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TITLE: Developing an immunohistochemistry test for programmed cell death ligand 1 (pd-l1) as a companion diagnostic for pembrolizumab

ABSTRACT: Tumors escape from immunosurveillance in part by expressing PD-L1, which down-regulates the cytotoxic T-cell response. Pembrolizumab blocks this down-regulation pathway and thus effectively treats a number of cancers, including non-small cell lung cancer (NSCLC). The rapid clinical development of pembrolizumab for NSCLC required even more rapid development of a PD-L1 immunohistochemistry assay. The assay was developed initially to assess PD-L1 as a predictive biomarker, and then to enrich clinical trials. Merck subsequently partnered with Dako/Agilent to develop the first FDA-approved companion diagnostic in cancer immunotherapy, which ultimately enabled pembrolizumab to become the first immunotherapy approved for first-line treatment of NSCLC. This program will recount the rapid decisions which had to be made during assay development. It will discuss how the assay enabled "breakthrough" status with FDA; accelerated approval of pembrolizumab for advanced, previously treated NSCLC which express PD-L1, from a single arm trial; and finally approval of pembrolizumab as a first-line therapy for NSCLC with high PD-L1 expression in a randomized, controlled trial.