PROLIFERATING CELL NUCLEAR ANTIGEN ANTIBODY TESTING – GETTING THEM ALL

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Proliferating cell nuclear antigen antibody (PCNA) is associated with systemic lupus erythematosus (SLE) and characterises a cohort of patients at risk of renal or central nervous system involvement. The antibody has also been reported in patients with hepatitis B and C virus infection. It has a pleomorphic nuclear cell cycle dependant pattern on antinuclear antibody (ANA) testing by indirect immunofluorescence (IFA).

In this laboratory PCNA has been historically reported from the IFA pattern on Hep2000 cells (Immuno Concepts, USA) and not confirmed on a secondary test.

An audit of PCNA pattern reported from ANA testing and incidental characterisation by immunoblot was undertaken to determine the frequency of PCNA detected. Over 4 years 34 PCNA results were reported. Clinical details provided included SLE, joint pain and acute hepatitis.

Extractable nuclear antigen antibody characterisation by immunoblot incidentally identified a further 20 samples with PCNA not reported on ANA. ANA patterns included speckled, homogeneous and nucleolar. Clinical details in this group also included SLE and joint pain.

This investigation demonstrates that IFA testing alone for PCNA may miss clinically relevant cases due to a strong dominant ANA pattern. Clinical characteristics and correlation with IFA is required to validate the immunoblot PCNA result.

ANALYTICAL COMPARISON OF A PD-L1 22C3 ANTIBODY LABORATORY-DEVELOPED TEST (LDT) PROTOCOL ON THE BENCHMARK XT AND PD-L1 IHC 22C3 PHARMDX: ANALYSIS OF PAN-TUMOUR AND OESOPHAGEAL CANCER SAMPLES

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PD-L1 IHC 22C3 pharmDx is an FDA-approved companion diagnostic to pembrolizumab designed for use on Autostainer Link 48. We compared our PD-L1 22C3 antibody-based LDT¹ on BenchMark XT with PD-L1 IHC 22C3 pharmDx. Head and neck squamous cell carcinoma (HNSCC), urothelial carcinoma (UC), and oesophageal SCC (ESCC) tumour specimens were stained with 22C3 antibody, scored using the LDT on BenchMark XT, and compared with PD-L1 IHC 22C3 pharmDx. PD-L1 was measured using combined positive score (CPS) and standard cutoffs (HNSCC, ≥ 1 ; UC, ≥ 10 ; ESCC, ≥ 10). 327 samples were evaluated (HNSCC, $n=126$; UC, $n=121$; ESCC, $n=80$). Pan-tumour intraclass correlation coefficient (ICC) of

PD-L1 CPS as a continuous variable was 0.96 (95% CI, 0.95–0.97); Spearman correlation was 0.95. For ESCC, ICC was 0.92 (95% CI, 0.88–0.95); Spearman correlation was 0.89. Interpretation of PD-L1 status (CPS ≥ 10) for ESCC using the two assays resulted in NPA of 92% (95% CI, 80–97), PPA of 88% (95% CI, 74–95), and OPA of 90% (95% CI, 81–95). 22C3 antibody-based LDT on BenchMark XT demonstrated high concordance with PD-L1 IHC 22C3 pharmDx. These findings suggest comparability of PD-L1 IHC 22C3 pharmDx with an LDT based on the 22C3 antibody across several tumour types.

Reference

1. Neuman T, London M, Kania-Almog J, *et al.* A harmonization study for the use of 22C3 PD-L1 immunohistochemical staining on Ventana's platform. *J Thorac Oncol* 2016; 11: 1863–8.

CONTRIBUTION OF TUMOUR AND IMMUNE CELLS TO PD-L1 AS A PREDICTIVE BIOMARKER IN METASTATIC TRIPLE-NEGATIVE BREAST CANCER (MTNBC): ANALYSIS FROM KEYNOTE-119

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Background: We evaluated whether PD-L1 expression on tumour cells contributes to PD-L1 as a predictive biomarker for pembrolizumab in mTNBC.

Methods: Patients with mTNBC received pembrolizumab or chemotherapy. PD-L1 expression (PD-L1 IHC 22C3 pharmDx) was quantified per tumour proportion score (TPS; percentage of PD-L1-expressing tumour cells [partial or complete membrane staining] relative to total number of tumour cells) and combined positive score (CPS; number of PD-L1-staining cells [tumour cells, lymphocytes, macrophages] divided by total number of viable tumour cells, multiplied by 100). Quantitative immune cell