

10/20/2015 - New Release, Quest Diagnostics Nichols Institute, Valencia

NEW TESTS			
Please Note: Not all test codes assigned to each assay are listed in the table of contents. Please refer to the complete listing on the page numbers indicated.			
Test Code	Test Name	Effective Date	Page #
<u>93359</u>	PD-L1 Lung (Nivolumab), IHC	10/20/2015	1

**Quest Diagnostics Introduces Dako's PD-L1 Complementary Diagnostic Test to Support Bristol-Myers Squibb's OPDIVO® Anti-PD-1 Therapy for Non-squamous Non-small Cell Lung Cancer**

The new Quest test service is based on the first FDA-approved complementary diagnostic

Quest Diagnostics announced that it now provides clinical laboratory testing using the PD-L1 IHC 28-8 pharmDx immunohistochemistry test, available through Dako, an Agilent Technologies company.

On October 9, 2015 the U.S. Food and Drug Administration (FDA) approved Bristol-Myers Squibb's OPDIVO® (nivolumab) for the treatment of patients with previously treated metastatic non-small cell lung cancer (NSCLC). The approval expands the indication for OPDIVO® to include both previously treated squamous and non-squamous NSCLC.

Also on October 9, 2015 the FDA approved the PD-L1 IHC 28-8 pharmDx as a complementary diagnostic for non-squamous non-small cell carcinoma. The Dako test was used to assess PD-L1 expression in the Phase 3 CheckMate 057 trial, in which OPDIVO® demonstrated superior overall survival in patients with previously-treated metastatic non-squamous NSCLC compared to chemotherapy. These complementary tests are distinct from companion diagnostics, which are essential for safe and effective use of a drug. Biomarker testing is not required for OPDIVO®; but it may provide additional information for physicians and inform patient dialogue

Physicians in the United States may order the PD-L1 IHC 28-8 pharmDx test service directly from Quest Diagnostics.

*(The above is excerpted from a news release issued to the media.)*

<http://newsroom.questdiagnostics.com/2015-10-09-Quest-Diagnostics-Introduces-Dakos-PD-L1-Complementary-Diagnostic-Test-to-Support-Bristol-Myers-Squibbs-OPDIVO-Anti-PD-1-Therapy-for-Non-squamous-Non-small-Cell-Lung-Cancer>

## New Test Offerings

The following tests will be available through Quest Diagnostics on the dates indicated below.

PD-L1 Lung (Nivolumab), IHC	
Clinical Significance	The PD-L1 IHC 28-8pharmaDx qualitative assay is intended for use in the detection of PD-L1 expression in formalin-fixed, paraffin embedded (FFPE) non-squamous non-small cell lung carcinoma (NSCLC). PD-L1 expression in non-squamous NSCLC may be associated with enhanced survival from OPDIVO (nivolumab).
Effective Date	10/20/2015
Test Code	93359
CPT Codes	88342
Specimen Requirements	<b>Preferred:</b> Formalin fixed paraffin embedded tissue in IHC specimen transport kit  <b>Acceptable:</b> 5 Unstained charged(+) slides in IHC specimen transport kit
Reject Criteria	Baked or melted slides; previously stained slides; cytopins; tissue types other than lung cancer

	<b>specimens; cytology cell block; decalcified specimens; fixatives other than formalin</b>			
Instructions	<b>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 specimen.</b>			
Transport Temperature	<b>Room temperature</b>			
Specimen Stability	<b>Formalin fixed paraffin embedded tissue</b>	<b>Room temperature and Refrigerated</b>	<b>5 years</b>	
	<b>Formalin fixed paraffin embedded tissue</b>	<b>Frozen</b>	<b>Unacceptable</b>	
	<b>Unstained charged(+) slides</b>	<b>Room temperature</b>	<b>Unacceptable</b>	
	<b>Unstained charged(+) slides</b>	<b>Refrigerated</b>	<b>30 days</b>	
	<b>Unstained charged(+) slides</b>	<b>Frozen</b>	<b>Unacceptable</b>	
Set-up/Analytic Time	<b>Set up: Mon-Fri; Report available: 3-5 days</b>			
Methodology	<b>Immunohistochemical Stain</b>			
Performing Site	<b>Quest Diagnostics Nichols Institute, San Juan Capistrano</b>			
Interface Mapping	<b>Result Code</b>	<b>Type</b>	<b>Result Name</b>	<b>Unit Of Measure</b>
	<b>86007405</b>	<b>Prompt-Result</b>	<b>Paraffin Block Number:</b>	
	<b>86007575</b>	<b>Prompt-Result</b>	<b>Primary Tumor Site:</b>	
	<b>86001727</b>	<b>Prompt-Result</b>	<b>Collection Site:</b>	
	<b>86014288</b>	<b>Prompt-Result</b>	<b>Tumor Type:</b>	
	<b>86014129</b>	<b>Prompt-Result</b>	<b>Stage:</b>	
	<b>86010179</b>	<b>Prompt-Result</b>	<b>Grade:</b>	
	<b>86014289</b>	<b>Prompt-Result</b>	<b>Oncologist Name:</b>	
	<b>86014290</b>	<b>Prompt-Result</b>	<b>Oncologist NPI:</b>	
	<b>86014291</b>	<b>Prompt-Result</b>	<b>Pathologist Name:</b>	
	<b>86014292</b>	<b>Prompt-Result</b>	<b>Pathologist NPI:</b>	
	<b>86003734</b>		<b>Quest Internal Number:</b>	
<b>86014427</b>		<b>PD-L1 expression</b>	<b>%</b>	