

Biomarker Testing for Checkpoint Inhibitors

KEYTRUDA[®] (pembrolizumab) anti-PD-1 **OPDIVO[®]** (nivolumab) anti-PD-1 **TECENTRIQ[®]** (atezolizumab) anti-PD-L1 **BAVENCIO[®]** (avelumab) anti-PD-L1 **IMFINZI[™]** (durvalumab) anti-PD-L1

Breast Carcinoma, Triple Negative			FDA approved with PD-L1 SP142^Δ ≥1% IC		
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 1st Line	FDA approval pending PD-L1 22C3 ≥20 CPS KEYNOTE-048 data presented ESMO 2018	FDA approved with PD-L1 28-8[†] ≥1% TPS			
Head & Neck Squamous Cell CA 2nd Line	FDA approved; no testing required				
Hepatocellular Carcinoma	FDA approved; no testing required	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			FDA approved; no testing required	
NSCLC 1st Line, metastatic squamous	FDA approved; no testing required				
Non Squamous 1st Line Combo Treatment with Chemotherapy	FDA approved; no testing required in patients with negative ALK and EGFR		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	FDA approved; no testing required (extensive stage)		
Urothelial CA (Bladder)	FDA approved with PD-L1 22C3^Δ CPS ≥ 10 in patients ineligible for cisplatin-containing therapy *see comment below	FDA approved with PD-L1 28-8[†] ≥1% TPS	FDA approved with PD-L1 SP142[†] CPS ≥ 10 in patients ineligible for cisplatin-containing therapy **see comment below	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

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.