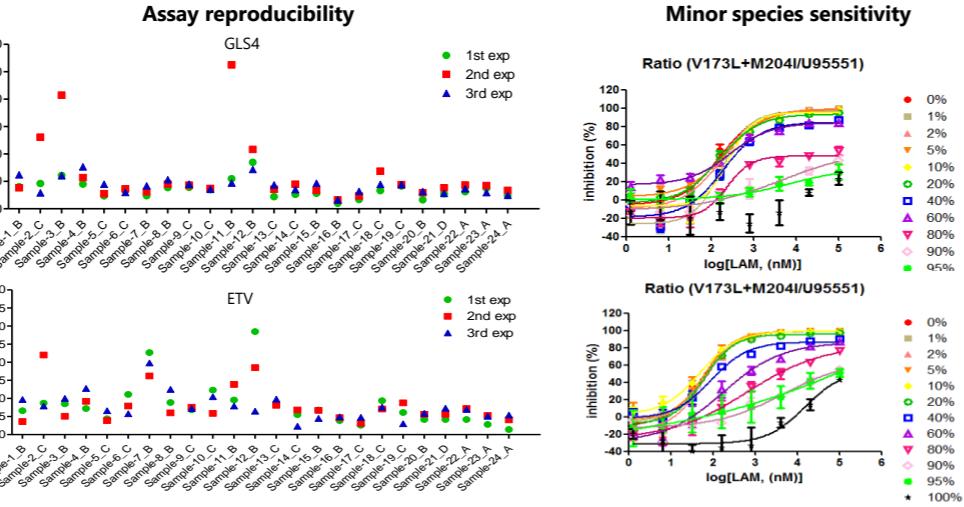


HBV Phenotyping Assays

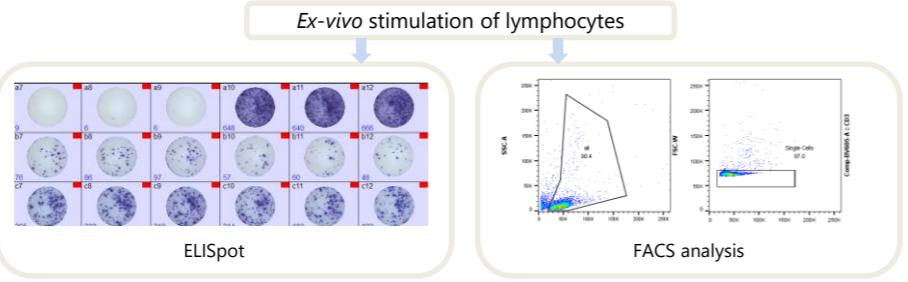
- Full-length, pol/RT and core gene replication-competent shuttle vectors
- Fitness test for HBV clinical constructs: >400 constructs evaluated
- Drug susceptibility: >1000 compounds/constructs evaluated

HBV titer (log ₁₀ copies/ml)	PCR success rate
8-9	100% (2/2)
7-8	100% (3/3)
6-7	100% (3/3)
5-6	75% (3/4)
4-5	100% (4/4)
3-4	100% (4/4)
2-3	33.3% (1/3)
Total	87% (20/23)



Immunological Assays

- Isolation of PBMC
- T and B cell ELISpot
- FACS analysis
- Intracellular staining (ICS)



Other Assays

Oncolytic virus

- Immunogenicity tests
 - NAB detection
- Biodistribution/PK tests
 - Q-PCR detection with serum, saliva or urine
 - Plaque assays and TCID₅₀ for detection of infectious virus shedding
 - Virus replication in tumor: IHC
- Immune responses
 - Transgene expression/functional assay
 - Cytokines and inflammation
 - Immune cell activation

CAR-T/TCR-T

- RCL/RCR Assay
- Vector copy number
- TCR sequencing
- T cell phenotype or differentiation
- Cytokine or chemokine expression and secretion
- LDH (lactate dehydrogenase) assay
- IFN-gamma ELISpot
- FACS

WuXi AppTec

Clinical Virology and Advanced Therapy

Platforms Research Services

Contact

Zhengxian Gu
Executive Director
Mobile: +86 189-3083-0132
Tel: 86-21-5046-3753
Email: gu_zhengxian@wuxiapptec.com

www.wuxiapptec.com
www.wuxibiology.com


The CAP Accredited Molecular Testing Laboratory

Biomarker Platform

- Clinical virology
- Oncolytic virus pharmacokinetics (PK) and pharmacodynamics (PD)
- Vaccine immune responses
- Cell therapy PK and PD



Technologies

- qPCR, RT-qPCR, ddPCR
- Line probe assay: LiPA
- Sanger and NGS
- ELISA
- Multiplex immunoassays: Luminex and MSD
- Immunological assays: antigen and antibody detections, ELISpot and FACS
- Virus infection assays: TCID₅₀, plaque assay, neutralization antibody, virus isolation from clinical samples, etc.



Clinical Experiences

HBV clinical support

- Viral load determination
- Phenotyping
- Whole genome sequencing
- Sanger sequencing of pol-RT gene
- INNO-LiPA HBV Multi-DR assay
- HBV serological markers: HBsAg, HBsAb, HBeAg, HBeAb and HBcAb, HBcrAg, cytokines
- HBV RNA quantification
- HBV RNA sequencing
- ISGs and cytokines
- Human gene testing
- HBV vaccines: Antigens and antibodies, immunological markers by ELISpot and FACS

HCV clinical support

- Deep sequencing
- Sanger sequencing
- Clonal sequencing
- Genotyping
- RNA VL
- Phenotyping

RSV clinical support

- Virus identification from NP swabs
- Genotyping: qPCR and sequencing
- Sanger population and clonal sequencing: F and G genes
- RNA VL: qPCR and plaque assay
- Virus isolation: propagation TCID₅₀ titration

Cell therapy support

- VCN
- RCL
- Cytokines
- IFN-γ ELISpot
- FACS
- ADA
- Nab

Other clinical support

- NASH
- Oncolytic virus
- Human genes: CYP2D6, IL28B, TLR, UGT1A9, UGT1A1, etc.
- Gene expression

Particular Solutions

Clinical virology

Viral load, sequencing, genotyping, TCID₅₀, phenotyping, virus isolation and characterization, serology

Vaccines

Detection of antigen, antibody and virus, titration of neutralization Ab, assessment of evaluation of cellular immune responses and cytokines

Advanced therapies (Viral vector and cell therapies)

Vector copy number and RCL by qPCR, T cell phenotype, cytokine/chemokine expression and secretion, cytotoxicity assay, titration of neutralization Ab, PK by qPCR, plaque assay, TCID₅₀ and IHC, transgene expression and functional assays, cytokines and inflammation markers, immune cell activation

Genotyping and biomarkers

Biomarkers for NASH, CYP2D6, IL28B, UGT1A9 genotyping, Gene expression by RT-qPCR, NGS

WuXi HBV Clinical Virology Platform

HBV Genotyping Assays

Test	Method	Standard	Status
HBV DNA VLD	COBAS	CAP	In service
	ddPCR	CAP	In service
HBV whole genome sequencing	Sanger	CAP	In service
	NGS	Non-CAP	
HBV pol-RT sequencing	Sanger	CAP	In service
HBV core sequencing	Sanger	CAP	In service
HBV RNA quantification	qPCR	CAP	In service
HBV RNA sequencing	Sanger	Non-CAP	In service

HBV Serology Assays

Test	Method	Quantitative/qualitative	Standard/Status
HBsAg	ECL	Quantitative	CAP/In service
Anti-HBs	ECL	Qualitative	
HBeAg	ELISA	Quantitative	
	ECL	Qualitative, semi-quantitative	
Anti-HBe	ECL	Qualitative, semi-quantitative	
Anti-HBc	ECL	Qualitative, semi-quantitative	
Serum HBcrAg	LumiPulse G1200	Quantitative	

Other Markers

Test	Method	Standard	Status
HBV phenotyping	HBV full-length, pol and capsid shuttle vectors	Non-CAP	In service
IFN-γ	ELISpot	Non-CAP	In service
Immunological markers	FACS	Non-CAP	In service
Cytokines	Luminex, MSD, ELISA	CAP non-CAP	In service
ISG gene expression	RT-qPCR	CAP	In service