Antibodies against PD-1 and PD-L1 can cause strong and durable anti-tumor immune responses in non-small cell lung cancer (NSCLC). Immunohistochemistry for PD-L1 (PD-L1 IHC) was tested as a predictive biomarker. Several IHC assays and interpretation criteria were developed in parallel. The clinical significance of PD-L1 IHC in NSCLC and the optimum method for staining and interpretation of the results are the subject of ongoing studies. The diagnostic application of immunotherapy in NSCLC necessitates harmonization of PD-L1 IHC to obtain evidence for guidelines; therefore, a consensus opinion on a well-founded diagnostic mode of testing should be defined based on published studies and the results of the first German PD-L1 IHC harmonization study.
various proportional cut-offs used to interpret the staining results can be summarized in a total score, which can be reproducibly assessed. The staining patterns of the four assays investigated were, however, not congruent in all situations. In principle, the use of PD-L1 IHC for assessment of the expression in tumor cells is a reliably determinable biomarker. Evaluation algorithms should be based on published clinical trials. For NSCLC approvals with obligatory PD-L1 IHC are to be expected but it remains to be seen to what extent PD-L1 IHC will be implemented in the clinical routine.