PhenoPath

Diagnoses you can count on®

Updated 07OCT2017

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*
Colorectal Carcinoma	**dMMR or MSI-H**	**dMMR or MSI-H**			
Gastric Carcinoma	**FDA approved with PD-L1 22C3Δ ≥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 22C3Δ ≥50% TPS**				
NSCLC 1st Line Combo Treatment with Chemotherapy	**FDA approved; no testing required**				
NSCLC 2nd Line	**FDA approved with PD-L1 22C3Δ ≥1% TPS**	**FDA approved with PD-L1 28-8† ≥1%, ≥5%, ≥10% TPS**	**FDA approved with PD-L1 SP142† ≥50% TC / ≥10% IC**		
Renal Cell CA		**FDA approved; no testing required**			
Urothelial CA (Bladder)	**FDA approved; no testing required**	**FDA approved with PD-L1 28-8† ≥1% TPS**	**FDA approved with PD-L1 SP142† ≥5% IC**	**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**				

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

www.phenopath.com • 888-927-4366