PhenoPath

Diagnoses you can count on®

Updated 4JAN2019

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 approval pending PD-L1 **SP142** ≥1% IC NEJM 379(22), 2018		
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 approved; no testing required	FDA approved with PD-L1 **28-8**† ≥1% TPS			
Head & Neck Squamous Cell CA 2nd Line	FDA approval pending PD-L1 **22C3** ≥20 CPS KEYNOTE-048 data presented ESMO 2018				
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			
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

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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

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