the assay on other immunohistochemistry platforms allowing public sector laboratories with diverse IHC platforms to provide PD-L1 screening as part of their diagnostic services.