

10/12/2015 - 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 #
93279	PD-L1 Lung (Pembrolizumab), IHC	10/6/2015	1

Quest introduces Dako's PD-L1 companion diagnostic for KEYTRUDA

Quest Diagnostics announced that it will provide clinical laboratory testing using the PD-L1 IHC 22C3 PharmDx™ immunohistochemistry companion diagnostic.

On October 2, 2015, the U.S. Food and Drug Administration (FDA) approved Merck's KEYTRUDA® (pembrolizumab), an anti-PD-1 therapy at a dose of 2 mg/kg every three weeks, for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors express PD-L1 as determined by an FDA-approved test and who have disease progression on or after platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving KEYTRUDA.

Physicians in the United States may order PD-L1 IHC 22C3 pharmDx testing directly from Quest Diagnostics.

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

<http://newsroom.questdiagnostics.com/2015-10-02-Quest-Diagnostics-Introduces-Dakos-PD-L1-Companion-Diagnostic-for-KEYTRUDA-Mercks-Anti-PD-1-Therapy-for-Metastatic-Non-Small-Cell-Lung-Cancer-Whose-Tumors-Express-PD-L1-with-Disease-Progression-On-or-After-Platinum-Containing-Chemotherapy>

New Test Offerings

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

PD-L1 Lung (Pembrolizumab), IHC			
Clinical Significance	The PD-L1 pharmaDx qualitative assay is intended for use in the detection of PD-L1 in formalin-fixed, paraffin embedded (FFPE) non-small cell lung carcinoma (NSCLC). PD-L1 IHC 22C3 pharmDx is indicated as an aid in identifying NSCLC patients for treatment with KEYTRUDA (pembrolizumab).		
Effective Date	10/6/2015		
Test Code	93279		
CPT Codes	88342		
Specimen Requirements	Preferred: Formalin fixed paraffin embedded tissue in IHC specimen transport kit Acceptable: 5 Unstained charged(+) slides in IHC specimen transport kit		
Reject Criteria	Baked or melted slides; previously stained slides; cytopspins; lung cancer specimens are the only acceptable tissues type; other tissue types submitted will be rejected		
Instructions	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.		
Transport Temperature	Room temperature		
Specimen Stability	Formalin fixed paraffin embedded tissue	Room temperature and Refrigerated	5 years
	Formalin fixed paraffin embedded tissue	Frozen	Unacceptable

	<table border="1"> <tr> <td>Unstained charged(+) slides</td> <td>Room temperature</td> <td>Unacceptable</td> </tr> <tr> <td>Unstained charged(+) slides</td> <td>Refrigerated</td> <td>30 days</td> </tr> <tr> <td>Unstained charged(+) slides</td> <td>Frozen</td> <td>Unacceptable</td> </tr> </table>	Unstained charged(+) slides	Room temperature	Unacceptable	Unstained charged(+) slides	Refrigerated	30 days	Unstained charged(+) slides	Frozen	Unacceptable																																															
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Set-up/Analytic Time	Set up: Mon-Fri; Report available: 3-5 days																																																								
Methodology	Immunohistochemical Stain																																																								
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano																																																								
Interface Mapping	<table border="1"> <thead> <tr> <th>Result Code</th> <th>Type</th> <th>Result Name</th> <th>Unit Of Measure</th> </tr> </thead> <tbody> <tr> <td>86007405</td> <td>Prompt-Result</td> <td>Paraffin Block Number:</td> <td></td> </tr> <tr> <td>86007575</td> <td>Prompt-Result</td> <td>Primary Tumor Site:</td> <td></td> </tr> <tr> <td>86001727</td> <td>Prompt-Result</td> <td>Collection Site:</td> <td></td> </tr> <tr> <td>86014288</td> <td>Prompt-Result</td> <td>Tumor Type:</td> <td></td> </tr> <tr> <td>86014129</td> <td>Prompt-Result</td> <td>Stage:</td> <td></td> </tr> <tr> <td>86010179</td> <td>Prompt-Result</td> <td>Grade:</td> <td></td> </tr> <tr> <td>86014289</td> <td>Prompt-Result</td> <td>Oncologist Name:</td> <td></td> </tr> <tr> <td>86014290</td> <td>Prompt-Result</td> <td>Oncologist NPI:</td> <td></td> </tr> <tr> <td>86014291</td> <td>Prompt-Result</td> <td>Pathologist Name:</td> <td></td> </tr> <tr> <td>86014292</td> <td>Prompt-Result</td> <td>Pathologist NPI:</td> <td></td> </tr> <tr> <td>86003734</td> <td></td> <td>Quest Internal Number:</td> <td></td> </tr> <tr> <td>86014281</td> <td></td> <td>Tumor Proportion Score</td> <td>%</td> </tr> <tr> <td>86014283</td> <td></td> <td>Interpretation</td> <td></td> </tr> </tbody> </table>	Result Code	Type	Result Name	Unit Of Measure	86007405	Prompt-Result	Paraffin Block Number:		86007575	Prompt-Result	Primary Tumor Site:		86001727	Prompt-Result	Collection Site:		86014288	Prompt-Result	Tumor Type:		86014129	Prompt-Result	Stage:		86010179	Prompt-Result	Grade:		86014289	Prompt-Result	Oncologist Name:		86014290	Prompt-Result	Oncologist NPI:		86014291	Prompt-Result	Pathologist Name:		86014292	Prompt-Result	Pathologist NPI:		86003734		Quest Internal Number:		86014281		Tumor Proportion Score	%	86014283		Interpretation	
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