

## **NEW TEST**

**NOTIFICATION DATE:** July 24, 2017 **EFFECTIVE DATE:** September 8, 2017

## PD-L1 (22C3), SEMI-QUANTITATIVE IMMUNOHISTOCHEMISTRY, MANUAL

Test ID: PDL12

**USEFUL FOR:** Identification of neoplasms expressing programmed cell death 1-ligand 1

**METHOD**: Immunohistochemistry

**NECESSARY INFORMATION:** 

A pathology/diagnostic report and a brief history are required.

**SPECIMEN REQUIREMENTS:** 

**Supplies:** Pathology Packaging Kit (T554)

**Specimen Type:** Formalin-fixed, paraffin-embedded tissue block; or 3 unstained glass, "positively charged" slides with 4-microns formalin-fixed, paraffin-embedded tissue

Container/Tube: Pathology Packaging Kit (T554)

Additional Information: One slide will be stained with hematoxylin and eosin and returned

## **SPECIMEN STABILITY INFORMATION:**

Specimen Type	Temperature	Time
Special	Ambient (preferred)	
	Refrigerated	

**CAUTIONS:** Preclinical studies suggest that positive PD-L1 immunohistochemistry in tumor cells may predict tumor response to therapy with immune checkpoint inhibitors. This result should not be used as the sole factor in determining treatment, as other factors (eg, tumor mutation burden and microsatellite instability) have also been studied as predictive markers.

This test has been validated for nondecalcified paraffin-embedded tissue specimens fixed in 10% neutral-buffered formalin. This assay has not been validated on tissues subjected to the decalcification process or use of alternative fixatives for bone and bone marrow specimens or cell blocks

**CPT CODE**: 88360

**DAY(S) SET UP:** Monday through Friday **ANALYTIC TIME:** 5 days