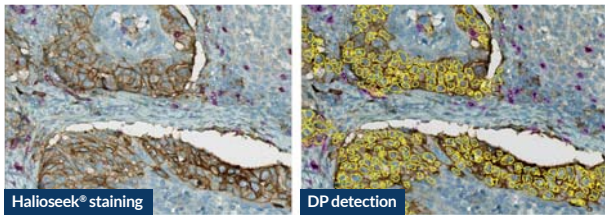
HALIOSEEK® PD-L1/CD8

Data presented at SITC 2017

Halioseek® PD-L1/CD8 is a standardized dual-staining IVD assay which, in addition to PD-L1 detection, provides critical information on the tumor immune infiltrate through the detection of CD8+ cells on the same tissue section. Halioseek® PD-L1/CD8 includes a Digital Pathology (DP) analysis module to determine PD-L1+ and CD8+ cell density as well as the proximity between these cell types.

HALIOSEEK® PD-L1/CD8 DIGITAL PATHOLOGY TOOL PERFORMANCE

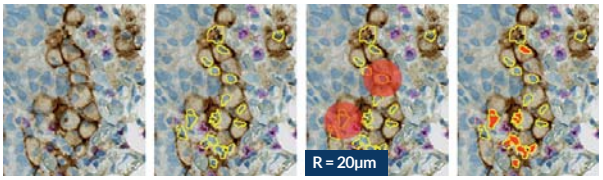
CD8+ and PD-L1+ cell detection



PD-L1+ cell nucleus detected by Halioseek® software

CD8+ cell detected by Halioseek® software

Proximity index calculation between CD8+ and PD-L1+ cells

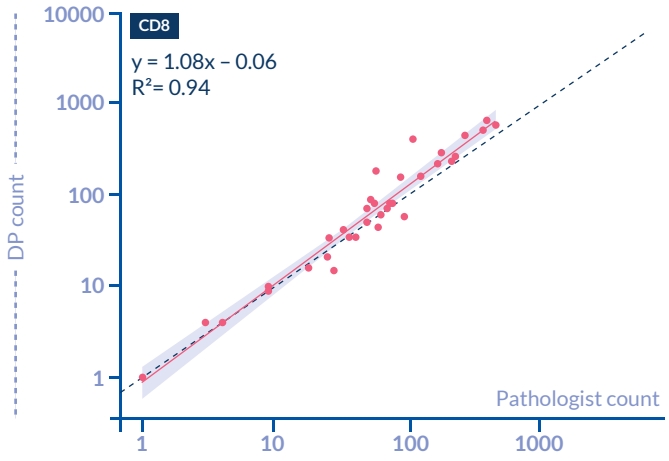


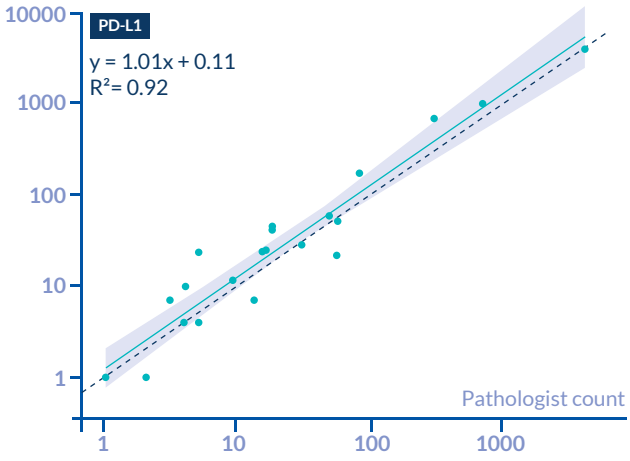
20µm radius circles surrounding PD-L1+ cells

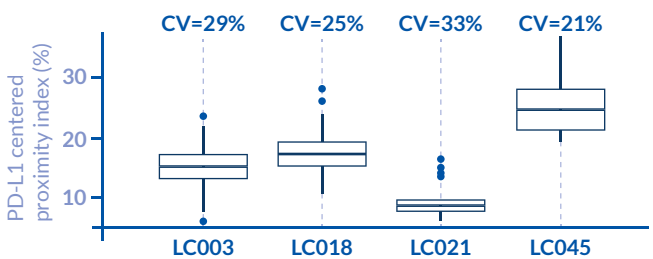
PD-L1+ cell with at least 1 CD8+ cell at less than 20µm

Detection Accuracy

34 zones from 25 NSCLC samples (CD8) and 22 zones from 11 NSCLC samples (PD-L1) were analyzed: pathologist absolute cell count of positive cells is highly correlated to DP cell count for both CD8 and PD-L1.







Precision of the proximity index

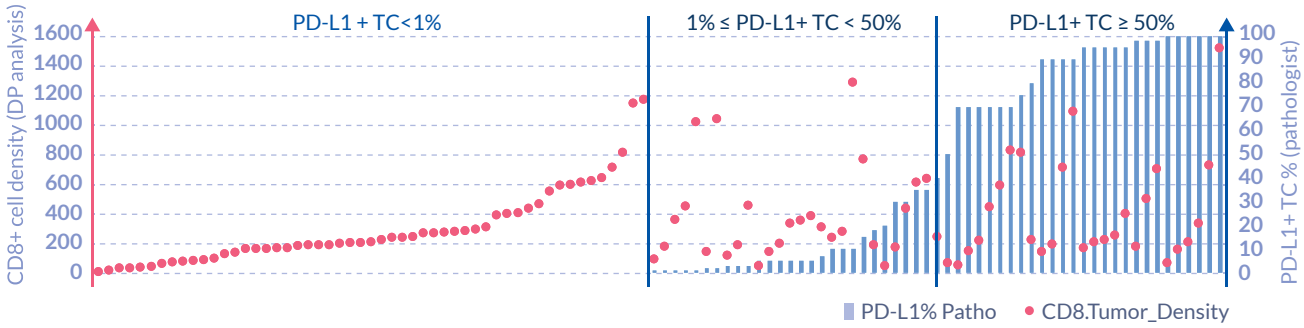
21 to 28 consecutive slides from 4 NSCLC samples were stained across 4 IHC runs with 3 Halioseek® antibody batches, 3 revelation kit batches on 2 Benchmark XT instruments.

LC003	LC018	LC021	LC045	
329	407	178	316	Mean CD8 density (cells/mm²)
710	313	1945	83	Mean PD-L1 density (cells/mm²)

SAMPLES STRATIFICATION WITH DIGITAL PATHOLOGY OUTPUTS

The distribution of PD-L1+ TC % and CD8+ cell densities across 108 NSCLC samples.

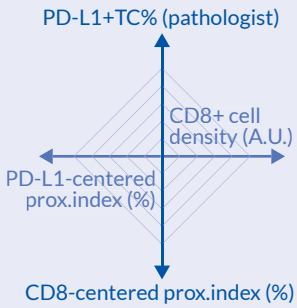
PD-L1+ TC % was assessed by pathologists. CD8+ cell density within the tumor area was determined by DP. Different T cell infiltration levels are observed for NSCLC samples with the same PD-L1 status.

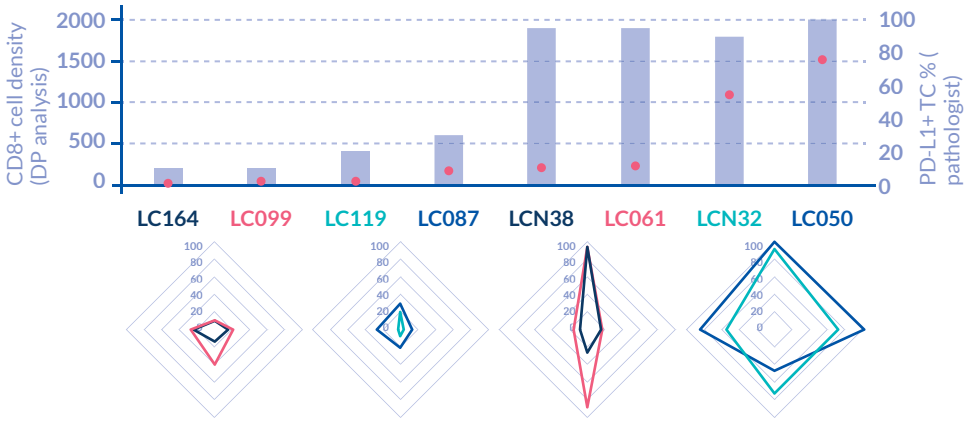


Examples of distinct proximity indexes for samples with similar PD-L1 and CD8 levels:

proximity indexes could allow further stratification of patients.

Tumor spatial architecture is examined through proximity indexes which may be clinically relevant.





CONCLUSION

Halioseek® PD-L1/CD8 is a new robust IVD assay leveraging the advantages of DP to combine tumor-infiltrating lymphocytes (TILs) and PD-L1 quantification within the tumor microenvironment.
Halioseek® PD-L1/CD8 could have a higher predictive performance than existing IVD tests and could fill a major gap in the management of ICI administration. In a next step we intend to investigate the predictive value of the assay on samples from ICI treated patients.

Halioseek® PD-L1/CD8 is available as a CE-IVD assay and as an RUO solution in the Rest of The World.*
**intended for Research Use Only. Not for use in diagnostic procedures.*

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