Interlaboratory concordance of PD-L1 immunohistochemistry for non-small-cell lung cancer.

Programmed death ligand 1 (PD-L1) immunohistochemistry has become a mandatory diagnostic test in the treatment of lung cancer. Several research initiatives have started to harmonise the five PD-L1 immunohistochemistry assays that have been used in clinical trials. Here, we report data on interlaboratory and interassay concordance for commercial assays (‘assays’) and laboratory-developed tests (LDTs) at 10 German testing sites. To assess interlaboratory concordance, a tissue microarray containing 21 pulmonary carcinoma specimens was centrally prepared. Pre-cut sections were stained at 10 sites by the use of assays 28-8, 22C3, SP263, and SP142, as well as 11 LDTs. Assay performance was evaluated with a second tissue microarray containing 11 cell lines with defined PD-L1 expression. Quality control was centrally performed by manual and digital analyses. The assays yielded reproducible IHC staining patterns at all sites. In agreement with previous studies, 22C3, 28-8 and SP263 showed similar staining patterns, whereas SP142 was distinct. Among
the LDTs, six of 11 protocols showed staining patterns similar to those of assays 22C3 and 28-8. Interlaboratory concordance of tumour cell scoring by use of a six-step system was moderate (Light's \( \kappa = 0.43-0.69 \)), whereas the clinically approved cut-offs of \( \geq 1\% \) and \( \geq 50\% \) showed substantial concordance (\( \kappa = 0.73-0.89 \)). Immune cell scoring by the use of SP142 yielded moderate concordance (\( \kappa = 0.42 \)). The data confirm the previously described staining patterns of the assays, and show that they can be reproducibly employed at different sites. LDTs with staining results similar to those of the assays are implementable, but have to be carefully validated.