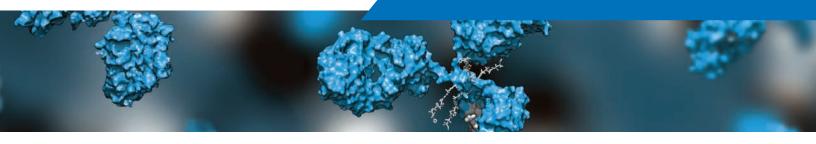


## **ADC In Vitro/In Vivo Characterization Services**



The in vitro and in vivo characterization of ADCs (Antibody-Drug Conjugates) during early-stage R&D is critical to ensure the selection of efficacious and safe drug candidates. In vitro characterization includes the assessment of ADC internalization, stability, specificity, cytotoxic potency cytotoxicity, and antigen binding and developability before and after conjugation to understand the ADC's efficacy to it's target and to elucidate any off-target effects. In vivo characterization, on the other hand, provides critical insights into pharmacokinetics, biodistribution, and toxicity profiles, which are indispensable for predicting how ADCs will perform within a living organism. WuXi Biologics offers comprehensive, one-stop in vitro and in vivo characterization services to assist our clients and enable them to discover the ideal ADC candidate to move into CMC development and on to clinical trials.

#### ADC in vitro Characterization Platform

Comprehensive antibody screening and characterization assays throughout the lead identification and optimization process are provided. We also offer assay development services as required for your specific project needs.

#### ADC in vitro characterization services include:

- Antigen-Antibody binding before and after conjugation
- Internalization analysis: Multiple methods
- · Cytotoxicity and Bystander killing evaluation
- Serum/plasma stability studies



#### The following diagrams and case studies highlight our various capabilities:

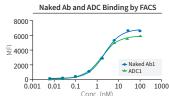
Method 1:

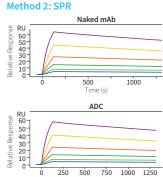
pHrodo based

#### **Antigen-Antibody Binding Before/After Conjugation**

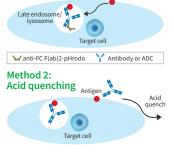
Various binding assays for a thorough evaluation of ADC binding activity: ELISA/FACS/SPR

#### Method 1: FACS

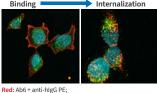




#### **Internalization Analysis**



#### Method 3: Lysosome tracking



Green: FITC stained lysoso Blue: DAPI stained nuclei; : Ab6 co-localized with lysosome.

Time-course experiment can also be provided for real-time internalization tracking.

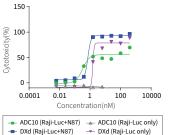
#### Cytotoxicity and **Bystander Killing**

#### High-throughput and quick cytotoxicity assessment

Anti-Fc F(ab)2-payload assay can be used to evaluate the potential of mAbs as ADC candidates

- · Candidate mAbs are pre-incubated with anti-Fc F(ab)2-payload to enable high-throughput and quick cytotoxicity assay without conjugation.
- · Tailor designed Fab-payload for candidate selection

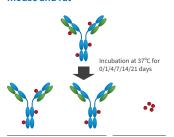
#### **Bystander killing**



ADC showed bystander killing effect to Raji (HER2-) when co-cultured with NCI-N87 (HFR2+).

#### **Serum/Plasma Stability**

#### Serum/Plasma: human, cyno, mouse and rat



- Released payload
- · Free-payload release and drug-to-antibody ratio (DAR) can be assessed by LC-MS in various serum or plasma samples.
- Antigen binding (by ELISA/FACS), total ADC & antibody (by ELISA/LC-MS) can also be tested to evaluate ADC stability.
- · Comprehensive developability evaluation package is available.

### ADC in vivo characterization platform

Our highly-experienced scientists and experts provide the full-spectrum of *in vivo* characterization services including *in vivo* efficacy evaluation of therapeutic antibodies, ADCs and other large molecules for the treatment of tumors and inflammatory disease.

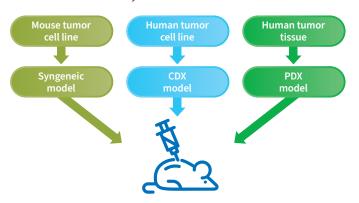
#### Capabilities include:

- Comprehensive in vivo efficacy evaluation models and PK profiling methods
- Extensive capacity for PD and histological evaluation



#### Comprehensive In Vivo Efficacy Evaluation Models and PK Profiling Methods

WuXi Biologics provides an extensive collection of tumor/mouse models for *in vivo* efficacy assessment of ADCs.



WuXi Biologics has established a variety of methods validated for consistency and accuracy, to detect total antibody, total ADC and free drug.

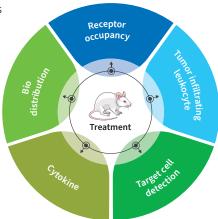
#### **Methods:**

- LC-MS
- ELISA, MSD: Fc-Fc, Fc-Fab, Fc-Drug

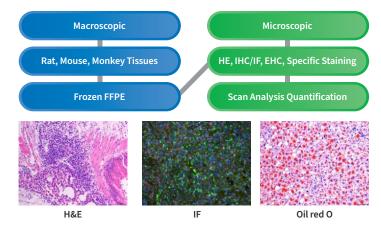


#### **Extensive Capacity for PD and Histological Evaluation**

WuXi Biologics provides high-quality PD evaluation services and has experts with years of experience utilizing FACS, ELISA, MSD and IVIS systems.



We offer comprehensive, high-quality pathology services utilizing advanced instruments.



#### **About WuXi Biologics**

WuXi Biologics is a leading contract research, development and manufacturing organization (CRDMO) that provides end-to-end capabilities to healthcare organizations worldwide. With operations in China, the United States, Ireland, Germany, and Singapore, we enable our partners to effectively and efficiently bring biologics and vaccines to patients worldwide through our comprehensive and high-quality drug development model.

 $\label{thm:concept} \textbf{The world's leading global single-source platform from concept to commercialization.} \\$ 

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# **Learn more:**ADC *In Vitro/In Vivo*Characterization Services

