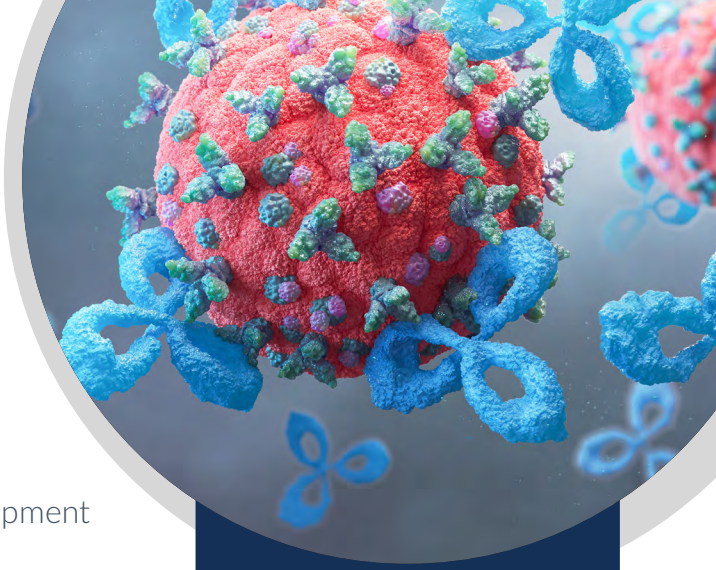
StageBio

Tissue Cross-Reactivity Studies

Identify Tissue-Binding Risk Before First-in-Human Development



- **End-to-End** TCR Delivery
- **3 Full Human** Tissue Panels
- **GLP** Pathology & Reporting

CONSULTING

NECROPSY

HISTOLOGY

IMAGING

PATHOLOGY

BIOREPOSITORY & ARCHIVING

De-Risk Your Therapeutic Candidate

A TCR study helps characterise where an antibody or related biologic binds across normal human tissues. ICH S6(R1) recommends considering human tissue cross-reactivity within the nonclinical safety package for many monoclonal antibodies and related biologics. Planning the study early can help identify unexpected tissue binding and reduce the risk of delays to IND, CTA or first-in-human development.

TCR findings do not independently prove that biological activity or toxicity will occur in vivo. This is why experienced pathology interpretation is essential. As part of StageBio's TCR studies, our pathologists evaluate the location, distribution and intensity of staining and help interpret the potential significance of the findings.

Ask Our Experts

Have you faced challenges in...

- Determining whether your Test Item is ready for TCR evaluation?
- Which controls and tissues should be included?
- How unexpected staining should be interpreted?

A TCR study can identify:

- Expected binding to the intended target
- Previously unrecognised on-target tissue distribution
- Unexpected or potentially off-target binding
- The tissues, cell types and anatomical structures involved

Plan Early | Meet with a TCR Specialist

Discuss your candidate, control strategy, tissue requirements and development timeline with StageBio.

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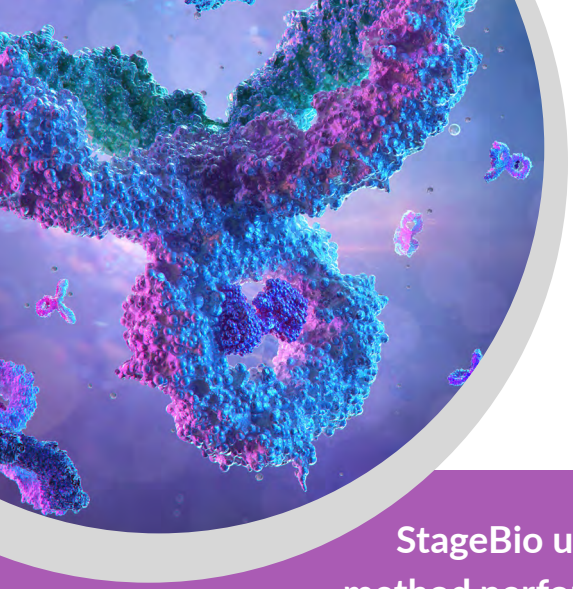

StageBio

From Method Development to **GLP Tissue Screening**

StageBio uses a two-phase approach to establish that the staining method performs reliably before progressing to formal tissue evaluation.

Phase 1: Method Development & Validation

StageBio develops and validates an automated IHC method using the Test Item, Control Item, and suitable positive and negative control tissues.

Includes: Concentration optimization, antigen retrieval, detection setup, platform transfer, and reproducibility testing.

Phase 2: GLP TCR Study

The validated method is applied across three independent full human tissue panels.

A board-certified pathologist assesses staining location, distribution, intensity, and any unexpected binding.

Includes: GLP tissue screening, pathology interpretation, images, summary tables, and final reporting.

Human & Toxicology-Species Tissue Access

- Multiple Full-panel Human Tissue
- Cynomolgus/Rhesus Monkey Tissue
- Rat & Mouse Tissues
- Marmoset Tissues
- Guinea Pig Tissues
- Other Species

Clients may also provide their own FFPE tissues or organs for inclusion.

Expert Pathology Evaluation

GLP-compliant TCR studies designed to support FDA and EMA regulatory submissions

- Where staining occurs
- Which cell types and anatomical structures are involved
- Staining Location, Distribution & Intensity
- Whether findings are expected or unexpected
- Whether staining differs from the matching Control Item
- The potential biological context of the findings

Start Planning Your TCR Study

Not sure every detail is locked in yet? StageBio can review your candidate, flag what's missing, and chart your path from feasibility through GLP screening to final pathology reporting.

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