

Biomarker Testing for Checkpoint Inhibitors

KEYTRUDA[®] (pembrolizumab) <i>anti-PD-1</i>	OPDIVO[®] (nivolumab) <i>anti-PD-1</i>	TECENTRIQ[®] (atezolizumab) <i>anti-PD-L1</i>	BAVENCIO[®] (avelumab) <i>anti-PD-L1</i>	IMFINZI[™] (durvalumab) <i>anti-PD-L1</i>
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Cervical Cancer	FDA approved with PD-L1 22C3^Δ ≥1 CPS				
Colorectal Carcinoma	dMMR or MSI-H	dMMR or MSI-H			
Gastric Carcinoma	FDA approved with PD-L1 22C3^Δ ≥1 CPS				
Head & Neck Squamous Cell CA	FDA approved; no testing required	FDA approved with PD-L1 28-8[†] ≥1% TPS			
Hepatocellular Carcinoma		FDA approved; no testing required			
Hodgkin Lymphoma	FDA approved; no testing required	FDA approved; no testing required			
Melanoma	FDA approved; no testing required	FDA approved with PD-L1 28-8[†] ≥1% TPS			
Merkel Cell Carcinoma				FDA approved; no testing required	
NSCLC 1st Line	FDA approved with PD-L1 22C3^Δ ≥50% TPS				
Non Squamous 1st Line Combo Treatment with Chemotherapy	FDA approved; no testing required in patients with negative ALK and EGFR				
NSCLC 2nd Line	FDA approved with PD-L1 22C3^Δ ≥1% TPS	FDA approved with PD-L1 28-8[†] ≥1%, ≥5%, ≥10% TPS	FDA approved with PD-L1 SP142[†] ≥50% TC / ≥10% IC		
Primary Mediastinal Large B-cell Lymphoma	FDA approved; no testing required				
Renal Cell CA		FDA approved; no testing required			
Small Cell Lung Cancer		FDA approved; no testing required			
Urothelial CA (Bladder)	FDA approved with PD-L1 22C3^Δ CPS ≥ 10 in patients ineligible for cisplatin-containing therapy <i>*see comment below</i>	FDA approved with PD-L1 28-8[†] ≥1% TPS	FDA approved with PD-L1 SP142[†] CPS ≥ 10 in patients ineligible for cisplatin-containing therapy <i>**see comment below</i>	FDA approved; no testing required	FDA approved with PD-L1 SP263[†] ≥ 25% of TC exhibit membrane staining; or, ICP > 1% & IC+ ≥ 25%; or, ICP = 1% & IC+ = 100%
"Pan Tumor" Tumor Agnostic	dMMR or MSI-H				

**OR patients who are not eligible for any platinum-containing chemotherapy regardless of PD-L1 status*

***OR patients who are not eligible for any platinum-containing chemotherapy regardless of PD-L1 status*

Δ = FDA approved companion diagnostic (required); **†** = FDA approved complementary diagnostic (optional)

TPS = Tumor proportion score; **CPS** = Combined positive score; **TC** = Tumor cells; **IC** = Immune cells;

ICP = Immune cells present; **MSI-H** = Microsatellite instability (high); **dMMR** = Mismatch repair (deficient)

Testing available NOW at PhenoPath	22C3 Dako Link 48	28-8 Dako Link 48	SP142 Ventana Ultra	E1L3N Generic	MMR IHC or MSI PCR Generic
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Specimen requirements: FFPE block or 4 to 5 unstained slides cut at 4μm

To submit a specimen: Request supplies or use any requisition form at www.phenopath.com; indicate PD-L1 clone desired; ship FedEx standard overnight in secure shipping container (provided by PhenoPath upon request)

Turnaround time: 24-48 hours from receipt of specimen (PD-L1 and MMR IHC); 5-8 days from receipt of specimen (MSI PCR)

References: keytruda.com, opdivo.com, tecentriq.com, bavencio.com, imfinzi.com, dako.com, ventana.com, fda.gov, drugs.com

Disclaimer: The content of this poster should not be relied upon as the sole source of information to guide specimen testing or patient treatment.