CD8-  CD8+

Type I: Concordant

Halioseek® AACR 2017
SITC 2017
≥50% [95% CI]
OA 50% cut-off

Comparison to Lab routine PD-L1
[95% CI] [83.5 - 96.7]
OA 1% cut-off

Halioseek.com
92.4

Halioseek® PD-L1 assay

CD8+ density (cells/mm²)

0 1000
200
600
25

0 25 50 75 100
PD−L1+ TC

Halioseek® PD-L1/CD8

The dual staining of Halioseek® allows simultaneous evaluation of PD-L1+ and CD8+ cells on the same tissue section.

Halioseek® PD-L1 staining allows accurate detection of positive tumor cells in NSCLC and is equivalent to other PD-L1 IVD assays.


Halioseek® provides complementary characterization of the tumor microenvironment without requiring additional precious tumor samples.

The assay also includes a Digital Pathology (DP) analysis module to determine CD8+ cell density and a proximity index between CD8+ and PD-L1+ cells.

Materials & Methods
Two multi-centric studies including 5 laboratories were performed in order to:

1) Further demonstrate the inter-laboratory reproducibility of the Halioseek® assay
2) Compare Halioseek® results to routine PD-L1 IHC results
3) Explore Halioseek® Analyzer DP tools to further characterize NSCLC samples

Study 1: Slides containing sections from 10 NSCLC FFPE blocks were sent to 5 independent laboratories for Halioseek® testing. PD-L1 staining was analyzed by each lab. Slated slides were returned to Halioseek® measured by another pathologist and analyzed using digital pathology tools.

Comparison with SP263 assay
High overall agreement with Ventana SP263 assay was observed in a study including n = 216 NSCLC samples (biopsies and resections).

Digital pathology: Halioseek® Analyzer

Halo dx

Concordance
1% cut-off 50% cut-off
Pathologists from each Lab 94% (47/50) 90% (45/50)
Pathologist from Central Lab 100% (50/50) 94% (47/50)

Reproducible results were obtained using Halioseek® assay in 5 independent laboratories (n=50) Consistency is even higher when the same pathologist analyzed all the slides (right).

Conclusion:
Halioseek® is a robust and reproducible assay leveraging the advantages of DP to combine TILs and PD-L1 assessment from the same slide.

Halioseek® is equivalent to PD-L1 routine tests from independent laboratories in a clinical setting (OA ≥ 92%).

The predictive performance of Halioseek® for the response to ICI needs to be further investigated in clinical studies.

See also posters
AACR 2017 (ST. 510)
SITC 2017 (P72)