



Checkpoint Inhibitor Companion and Complementary Diagnostic

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available at NeoGenomics

Cancer Type	Therapy	Test	Test Required per Drug Label?	Test Cut-Off
Non-Small Cell Lung Carcinoma (NSCLC)	Keytruda® (pembrolizumab)	PD-L1 IHC 22C3 pharmDx	yes	TPS ≥1%
	Opdivo® (nivolumab)	PD-L1 IHC 28-8 pharmDx	optional	≥1% TC
	Tecentriq® (atezolizumab)	Ventana PD-L1 SP142 Assay (IHC)	optional	≥50% TC OR ≥10% IC
Breast, Triple-Negative (TNBC)	Tecentriq® (atezolizumab)	Ventana PD-L1 SP142 Assay (IHC)	yes	≥1% IC
	Keytruda® (pembrolizumab)	Mismatch Repair (MMR) IHC or Microsatellite Instability (MSI) lab-developed test OK	yes	MMR-deficient or MSI-high
Colorectal Cancer	Keytruda® (pembrolizumab)	Mismatch Repair (MMR) IHC or Microsatellite Instability (MSI) lab-developed test OK	yes	MMR-deficient or MSI-high
	Opdivo® (nivolumab)	PD-L1 IHC 22C3 pharmDx	yes	CPS ≥1
Gastric/GEA, Cervical	Keytruda® (pembrolizumab)	PD-L1 IHC 22C3 pharmDx	yes	CPS ≥10
Esophageal (ESCC)	Keytruda® (pembrolizumab)	PD-L1 IHC 22C3 pharmDx	yes	CPS ≥1
	Opdivo® (nivolumab)	PD-L1 IHC 28-8 pharmDx*	optional	≥1% TC
	Tecentriq® (atezolizumab)	Ventana PD-L1 (SP142) Assay (IHC)	yes	≥5% IC
Head & Neck (HNSCC)	Imfinzi® (durvalumab)	Ventana PD-L1 (SP263) Assay (IHC)	optional	≥25% TC with membrane staining OR ICP>1% and IC≥25% OR ICP=1% and IC=100%
	Opdivo® (nivolumab)	PD-L1 IHC 28-8 pharmDx*	optional	≥1% TC
	Keytruda® (pembrolizumab)	PD-L1 IHC 22C3 pharmDx	yes	CPS ≥10
Urothelial Carcinoma (UC)	Imfinzi® (durvalumab)	Ventana PD-L1 (SP263) Assay (IHC)	optional	≥25% TC with membrane staining OR ICP>1% and IC≥25% OR ICP=1% and IC=100%
	Opdivo® (nivolumab)	PD-L1 IHC 28-8 pharmDx*	optional	≥1% TC
Urothelial Carcinoma (UC)	Keytruda® (pembrolizumab)	PD-L1 IHC 22C3 pharmDx	yes	CPS ≥10

**ease refer to full drug prescribing information to verify approval status
or your patient's case. There may be indications unrelated to testing.**

B-8 pharmDx testing on HNSCC and UC tissues uses controls of non-matched tissue types which is a variation from the kit instructions. NSCLC controls are tissue-matched per kit instructions.

References

1. IHC 22C3 pharmDx [package insert]. Carpinteria, CA, Dako; P03951_11/5K00621. 2019.08
2. PD-L1 IHC 28-8 pharmDx [package insert]. Carpinteria, CA, Dako; P04163_05/5K00521/2017.09
3. VENTANA PD-L1 (SP142) Assay [package insert]. Tucson, AZ, Ventana Medical Systems, Inc.; 1017981US Rev B; 2019-03-08
4. PD-L1 SP263 Assay [package insert]. Tucson, AZ, Ventana Medical Systems, Inc.; 1014737US Rev A; 2017-04-21

Abbreviations

- CPS = Combined Positive Score
- IC = Percent Positive Tumor-Associated Immune Cells
- ICP = Percent of Tumor Area with Immune Cells Present
- TC = Positive Tumor Cells
- TPS = Tumor Proportion Score