PROFESSIONAL ASSAY SERVICES

DEDICATED RNAscope™ ISH PROVIDER

ACD™
a bio-techne® brand

We've had a great experience in working with ACD. Using their service team we are able to move faster through our testing for Phase I trial. We are very happy with the quality of data, thoroughness in the reports we receive and would highly recommend them for ISH assay development and implementation.

Omar Kabbarah, PhD
Pharma/Biotech industry

PROFESSIONAL ASSAY SERVICES OFFERS GCLP COMPLIANT RNAscope, BASEScope, AND miRNAscope

in situ hybridization (ISH) assay services to support pre-clinical and clinical studies for pharma and biotech partners globally. Tissue sectioning, ISH staining, high resolution full slide scanning, scoring, and image analysis are performed by a dedicated team of highly trained specialists, scientists, and board-certified pathologists. With direct access to the developers of the technology, the Assay Services team provides unparalleled expertise in our ISH platform and delivers fast, high quality data designed to meet your study objectives and timelines.

EXPERTISE

Trust your study to the experts in RNAscope, BaseScope, and miRNAscope

QUALITY

Have confidence in the science, data, and research conclusions

SPEED

Receive actionable results in weeks rather than months

PROFESSIONAL ASSAY SERVICES SUPPORTS EVERY STEP OF THE DRUG DEVELOPMENT PROCESS

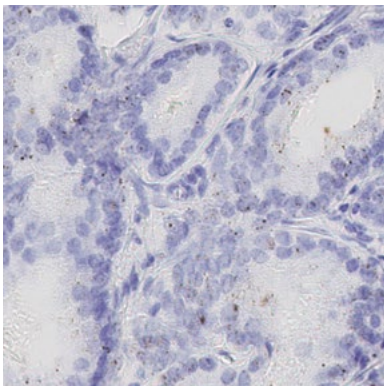
Early Discovery	Target Validation	Biomarker Assay Development	*In Vivo* Safety	Development
• Discovery research • Novel targets • Non-model organisms	• Clinical Development • Gene expression profiling • Disease association	• Assay precision studies • Assay validation	• Cell and gene therapy PD/PK • Safety/toxicology • Animal model studies	• Phase I/II clinical trials • CDx development

PROFESSIONAL ASSAY SERVICES OFFERINGS

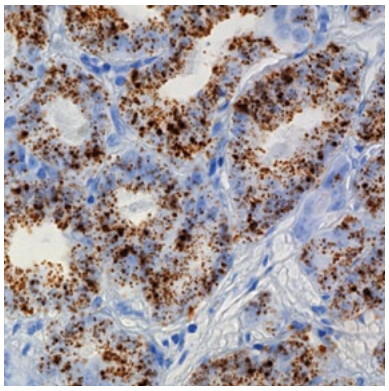
Tissue Bank and Sample Procurement	Embedding and Sectioning	RNAscope ISH Staining	Image Analysis	Reporting
Sample Sourcing	Embedding	RNAscope	Tissue QC	Study Brief
Pre-Qualified Tissues	Tissue Sectioning	BaseScope	Semi-Quantitative Scoring	Project Report
	H&E Stains	miRNAscope	Visual H-Scoring	Clinical Assay Protocols
	Full Slide Scans	Single/Duplex Chromogenic	Digital Image Analysis	
		Multiplex Fluorescent	Pathologist Review	
		ISH/IHC or ISH/IF		

TARGET DISCOVERY AND VALIDATION

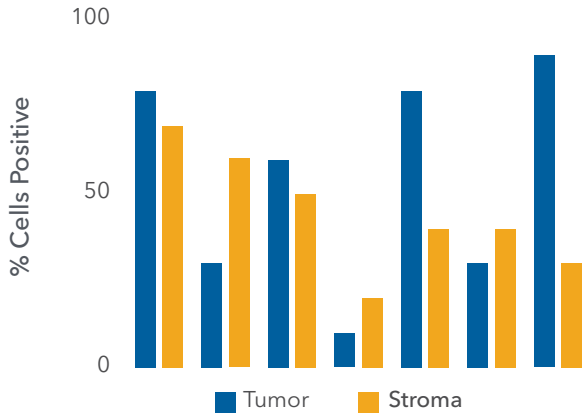
Screen, characterize, and validate candidate targets by evaluating expression in diseased vs. normal tissues with high sensitivity and specificity. Interrogate the molecular mechanism of the target in disease etiology with co-detection of cell-type markers or components of the signaling pathway.

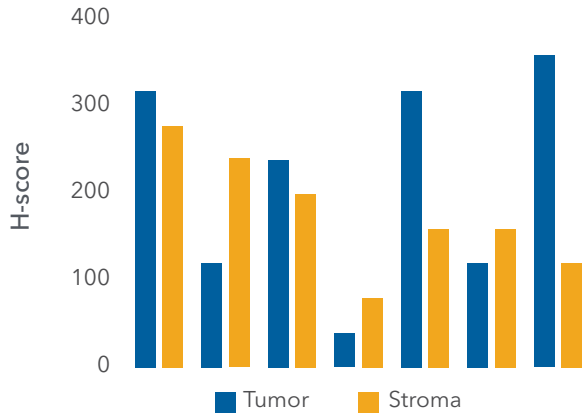


Normal



Diseased

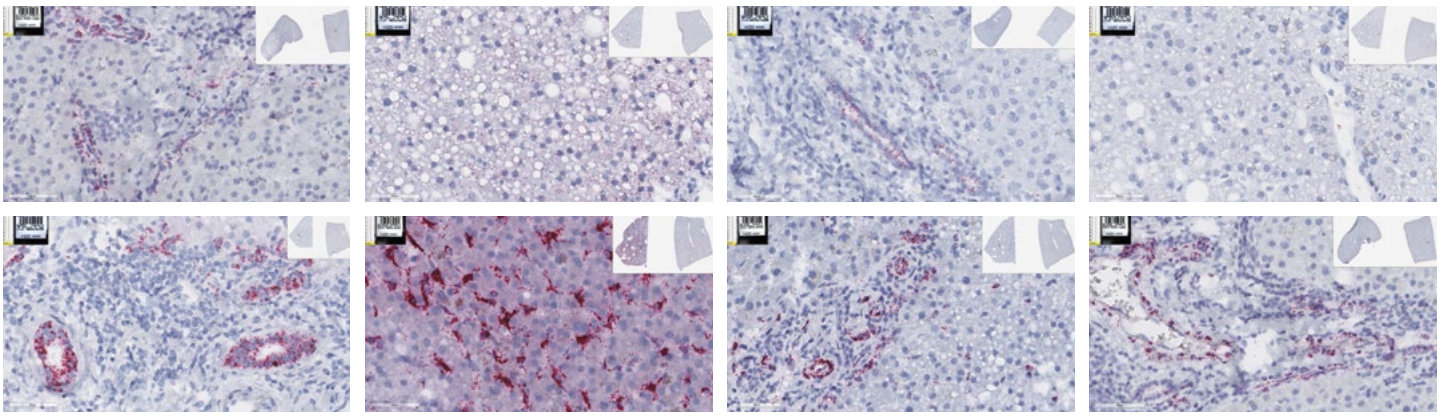




BIOMARKER ASSAY DEVELOPMENT

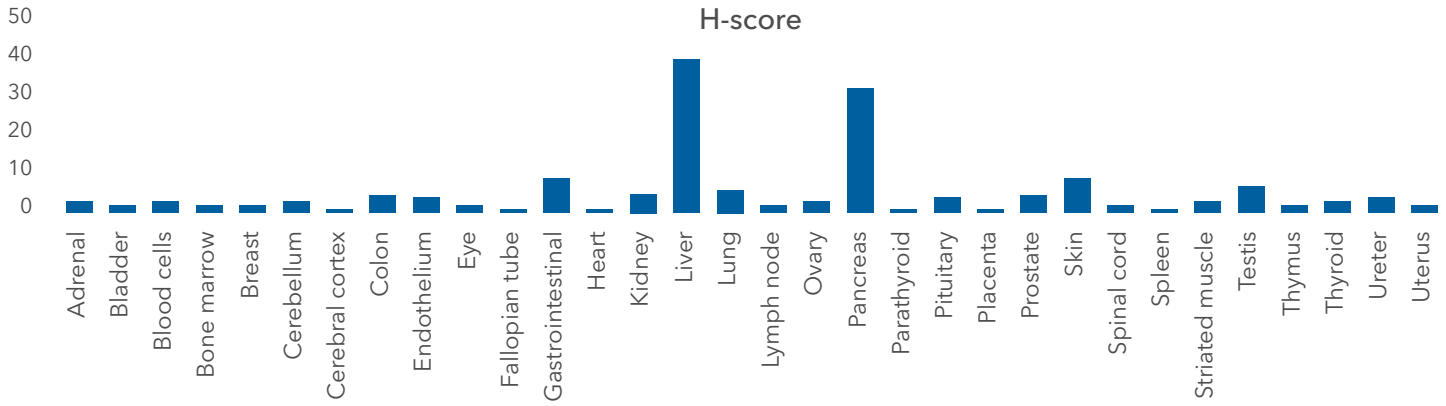
Qualify biomarkers with disease progression and/or clinical endpoints with high precision in order to stratify patient populations and to guide personalized treatment. Custom probes against novel targets can be designed in 1-2 weeks, dramatically shortening the time for development, and the RNAscope assay can provide lower limits of detection compared to IHC and other assays.

Diseased



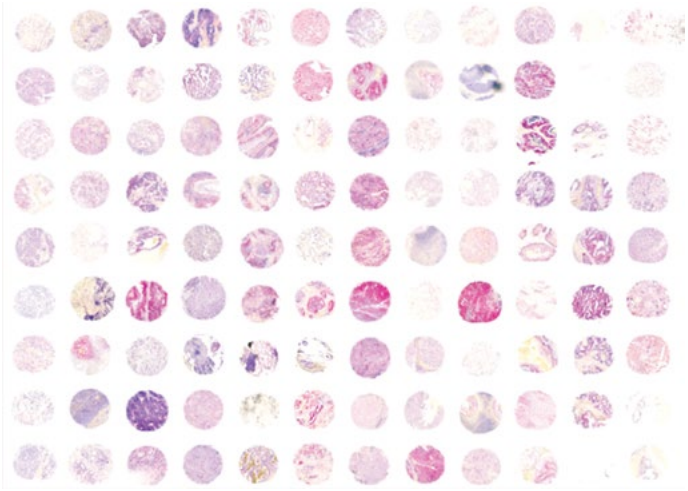
SAFETY / TOXICOLOGY TISSUE SCREENING

Single-molecule detection ensures high sensitivity in screening tissues for pre-clinical safety assessment in human and non-human primate models. Leverage tissue bank with a wide selection of pre-qualified normal tissues.



PRE-QUALIFIED TISSUES

Eliminate risk, shorten timelines, and reduce cost with ACD's pre-qualified tissue bank consisting of normal and diseased human tissues including various disease indications and solid tumors. Tissues have been pre-screened using RNAscope for RNA and tissue quality.



Tissue Bank is a set of high quality, pre-sourced and pre-qualified samples, available to our Professional Assay Services customers.

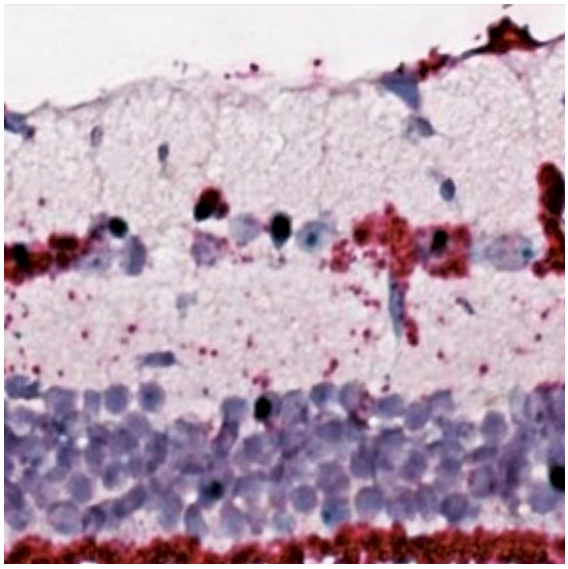
Pre-qualified samples include:

- Inflammatory bowel disease (Crohn's Disease and Ulcerative Colitis), and normal colon
- Non-alcoholic steatohepatitis (NASH) and normal liver
- Diabetic nephropathy, lupus nephritis, and normal kidney
- Psoriasis, atopic dermatitis, and normal skin
- Covid-19 positive lung
- Most human solid tumors available as blocks or TMAs
- Most human normal tissues available as blocks or TMAs
- Cynomolgus monkey, mouse, and rat tissues
- Various cell lines including induced PMBCs and cancer lines

AAV AND LENTIVIRUS BIODISTRIBUTION

Monitor the biodistribution of AAV or lentiviral vector simultaneously with genetically modified transgenes within the tissue context of animal models and human tissues. Quantify the spatial distribution of signal within vs outside of cellular boundaries, and co-stain with cell-type markers to assess viral tropism

TRANSGENE / AAV VECTOR



ILM (Inner limiting membrane)

NFL (Nerve fiber layers)

GCL (Ganglion cell layer)

IPL (Inner plexiform layer)

INL (Inner nuclear layer)

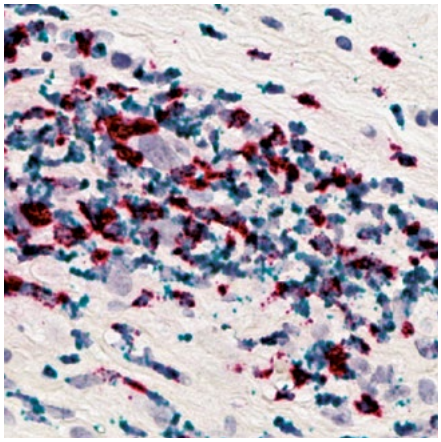
OPL (Outer plexiform layer)

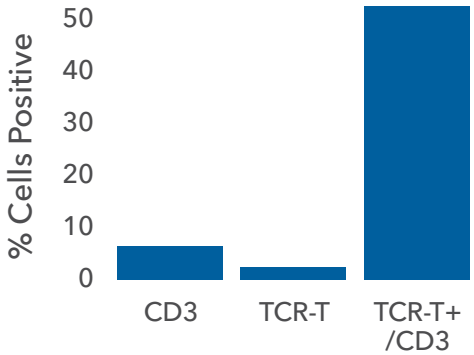
AAV-treated non-human primate retina stained with RNAscope LS Duplex ISH assay to detect the CB promoter sequence of the AAV vector (green) and the GFP transgene (red).

CAR AND TCR T-CELL INFILTRATION AND ACTIVATION

Visualize and quantify tumor infiltration of CAR-T or TCR-T cells within the tumor microenvironment (TME), and address safety by assessing off-target tissues with high sensitivity. Multiplex with markers tumor infiltrating lymphocytes (TILs) to assess antigen engagement and immune cell response.

TCR-T CELLS / CD3

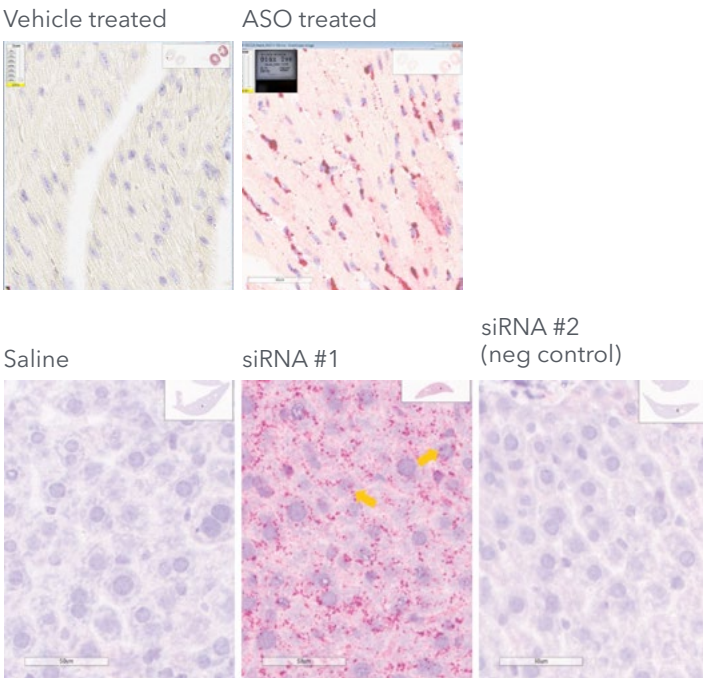




(Left) Human clinical liposarcoma FFPE sample stained with RNAscope Duplex ISH/IHC to detect modified TCR-T cells (red, RNAscope ISH) and CD3 (teal, IHC). (Right) Anti-tumor effects observed following TCR T-cell infusion. *Ramachandran et al, Adaptimmune, ASCO-SITC 2018.*

RNAi AND THERAPEUTIC OLIGO DELIVERY AND BIODISTRIBUTION

Evaluate therapeutic short non-coding RNA delivery, biodistribution, cellular uptake, and persistence at single-cell resolution with spatial and morphological context using the miRNAscope assay. Compatible with IHC/IF for co-detection of RNAi and oligo therapeutics together with target or cell marker protein.

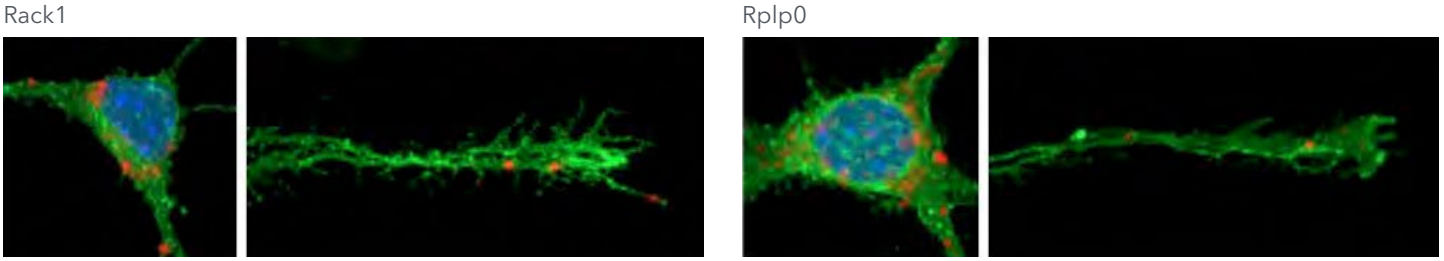


Examples of specific detection of ASO in mouse heart (top) and siRNA in mouse liver tissue (bottom).

> *Our experience working with ACD Bio has been all-around excellent. With their expertise and through clear communication, we developed several assays to detect both RNA and short oligonucleotides in tissue. Compared to standard complementary probes, the signal we obtained using ACD Bio was evident and specific. After seeing the first images, we immediately knew we wanted to use these techniques more frequently."*
>
> *Exicure, R&D Team*

NEUROSCIENCE APPLICATIONS

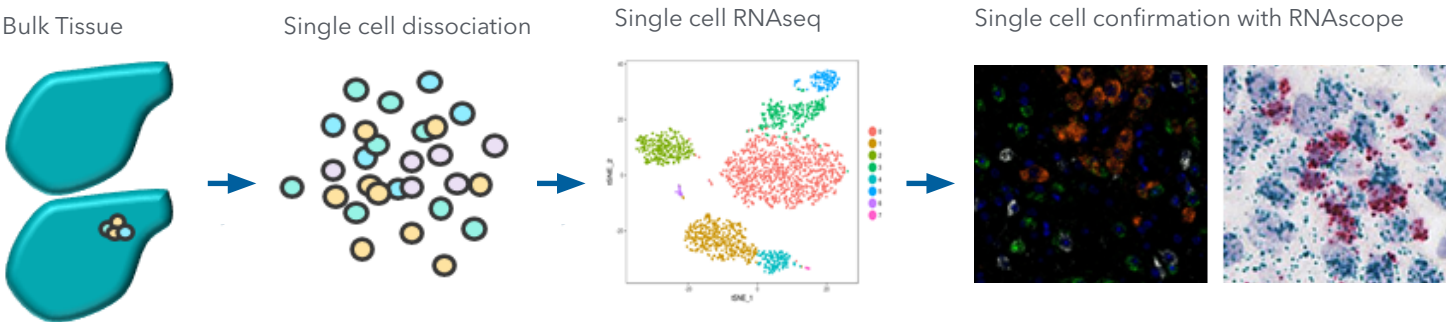
RNAscope and BaseScope are particularly well-suited for evaluating CNS targets given the complexity of the system and the importance of understanding the spatial organization of cellular subtypes GPCRs, growth factors, chemokines, cytokines, and lncRNAs can all be easily detected at the cellular level. Cellular identity can be defined using a variety of validated cell-type markers.



RNAscope 2.5 HD assay (red) for Rack1 or Rplp0 on cultured callosal projection neurons labeled with membrane-GFP (green). Nuclei were stained with DAPI (blue). Poulopoulos *et al., Nature, 2019*.

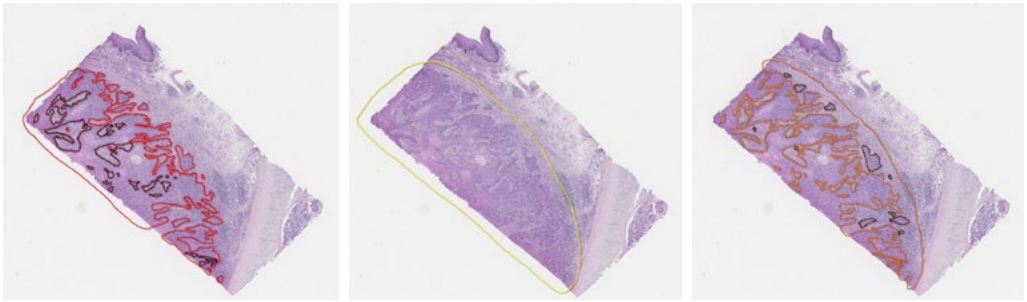
SINGLE-CELL RNAseq VALIDATION

Validation of single-cell RNA sequencing (scRNA-seq) gene expression results can be obtained using the RNAscope ISH assay, which retains spatial organization and provides spatial context. The multiplexing capabilities of the RNAscope Multiplex Fluorescent assay, with simultaneous detection of up to 4 targets, provides pivotal single cell imaging data to confirm and spatially map gene profiles identified by scRNA-seq in complex tissues.

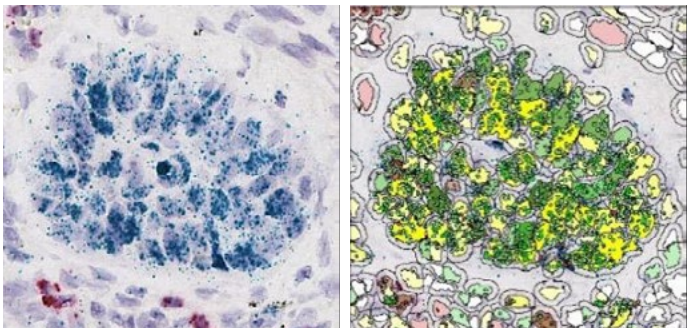


PATHOLOGIST SCORING AND IMAGE ANALYSIS

Scoring and analysis can be performed visually with annotations or histological assessment provided by a pathologist. Pathologist-guided scoring criteria can be used to establish cut-off scores for clinically relevant thresholds. Digital image analysis can also be used to quantify cell-by-cell signal and to assess co-expression in multiplexed assays. Expression is determined by scoring the number of dots per cell, with each dot corresponding to a single RNA molecule.



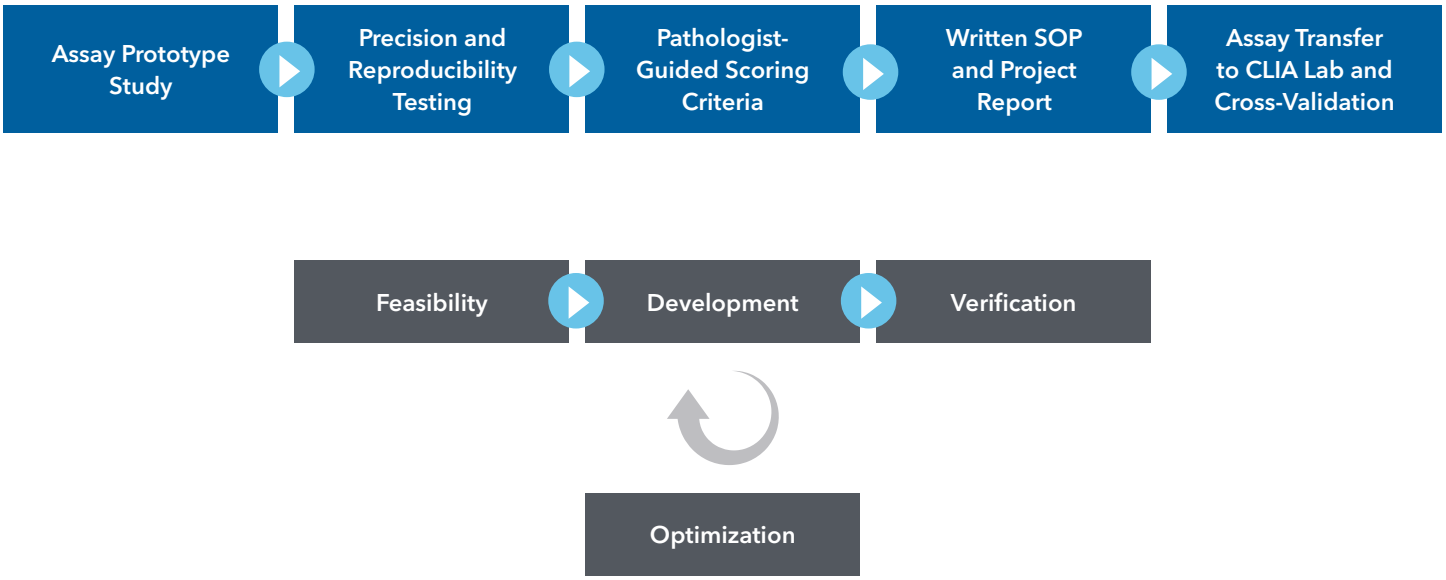
Tumor compartment only | Tumor and tumor-associated stroma | Tumor-associated stroma

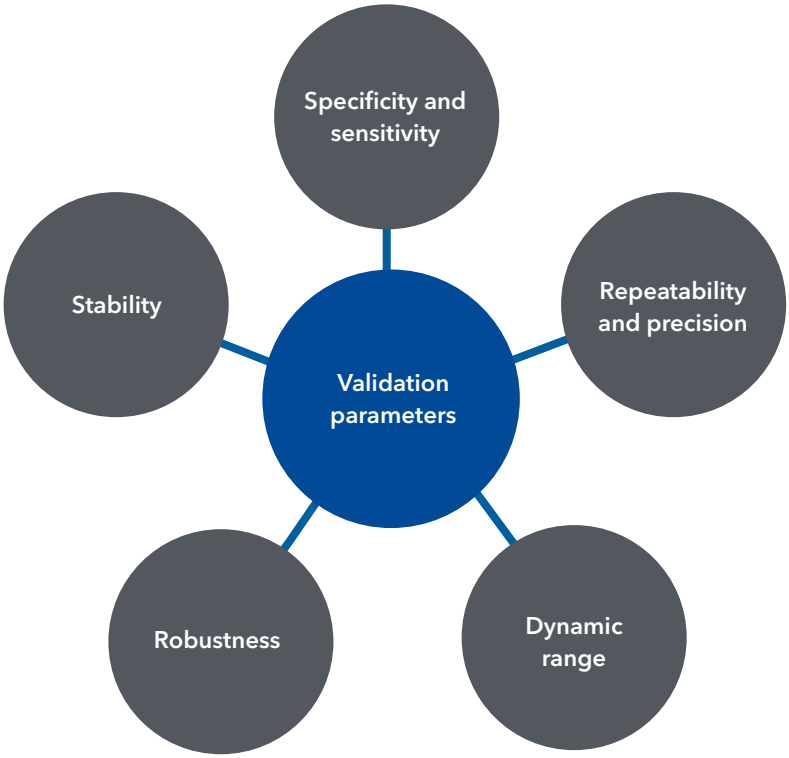


Raw image (left) and HALO™ (Indica Labs) image mask (right) of RNAscope duplex ISH staining of CD45 (red) and PD-L1 (green) in NSCLC tissue.

CDx AND CLINICAL ASSAY DEVELOPMENT

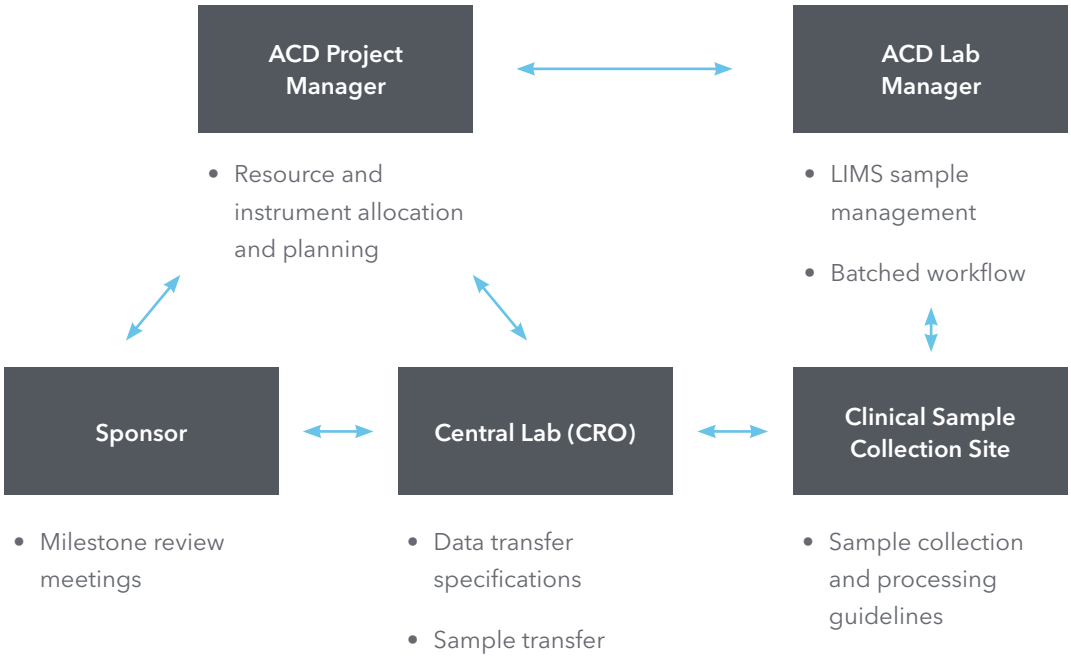
The Professional Assay Services team of scientists, pathologists, and technical experts has over a decade of experience in developing assays for clinical applications and enabling companion diagnostic development. The established workflow includes assay development and optimization followed by demonstration of specificity and sensitivity, stability, robustness, repeatability and intermediate precision, and other validation parameters.





SUPPORTING CLINICAL TRIALS

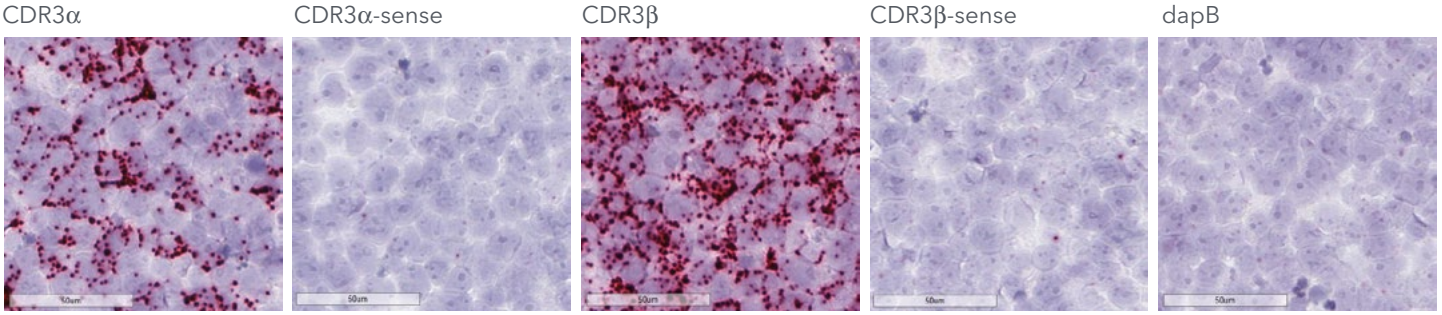
Clinical trials are supported by the experienced Professional Assay Services team, with a dedicated Project Manager who coordinates with the study sponsor, central lab, and the clinical sample collection site via the Lab Manager. Our team serves as consultative partners in the process and provide milestone-based project management. Each step in the process is governed by Standard Operating Protocols (SOPs) that follow Good Clinical Laboratory Practices (GCLP) guidelines.



We can transfer a developed protocol to a qualified laboratory with defined test requirements and acceptance criteria for cross-validation. On-site FAS support is available to facilitate the transfer.

CUSTOM ASSAY DEVELOPMENT

Consult with the Professional Assay Services scientific team to develop a custom assay for specific applications including point mutation detection, ISH/IHC or ISH/IF co-detection, repeat expansion quantification, circular RNA detection, and others. A validated SOP can be transferred in-house with the support of our Field Application Scientist team.



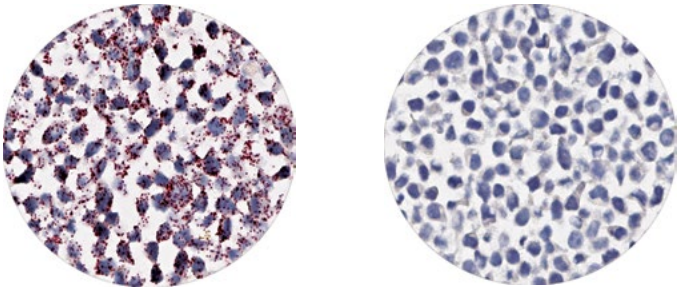
Distinguishing clonal T-cell receptors using the complementary determining region 3 (CDR3).

I have recently submitted several projects with very short timelines because of unexpected budget decision and program needs. The Assay Services team listened, adapted and went the extra mile to meet our needs. I am very impressed by the team striving for success no matter what it will take.

Qing Li, MD, PhD
Principal Scientist

QUALITY SYSTEMS AND SECURITY

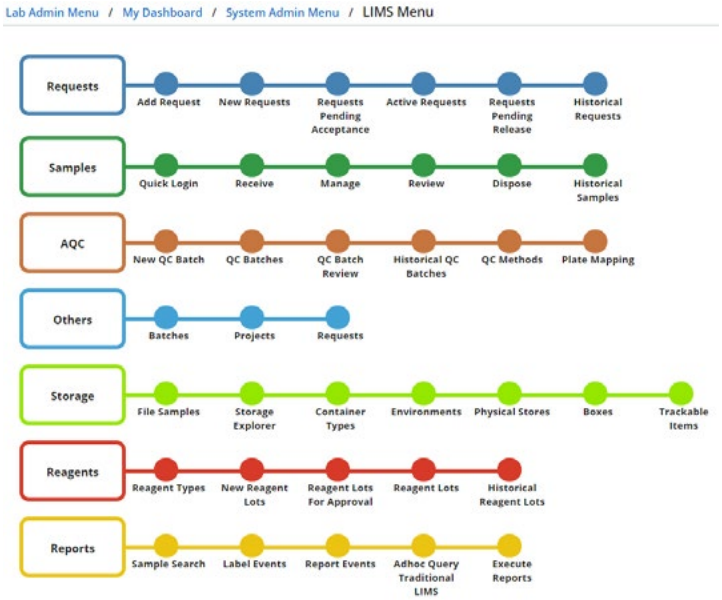
- GCLP (Good Clinical Laboratory Practices) compliant
- Defined sample management workflows
- Standard Operating Procedures (SOPs) Quality Control (QC) workflows and data review
- Run suitability requirements
- Internal reference controls



HeLa cell pellets serve as internal reference controls and are scored against the run suitability criteria to ensure the technical success of each assay run.

DATA PROTECTION

- Secure enterprise file sharing
- Restricted data access
- Electronic laboratory information management system



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