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MSD

PINPOINT

PD-L1 TESTING IN HNSCC

OVERVIEW OF PD-L1 TESTING[1]

Antibody	28-8	22C3	SP263*	SP142*
Instrument and detection systems required	Dako Autostainer Link 48 EnVision FLEX visualization system	Dako Autostainer Link 48 EnVision FLEX visualization system	Ventana BenchMark Ultra OptiView DAB IHC Detection Kit	Ventana BenchMark Ultra OptiView DAB IHC Detection Kit and OptiView Amplification Kit
Product for which assay was validated	nivolumab	pembrolizumab	durvalumab▼	atezolizumab▼

* The SP263 and SP142 Ventana Assays have not been commercially validated by the manufacturer for this tissue/tumour (HNSCC) and the associated products are also not indicated for the treatment of HNSCC.

CONCORDANCE BETWEEN ASSAYS BY SCORING ALGORITHM AND CUTOFFS

1 SCOTT *ET AL.* 2018

- All four assays (28-8, 22C3, SP142, SP263) were tested[2]
- SP263, 22C3 and 28-8 assays showed good analytical correlation for TC staining (Spearman's rank correlation coefficient 0.75–0.83)[2]
- Correlation was lower for IC staining (Spearman's rank correlation coefficient 0.66–0.77)[2]

Assay agreement with VENTANA SP263 at CPS ≥12

Cut-off (%)	PD-L1 IHC pharmDx 22C3			PD-L1 IHC pharmDx 28-8			VENTANA PD-L1 SP142		
	OPA	NPA	PPA	OPA	NPA	PPA	OPA	NPA	PPA
CPS ≥1	75	93	68	83	96	78	69	99	57

Adapted from Scott *et al.* 2018.[2]

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CONCORDANCE BETWEEN ASSAYS BY SCORING ALGORITHM AND CUTOFFS *(continued)*

2 CALDERON *ET AL.* 2019

- Two assays were tested, SP263 and 22C3[3]

PD-L1 positivity for two assays using CPS ≥1 in different tissues[3]

	Ventana SP263	Dako 22C3
Score	**n (%)**	**n (%)**
Overall (n=38)	36 (94.7)	32 (84.2)
Oral cavity* (n=20)	19 (95)	18 (90)
Oropharynx HPV+ (n=13)	12 (92.3)	10 (76.9)
Oropharynx HPV- (n=1)	1 (100)	1 (100)
Larynx (n=4)	4 (100)	3 (75)

Adapted from Calderon *et al.* 2019.[3]
* One case was positive with Ventana SP263 antibody and completely negative with Dako 22C3 antibody.

3 DE RUITER *ET AL.* 2019

- Two assays were tested: SP263 on the Ventana Benchmark Ultra, 22C3 on the Dako Link 48 and and 22C3 as an LDT on the Ventana Benchmark Ultra[4]

PD-L1 positivity in a cohort of 147 HNSCC patients using TPS and CPS[4]

TPS (%)	SP263	22C3-Dako	22C3-LDT
≥50%	7 (4.8%)	1 (0.7%)	5 (3.4%)

CPS (%)	SP263	22C3-Dako	22C3-LDT
≥1–20%	110 (74.8%)	66 (44.9%)	87 (59.2%)
>20%	18 (12.2%)	1 (0.7%)	7 (4.8%)

Adapted from de Ruiter *et al.* 2019.[4]
> PD-L1 positivity in the HNSCC patient cohort was low when using a TPS cut-off of ≥50%[4]
> Overall, concordance between the different staining assays was moderate for TPS (ICC=0.70) as well as for CPS (ICC=0.53)[4]

SUMMARY

There is a poorer agreement of PD-L1 assays in HNSCC than for other indications[2]

FURTHER INFORMATION

One laboratory-developed test (LDT) was tested, showing moderate concordance with the other tests[4]

REFERENCES

1. Ionescu DN *et al. Curr Oncol.* 2018; 25(3): e209–e216.
2. Scott M *et al.* Presented at ESMO 2018, Abstract P1051PD.
3. Calderon MR *et al.* Presented at ECP 2019, PS-03-019.
4. de Ruiter EJ *et al.* Presented at ECP 2019, PS-03-006.

ABBREVIATIONS

CPS, combined positive score
IC, immune cells
HNSCC, Head and neck squamous cell carcinoma
HPV, Human papillomavirus
LDT, laboratory- developed test
NPA, negative percent agreement
OPA, overall percent agreement
PD-L1, programmed death ligand-1
PPA, positive percent agreement
TC, tumour cells
TPS, tumour proportion score

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