50 EXTERNAL INTER-LABORATORY REPRODUCIBILITY OF PD-L1 IHC 22C3 PHARMDX (SK006) FOR BILIARY TRACT ADENOCARCINOMA AT CPS ≥ 1 AND CPS ≥ 10

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Background Biliary tract adenocarcinoma (BTAC) consists of cholangiocarcinoma, ampullary carcinoma, and gall bladder adenocarcinoma.[1] Previous studies have demonstrated PD-L1 expression in tumor-infiltrating immune cells in intrahepatic cholangiocarcinoma tumors.[2] [3] However, there are limited data on the reproducibility of the interpretation of PD-L1 expression in BTAC comparing multiple laboratories and evaluating pathologists. Here we provide evidence of the external inter-laboratory reproducibility of PD-L1 expression determination in BTAC utilizing PD-L1 IHC 22C3 pharmDx at the CPS ≥ 1 and CPS ≥ 10 cutoffs.

Methods External Inter-Laboratory reproducibility studies tested the inter-site, intra-site, inter-observer, and intra-observer assay reproducibility for BTAC at CPS ≥ 1 and CPS ≥ 10. To test inter- and intra-site reproducibility, five replicate sets of a BTAC specimen set were tested at each of the three external sites. For inter- and intra-observer reproducibility, three external sites evaluated one pre-stained set of BTAC specimens, with each pathologist evaluating the set three times. All sets assessed were blinded and randomized. Percent agreement was calculated using Negative Percent Agreement (NPA), Positive Percent Agreement (PPA), and Overall Percent Agreement (OA). Pre-specified acceptance criteria (AC) for all components of the analyses were ≥ 85.0% for the lower bound value of a 95% two-tailed percentile bootstrap confidence interval (CI) of each percent agreement parameters.

Results At the CPS ≥ 1 cutoff: (i) inter-and intra-site NPA/PPA/OA met AC with point estimates (PE) ≥94.2% and CI lower bounds ≥88.8%, and (ii) inter- and intra-observer NPA/PPA/OA met AC with PE ≥95.5% and CI lower bounds ≥91.4%. At the CPS ≥ 10 cutoff: (i) inter-and intra-site NPA/PPA/OA met AC, with PE ≥92.7% and CI lower bounds ≥87.3%, and (ii) inter- and intra-observer NPA/PPA/OA met AC, with PE ≥97.3% and CI lower bounds ≥94.6%.

Conclusions These studies demonstrate high external inter-laboratory reproducibility of PD-L1 IHC 22C3 pharmDx with respect to expression determination in BTAC at CPS ≥ 1 and CPS ≥ 10 cutoffs.

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Ethics Approval The external reproducibility study was approved by WCG IRB, study numbers 1309412, 1309593, and 1309602.

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