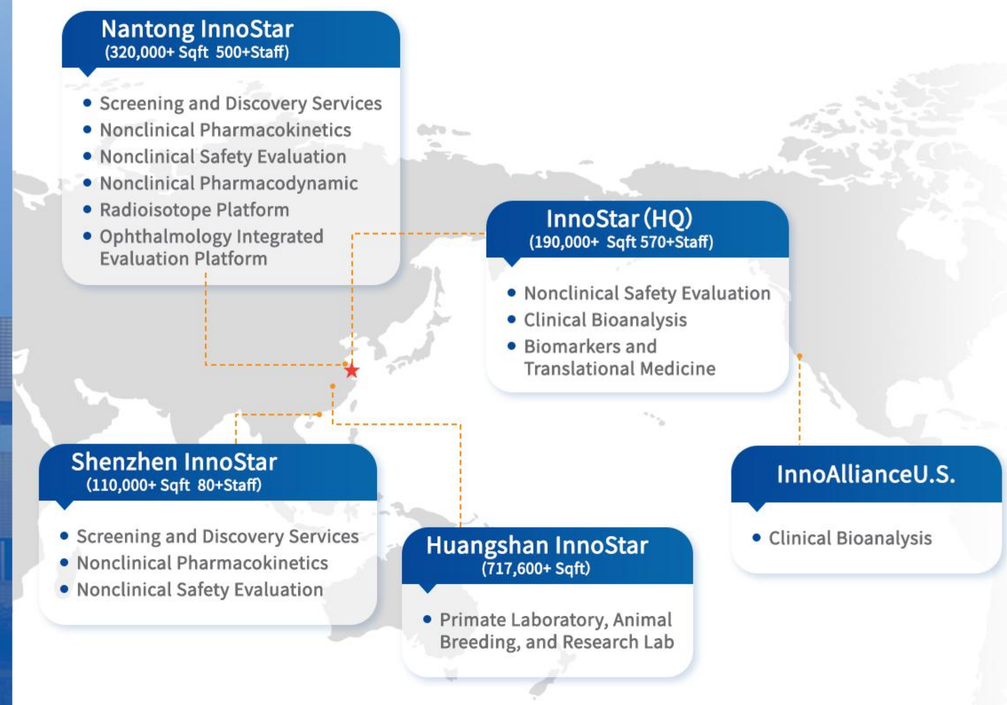
InnoStar

Biomarkers and Translational Research Platform

Specializing in R&D Services and
Empowering the Healthcare Industry

Shanghai InnoStar Bio-tech Co., Ltd. (InnoStar) was established in 2010. As a leading contract research organization, we strive for excellence through our services with high quality, win customers by recognized reputation, add values by technical innovation, and maintain efficiency by streamlined management. Our business scope covers screening and discovery services, nonclinical pharmacodynamics, nonclinical pharmacokinetics, nonclinical safety evaluation, clinical sample bioanalysis, biomarkers and translational research. InnoStar was listed on the STAR Market of Shanghai Stock Exchange on September 3, 2024 (Stock code: 688710).



NMPA GLP AUT | U.S.FDA GLP INSP | OECD GLP AUT | AAALAC AUT | 美国CAP AUT

SCOPE OF BUSINESS

InnoStar Provides One-stop Service From Nonclinical to Clinical Translation

PCC
- Screening and Discovery Services

IND
- Nonclinical Pharmacodynamics
- Nonclinical Pharmacokinetics
- Nonclinical Safety Evaluation

NDA
- Clinical Biological Sample Testing
- Biomarkers and Translational Research

Services of differentiated solutions designed by experts covering the life cycle of drug development

PROJECT EXPERIENCE

920+
Already served
New drug development clients

100+
Annual average IND package completed amount

30+
Annual NDA/BLA package completed amount

200+
We have served on both international and domestic "first-of-its-kind" innovative drug research and development projects.

140
Overseas IND Application Successful

3
FDA NDA/BLAs

Note: Data statistical interval: 2015-2024.12.31

Scan the QR code for more business inquiries

Table of Contents

Biomarkers and Translational Research Platform

Platform Introduction

InnoStar operates a cutting-edge Biomarker and Translational Research Platform designed to accelerate innovative drug development. Our platform delivers comprehensive, end-to-end biomarker services spanning discovery, validation, and clinical implementation.

By integrating cutting-edge technologies such as genomics, proteomics, and single-cell sequencing, the platform supports key aspects of drug development, including target identification, mechanism elucidation, patient stratification, and efficacy prediction. Utilizing high-throughput sequencing, multiplex immunohistochemistry (IHC) analysis, multiplex protein and cytokine detection, as well as flow cytometry, the platform enables precise biomarker screening and functional validation. This accelerates drug development, enhances clinical trial success rates, and provides scientific and technical support for companion diagnostic strategies in new drug development

Services

Pathology Platform

- Clinical immunohistochemistry (IHC) method development
- validation, and sample analysis (CAP-compliant)
- Preclinical IHC development and testing
- Patient enrollment
- Companion diagnostic product development
- RNAscope
- Pathologist review
- Digital pathology analysis

Protein Biomarker Detection Platform

- Soluble biomarker detection
- Cytokine panel detection
- ELISpot detection

NGS Platform

- Viral integration and off-target analysis
- TCR immunorepertoire sequencing
- RNA-seq
- ctDNA panel detection
- Single-cell sequencing

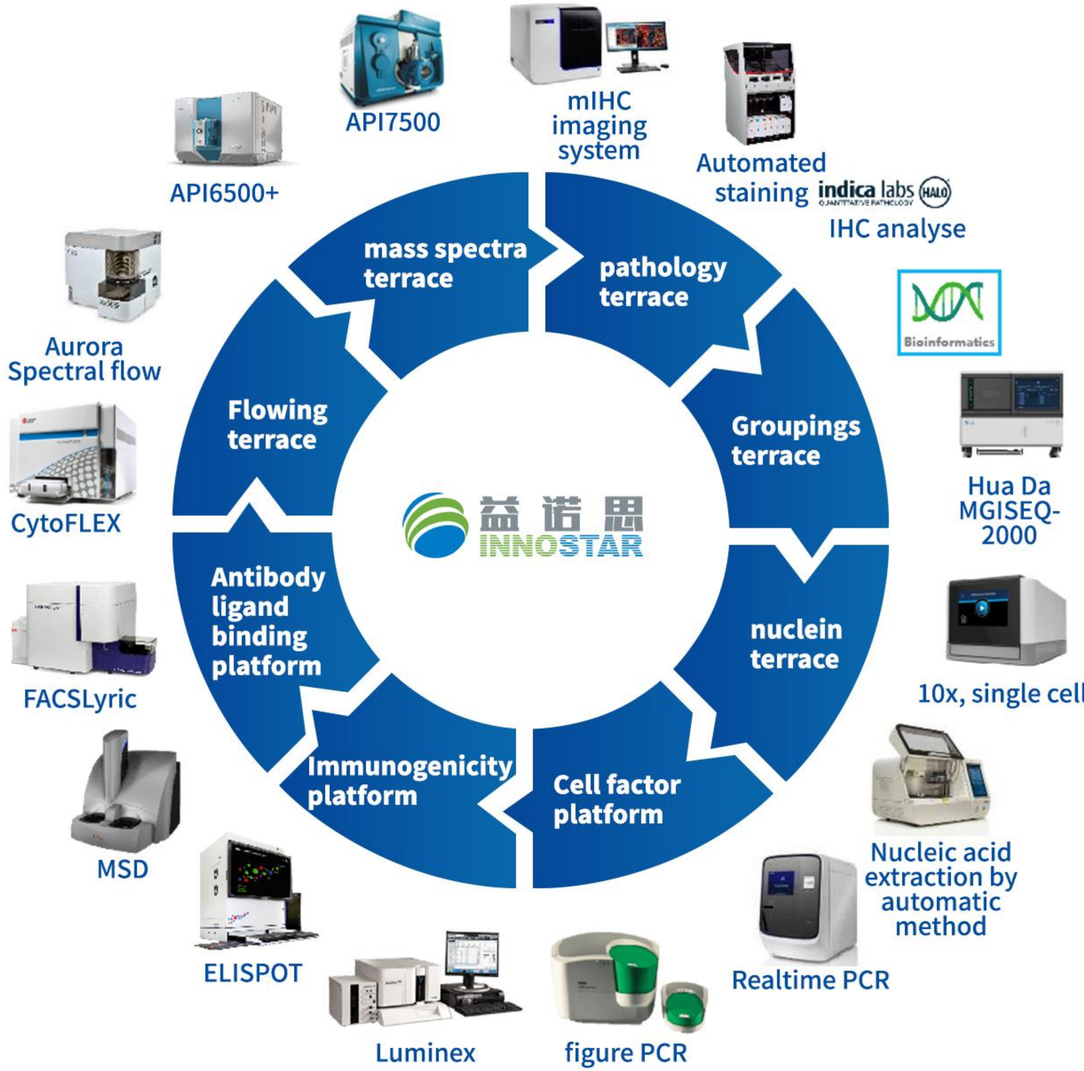
Flow Cytometry Analysis Platform

- Receptor occupancy detection
- Immune cell phenotyping

Mass Spectrometry Platform

- Endogenous biomarker detection

Bioanalytical Platform



Pathology platform

Opal kit Bond RX Automatic staining | **Akoya Vectra Polaris scan** | **HALO image analysis**

service content

- Clinical immunohistochemistry development and validation (in accordance with CAP)
- Multi-color immunofluorescence Panel was customized and validated
- Assist in the development of diagnostic products
- convention H&E
- ISH/FISH
- RNAscope

Verified / in the verification checklist

- Immunohistochemistry: PD-L1, Retinoblastoma protein, Claudin18.2, MMR, TROP2, ER, Her2
- Multi-color immunofluorescence (focused on tumor immune microenvironment)T cells, NK cells, macrophages, immune checkpoints, TLS, tumor markers, etc

HALO module

- Multiplex immunohistochemistry/Immunofluorescence analysis
- organization somatotype
- organization slug
- vacuole quantify
- space analyse
- Bright field / fluorescence Area quantification
- RNA scope ISH/FISH quantify

The pathology platform has obtained CAP accreditation.

COLLEGE of AMERICAN PATHOLOGISTS
Laboratory Quality Solutions

COLLEGE of AMERICAN PATHOLOGISTS

CERTIFICATE OF ACCREDITATION

Shanghai InnoStar Bio-Tech Co Ltd
Immunohistochemistry Lab
Shanghai, China
Yan Zhang, MD

CAP#: 9746264

The organization named above meets all applicable standards for accreditation and is hereby accredited by the College of American Pathologists' Laboratory Accreditation Program. Reinspection should occur prior to **January 21, 2027** to maintain accreditation.

Accreditation does not automatically survive a change in director, ownership, or location and assumes that all interim requirements are met.

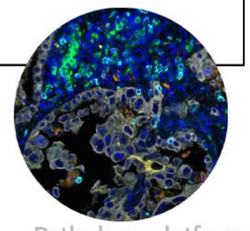
Kathleen G. Beavis, MD
Chair, Accreditation Committee

Donald S. Karcher, MD, FCAP
President, College of American Pathologists

CAP ACCREDITED

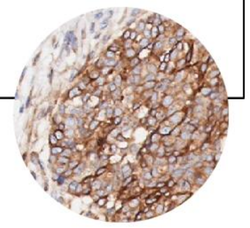
Experience in multiplex immunofluorescence

Drug type	R&D phase	mIF
TLR agonist	Clinical phase I	▪ T cells ▪ Protein expression: Immune checkpoint, dendritic cell antigen
Cytokine-based therapies	Clinical phase I	▪ T cells, NK cells ▪ PD-L1, Pan-CK
Oncolytic virus	Clinical phase I	▪ Immune cell (T cell, activation and proliferation) ▪ Macrophages (M1/M2), dendritic cells, leukocytes
ADC	Pre-clinical	▪ T, B, NK cells
In-house development	--	▪ Cancer-associated fibroblasts (CAFs) / Cancer-associated macrophages (CAMs): CD206, CD68, α-SMA, CD163, PDGFR, FAP (patent application accepted
In-house development	--	▪ CD3, CD4, CD8, PD-1, PD-L1, Pan-CK



Clinical Immunohistochemistry Testing Cases

Drug	Clinical Stage	IHC
CAR-T	IIT	▪ CAR-T Target Expression (CD24, enrolled)
Oncolytic Virus	Phase I	▪ Viral Expression (1 marker) ▪ Biomarkers related to oncolytic virus therapy (2 markers)



List of IHC-validated antibodies

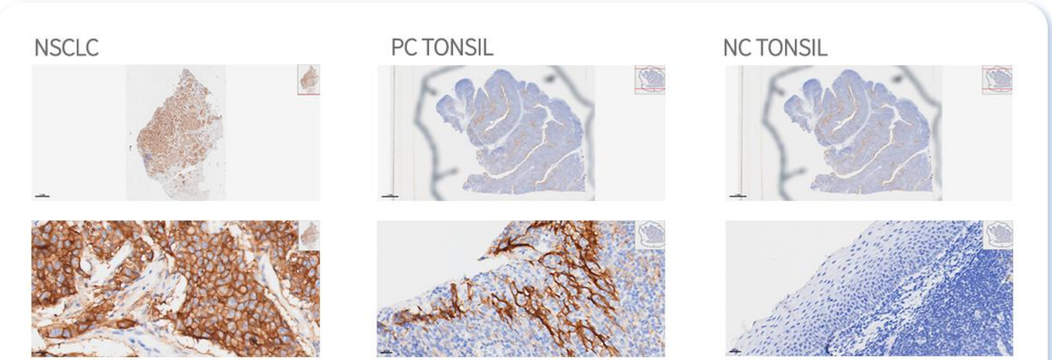
Testing indicators	Species	organization
MMP-13	rabbit	cartilage
collagen type II	rabbit	cartilage
collagen type II	rabbit	cartilage
TH, tryrosine hydroxylase	rat	substantia nigra
tyrosinase	mouse	skin
GBA	mouse	skin
CD68	mouse	spleen, lung, bone marrow, liver, brain
C3	mouse	kidney
IgG	mouse	kidney
MAT2A	mouse	lung
IbaI	monkey	striatum
GFAP	monkey	striatum
AADC	monkey	striatum
GDNF	monkey	striatum
salmonella	mouse	tumor
diphtheria toxin	mouse	tumor
HIF-1	mouse	tumor
HMB45	rabbit	skin
CD3	monkey	spleen
CD4	monkey	spleen
CD8	monkey	spleen
CD56	monkey	spleen
Ki67	monkey	spleen
MYBPC3	rabbit	liver, heart
GBA	rat	multiple organs
alpha-SMA	rat	musle
Collagen type I	rat	musle
Pan-CK	mouse	tumor model
p-ERK	mouse	tumor model
ATP7B	mouse/rat/monkey	liver
Her3	monkey	multiple organs
EGFR	monkey/human	multiple organs/cancer
TROP2	monkey/human	multiple organs
PD-L1	human	cartilage
c-met	human	cartilage
dMMR	human	cartilage
Claudin 18.2	human	cartilage
RB protein	human	cancer
C3	mouse	kidney
IgG	mouse	kidney
C3	Rat	kidney
IgG	Rat	kidney
C3	Monkey	kidney
IgG	Monkey	kidney
PEG	mouse	kidney

Testing indicators	Species	organization
PEG	Monkey	skin, kidney, spleen, lymph node, uterus
GDNF	Monkey	Testes
FOXJ1	mouse	brain
FOCG1	mouse	brain
PAX6	mouse	brain
TUJ1	mouse	brain
Ki67	mouse	brain
S100-β	mouse	brain
KU80	mouse	brain
EMA	mouse	brain
RPE65	Monkey	eye

Typical Case of Immunohistochemical Detection: PD-L1

Manufacturer	MJ Biotech
clone	E1L3N
Host	Rabbit
Drug	OPDIVO

PD-L1 Test Results	Judging Criteria
Negative (-) Staining	▪ Non-squamous non-small cell lung tumor:TC<1% or no target staining in tumor cells.
Positive (+) staining	▪ Non-squamous non-small cell lung tumor:TC21%6, cell membrane staining signal is seen in tumor cells



PD-L1 performance confirmation: consistency comparison with CAP certification laboratory

Pathology platform

Performance confirmation

order number	Sample number	Results are judged	Reference results	Comparison results
1	E05A0017-B30-C2-02	negative	negative	true negative
2	E05A0018-B30-C2-02	negative	negative	true negative
3	E05A0020-B30-C2-02	negative	negative	true negative
4	E05A0037-B30-C1-02	negative	negative	true negative
5	E05A0039-B30-C1-02	negative	negative	true negative
6	E05A0048-B30-C1-02	negative	negative	true negative
7	E05A0093-B30-C2-02	negative	negative	true negative
8	E05A0176-B30-C1-02	negative	negative	true negative
9	E05A0297-B30-C1-02	negative	negative	true negative
10	E05A0311-B30-C1-02	negative	negative	true negative
11	E05A0218-B30-C1-02	positive	positive	TP
12	E05A0118-B30-C1-02	positive	positive	TP
13	E05A0578-B30-C1-02	positive	positive	TP
14	E05A0806-B30-C1-02	positive	positive	TP
15	E05A0949-B30-C1-02	positive	positive	TP
16	E05A0075-B30-C1-02	positive	positive	false positive
17	E05A0085-B30-C1-02	positive	positive	TP
18	E05A0118-B30-C2-02	positive	positive	TP
19	E05A0142-B30-C3-02	positive	positive	TP
20	E05A1241-B30-C1-02	positive	positive	TP

Performance confirmation comparison results

	The result was positive	The result was negative
Positive for detection	9	1
The test was negative	0	10
amount to	9	11
Positive consistency rate	100.00%	
Consistency rate of negative	90.91%	
Overall agreement rate	95.00%	

NGS terrace

service content

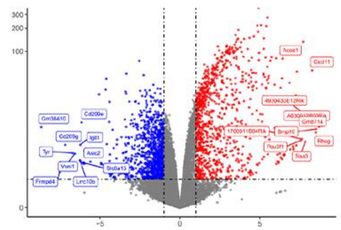
- **Detection matrix type:**
  - -Whole blood/plasma/serum
  - -Urine/bowel
  - -Fresh/frozen/FFPE tissue

Hua Da MGISEQ-2000

Qsep100 Fragment analyzer

Covaris Breaker

- **Types of nucleic acid detection:**
  - -DNA
  - -mRNA
  - -ctDNA
  - -16sRNA



Bioinformatics server and personalized analysis

10x single cell droplet workstation

Lentivious integration analysis

- LM-PCR
- LAM-PCR
- LTE-PCR

WES/WGS/mRNA

- Tumor mutation load calculation
- genetic screening
- gene fusion

Onco Panel

- Discovery and detection of biomarkers
- Tumor diagnosis and early screening
- Pharmacodynamic prediction

PK testing of non-editorial cell products

- TILs PK
- TCR diversity detection

SNP/CNV/INDEL

- Cancer driving mutation gene found
- Progression detection
- HLA typing

Single Cell Sequencing

- Mechanism of action and tumor development
- Single cell transcriptome & immune repertoire
- Surface protein detection was also performed

cf DNA

- cfDNA MRD
- Patient enrollment screening and efficacy prediction

Microbial identification 16S/18s rRNA

- Bacterial identification

AAV integration analysis

- TES probe capture

Protein biomarker detection

There are validated detection methods such as combination of inflammatory cytokines, TGF-β combination and chemokine combination (partially validated) to maximize the time and economic cost for customers

Protein analysis technology platform

-ELISA
-MSD
-Simoa
-Luminex
-ELISpot

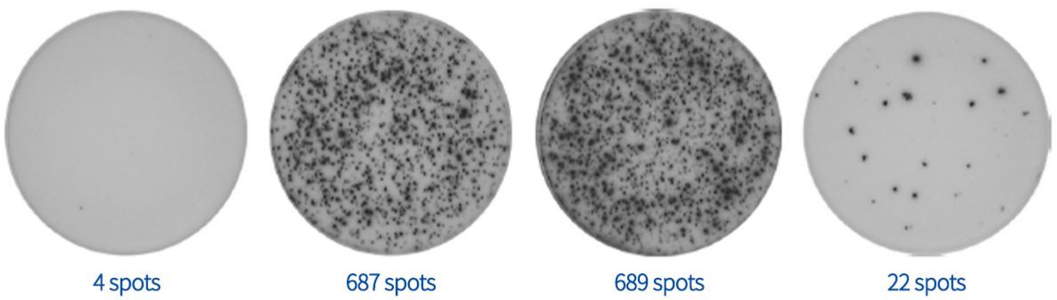
clinical applicability

-tumour
-Metabolic diseases, etc
-Endocrine system

service content

- Analysis of soluble drug markers (PD biomarker)
- Single factor, multi-factor cytokine analysis (Cytokines detection)
- Cytokine release assay (Cytokine release assay)

ELISPOT



Flow analysis platform

service content

- Receptor occupancy assay
- Immune phenotyping
- Other applications
  - -Cell proliferation analysis
  - -Cell apoptosis analysis

RO project

- CD47
- PD-1
- PD-L1
- CD3
- SIRP
- LAG3
- TIGIT
- IL-4R
- OX-40
- CD73
- CD39
- CLEC12A
- BTLA
- BTK
- TIM3

Cell phenotype

- CD3/CD4/CD8 /CD127 /CD45/CD25/CD16/CD56/Foxp3/CD27/CD69/CD11c, CD303/CD11b/Ki67……

Beckman Cytoflex

-4 laser 13 colors / 3 laser 10 colors

Cytek Aurora Full-spectrum flow cytometer 5 laser full spectrum

-Support single cell level and highly complex schemes
-Support all kinds of customized solutions

BD Lyric

-3 lasers, 12 colors

INNOSTAR

益诺思 INNOSTAR

Shanghai InnoStar Bio-tech Co., Ltd.

SHANGHAI HEADQUARTERS

No. 199 Guoshoujing Road, China (Shanghai) Pilot Free Trade Zone

BUSINESS CONSULTING

Tel:+86-21-60211999

Email: services@innostar.cn marketing@innostar.cn

Scan the code to follow