QF-Pro®

The spatial biology to predict response to anti-PD-1/PD-L1 therapies.

QF-Pro® predicts patient response to anti-PD-1/PD-L1 therapies.

Published in the Journal of Clinical Oncology, HAWK Biosystems have validated a QF-Pro® assay for the determination of PD-1/PD-L1 interaction state (functional checkpoint engagement) in non-small cell lung cancer (NSCLC). In this study, PD-1/PD-L1 interaction state, but not PD-L1 expression, was highly predictive of patient outcome and response to immune checkpoint blockade treatments[1].

QF-Pro® identified that patients with a high PD-1/PD-L1 interaction state in their biopsy samples responded positively to immune checkpoint blockade, irrespective PD-L1 expression. This accounts for almost 25% of all NSCLC patients who would, therefore, not routinely be selected for therapy despite responding.

PD-L1 Expression Levels fail to stratify patients for treatment.

Our QF-Pro® analyses were compared to classical PD-L1 expression scores (TPS) determined by IHC. PD-L1 expression alone did not predict response to immune checkpoint inhibitors. In this study, 22.5% of NSCLC patients with high PD-L1 expression but low PD-1/PD-L1 interaction states failed to respond to therapies. PD-L1 TPS assays lack specificity and quantification, leading to up to 20% of patients receiving different treatments due to operator variability[2].

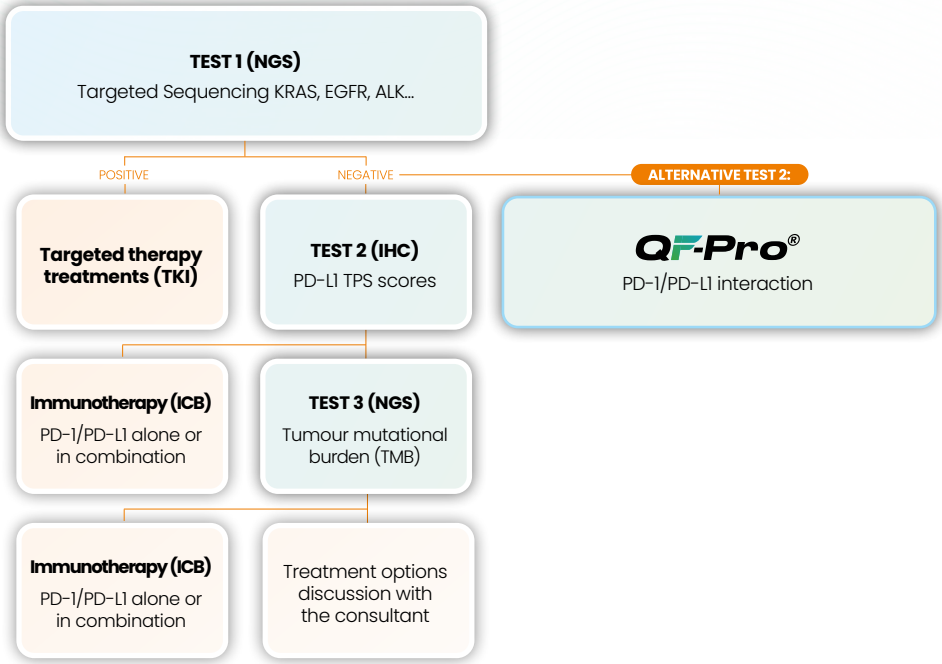
Tumour Mutational Burden is an expensive and poor predictor of patient response.

The analysis of patients' tumour mutational burden (TMB) by next-generation sequenc ing (NGS), FDA-approved for immunotherapy stratification, lacks robustness and pre dictive value. In NSCLC, 62% of responders may fall below the FDA threshold, while 19% of non-responders surpass it3. Statistical analyses for FDA approval are criticised, and NGS costs vary. TMB is a surrogate biomarker, costly, and not precise. QF-Pro® offers functional engagement analysis of PD-1/PD-L1, proving more cost-effective and targeting prescribed drugs directly.

HAWK Biosystems

Where does QF-Pro® enter the clinical workflow?

Being a modified immunofluorescence-based assay (akin to regular immunohistochemistry assays), QF-Pro® integrates smoothly into NSCLC clinical workflows. Current workflows begin with NGS-based assays targeting predictive biomarkers such as KRAS mutations. These patients receive targeted therapies, while negative ones undergo PD-L1 IHC assays for ICI therapy. QF-Pro® replaces PD-L1 and TMB analyses, providing accurate PD-1/PD-L1 interaction state. Our data demonstrate the ability of QF-Pro® to correctly stratify patients for ICI therapy, especially as a first-line treatment.



Note to Insurers:

The current PD-1/PD-L1 QF-Pro® assay is published in the Journal of Clinical Oncology and validated by the wider scientific community. The adoption of QF-Pro® into clinical workflows can match patients to the correct ICI therapies at the correct time, reducing healthcare costs, burdens and future hospitalisations. In most cases, patients receive ICI therapies under compassionate care schemes, the matching of these patients to the correct drugs reduces the need for this costly approach to prescribing therapies.

[i] Lissete Sánchez-Magraner et al., Functional Engagement of the PD-1/PD-L1 Complex but Not PD-L1 Expression Is Highly Predictive of Patient Response to Immunotherapy in Non–Small-Cell Lung Cancer. Journal of Clinical Oncology. 2023

[ii] Hans Brunnström et al., PD-L1 immunohistochemistry in clinical diagnostics of lung cancer: inter-pathologist variability is higher than assay variability. Modern Pathology. 2017.

[iii] Gurjao Carino., et al., Is tumor mutational burden predictive of response to immunotherapy? eLife. 2023.

[iv] Li WQ et al., Cost-effectiveness of programmed cell death ligand 1 testing and tumor mutational burden testing of immune checkpoint inhibitors for advanced non-small cell lung cancer. Chin Med J (Engl). 2020.