PhenoPath
A Quest Diagnostics Company

Insights to help optimize treatment and inspire new hope

Checkpoint inhibitor testing for therapeutics

PhenoPath is a leader in immunotherapy testing. Our depth of pathology expertise and comprehensive PD-L1, microsatellite instability (MSI), and mismatch repair (MMR) offerings provide you and your patients insight into potential immunotherapy treatment options.

The PhenoPath Checkpoint Inhibitor Testing Portfolio is organized by tumor type and will assist you in selecting the most effective therapy from a growing list of choices. As an industry leader in esoteric oncology and genetic diagnostics, we are committed to innovative solutions that provide new hope.

Look to PhenoPath as your expert resource

You can speak directly with any one of our board-certified pathologists, with expertise across numerous subspecialties, including breast, endocrinology, gastrointestinal, genitourinary, leukemia and lymphoma, lung, and renal.

One of our leading Medical Directors, Dr Allen Gown, has published more than 350 peer-reviewed articles, and is an available resource for your most challenging cases.

PD-L1 specimen requirements*

Preferred specimen(s)	Alternative specimen(s)	Minimum volume	Collection instructions	Transport container	Transport temperature	Specimen stability
Formalin-fixed, paraffin-embedded (FFPE) tissue block submitted in IHC specimen transport kit	5 unstained charged(+) slides submitted in IHC specimen transport kit	5 slides	FFPE: State any other type of fixative used. A pathology report which includes the paraffin block number, and both macroscopic and microscopic evaluation and diagnosis, should be sent with the specimens	IHC specimen transport kit	Room temperature	**Paraffin block** Room temperature: 5 years Refrigerated: 5 years Frozen: Unacceptable **Slides** Room temperature: 30 days Refrigerated: 30 days Frozen: Unacceptable

CPT code for all Checkpoint Inhibitor tests: 88360. **CPT for MSI:** 81301. **CPT for Mismatch Repair IHC:** 88342, 88341 (x3)

The CPT codes provided are based on AMA guidelines and are for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payer being billed.

*Specimen requirements for MSI and MMR can be found at PhenoPath.com

For more information, visit **PhenoPath.com**

Therapy	BAVENCIO® (avelumab)[1]	IMFINZI™ (durvalumab)[2]	KEYTRUDA® (pembrolizumab)[3]	OPDIVO® (nivolumab)[4]	TECENTRIQ® (atezolizumab)[5]
Diagnostic test	Biomarker E1L3N Generic	Biomarker SP263 Ventana Ultra	Biomarker 22C3 Dako Link 48	Biomarker 28-8 Dako Link 48	Biomarker SP142 Ventana Ultra
Breast Carcinoma, Triple Negative					FDA approved with PD-L1 **SP142**[b] ≥1% IC
Cervical Cancer			FDA approved with PD-L1 **22C3**[b] ≥1 CPS		
Colorectal Carcinoma			dMMR or MSI-H	dMMR or MSI-H	
Endometrial Carcinoma			MSI-L or pMMR		
Esophageal Cancer (Squamous)			FDA approved with PD-L1 **22C3**[b] ≥10% CPS		
Gastric/GEJ Adenocarcinoma			FDA approved with PD-L1 **22C3**[b] ≥1 CPS		
Head & Neck Squamous Cell CA 1st Line			FDA approved with PD-L1 **22C3**[b] ≥1 CPS no testing required		
Head & Neck Squamous Cell CA 2nd Line			FDA approved; no testing required	FDA approved with PD-L1 **28-8**[c] ≥1% TPS	
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		
Merkel Cell Carcinoma	FDA approved; no testing required		FDA approved; no testing required		
NSCLC 1st Line, Metastatic Squamous & Non-Squamous, Combo Treatment			FDA approved; no testing required in patients with negative ALK and EGFR		
NSCLC 1st Line, Stage 3 or Metastatic		FDA approved; no testing required	FDA approved with PD-L1 **22C3**[b] ≥1% TPS in patients with negative ALK and EGFR		
NSCLC, Metastatic, w/disease progression			FDA approved with PD-L1 **22C3**[b] ≥1% TPS		
NSCLC 2nd Line			FDA approved with PD-L1 **22C3**[b] ≥1% TPS	FDA approved with PD-L1 **28-8**[c] ≥1%, ≥5%, ≥10% TPS	FDA approved with PD-L1 **SP142**[c] ≥50% TC / ≥10% IC
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
Primary Mediastinal Large B-cell Lymphoma			FDA approved; no testing required		
Renal Cell CA 1st Line Combo Treatment	FDA approved; no testing required		FDA approved; no testing required	FDA approved; no testing required	
Small Cell Lung Cancer			FDA approved; no testing required	FDA approved; no testing required	FDA approved; no testing required (extensive stage)
Urothelial CA (Bladder)	FDA approved; no testing required	FDA approved with PD-L1 **SP263**[c] ≥25% of TC exhibit membrane staining; or, ICP >1% & IC+ ≥25%; or,ICP = 1% & IC+ = 100%	FDA approved with PD-L1 **22C3**[b] CPS ≥10 in patients ineligible for cisplatin-containing therapy[a]	FDA approved with PD-L1 **28-8**[c] ≥1% TPS	FDA approved with PD-L1 **SP142**[c] CPS ≥10 in patients ineligible for cisplatin-containing therapy[a]
Tumor Agnostic			dMMR or MSI-H		

a = OR patients who are not eligible for any platinum-containing chemotherapy regardless of PD-L1 status.
b = FDA approved companion diagnostic (required).
c = 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).
MSI-L = Microsatellite instability (low).
dMMR = Mismatch repair (deficient).
pMMR = Mismatch repair (proficient).

This information is provided for informational purposes only, and is not intended as medical advice. Test selection and interpretation, diagnosis, and patient management decisions are based on a physician's education, clinical expertise, and patient assessment. Please refer to the drug manufacturer's approved labeling for prescribing, warnings, side effects and other important information.

It's easy to order a Checkpoint Inhibitor test and submit a sample

1) Complete test requisition: Indicate the appropriate biomarker testing. If you need help finding the test code, please visit PhenoPath at **PhenoPath.com/Test-Menu**.

2) Ship sample: You can either ship via FedEx® standard overnight in a secure shipping container, or ship through your regular courier pick-up. Test requisitions and shipping containers available upon request from **PhenoPath.com**.

References
1. Bavencio. https://www.bavencio.com/hcp. Accessed January 8, 2020.
2. Imfinzi. https://www.imfinzihcp.com/non-small-cell-lung-cancer.html. Accessed January 8, 2020.
3. Keytruda. https://www.keytrudahcp.com. Accessed January 8, 2020.
4. Opdivo. https://www.opdivohcp.com. Accessed January 8, 2020.
5. Tecentriq. https://www.tecentriq-hcp.com. Accessed January 8, 2020.

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