

# Bio-Techne's Advanced Cell Diagnostics Pharma Assay Services for Cell and Gene Therapy

**A**s modified cell and gene therapies (C&GT) are showing increasing promise in treating rare diseases and cancers, accurate and precise tools for measuring biodistribution and safety are critical for the success of these therapies. Advanced Cell Diagnostics (ACD), a Bio-Techne brand, provides a powerful new tool for visualizing and quantifying modified cells and genes in tissue through RNAscope™, an advanced *in situ* hybridization (ISH) technology.

ACD is rapidly becoming established as the leader in the C&GT space due to its novel method of tracking the bio-distribution of genetically modified cells in the tissue. “We are proud to offer Bio-Techne’s portfolio to meet the needs of the growing cell and gene therapy field. The RNAscope ISH assay enables the quantification of modified cells and genes in intact tissue, a unique capability that relies on the robust technology that has resulted in thousands of publications worldwide,” states Kim Kelderman, President of Diagnostics and Genomics at Bio-Techne Corporation. The RNAscope assay can be used to detect CAR-positive cells within the tumor microenvironment (TME) to measure infiltration, activity, and T-cell activation and recruitment. Together with the diverse portfolio of Bio-Techne products, C&GT researchers are supported at every step of the workflow, from GMP grade reagents to transposon technology for CAR and TCR construct integration, to T-cell activation kits, to scalable cell culture systems, to Cloudz™-based cell selection technology.

At ACD, the Pharma Assay Services group has years of experience designing and executing studies for dozens of C&GT companies. Researchers who partner with Pharma Assay Services will receive on-demand access to the most specialized and technically experienced RNAscope hands of any CRO. By

partnering with our scientific experts for study design and data interpretation, our customers can be confident in the science, and actionable results can be in-hand in weeks rather than months.

In data presented by Bellicum at ASCO-GI in 2020, Bellicum



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partnered with ACD’s Pharma Assay Services to use RNAscope to evaluate biopsies collected from patients enrolled in Phase 1 of the BP-012 clinical trial in metastatic pancreatic cancer. RNAscope probes were designed to detect Bellicum’s GoCAR-T cell in solid tumors, and the assay was performed in biopsies taken at baseline and on-treatment. The RNAscope assay demonstrated clear infiltration of GoCAR-T cells in the solid tumors and concurrent evaluation of CD3-positive cells showed no difference in CD3-cell recruitment. This clearly shows the unique ability of RNAscope to visualize modified T-cells within the tumor, as well as the ability to concomitantly assess transduced versus untransduced T- cells recruited to the tumor. The RNAscope analysis was a crucial measure of GoCAR-T cell infiltration. It demonstrated a fundamentally new capability for cell therapy researchers to assess the biodistribution and persistence of modified T cells within tissues.

Today, ACD’s R&D team is continuing to expand the toolbox for spatial profiling of any target from any species in fixed frozen, fresh frozen and FFPE tissues. The BaseScope™ assay, for instance, can be used to distinguish codon-optimized transgenes from endogenous sequences. With the recent launch of the RNAscope HiPlex Assay,

researchers can simultaneously detect up to twelve (12) RNA targets on a single slide, thus generating more data per sample without compromising the morphological features of the tissue. The HiPlex Assay utilizes ACD’s patented signal amplification and background suppression technology to deliver unique specificity and sensitivity with optimal signal generation. 