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FDA approves Agilent's PD-L1 Assay as companion diagnostic

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Agilent Technologies Inc. has announced that the U.S. Food and Drug Administration has approved the company's PD-L1 IHC 28-8 pharmDx for expanded use in non-small cell lung cancer (NSCLC).

Now, physicians will be able to use the PD-L1 IHC 28-8 pharmDx assay as an aid in identifying patients with metastatic NSCLC for treatment with the dual immunotherapy combination of *Opdivo* (nivolumab) and *Yervoy* (ipilimumab), manufactured by Bristol Myers Squibb. Based on the results of the Phase 3 CheckMate -227 clinical trial, *Opdivo* in combination with *Yervoy* was approved as first-line treatment for patients with metastatic NSCLC whose tumors express PD-L1 (?1%) as determined by an FDA-approved test.

Agilent developed PD-L1 IHC 28-8 pharmDx in 2016 through a collaboration with Bristol Myers Squibb, and it has been previously approved as a complementary *in vitro* diagnostic for non-squamous non-small cell lung cancer, as well as other forms of cancer, including, squamous cell carcinoma of the head and neck, and urothelial carcinoma.