



中国动物卫生与流行病学中心
China Animal Health and Epidemiology Center

Current progress of Diagnostic Technologies and Vaccine Research in China

Shengqiang Ge, PhD



National Reference Laboratory
ASF | BSE



WOAH Reference Laboratory
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PPR

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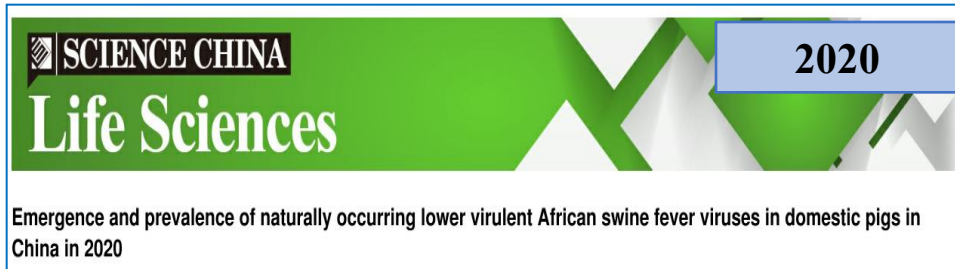
1. Types of ASFV strains circulating



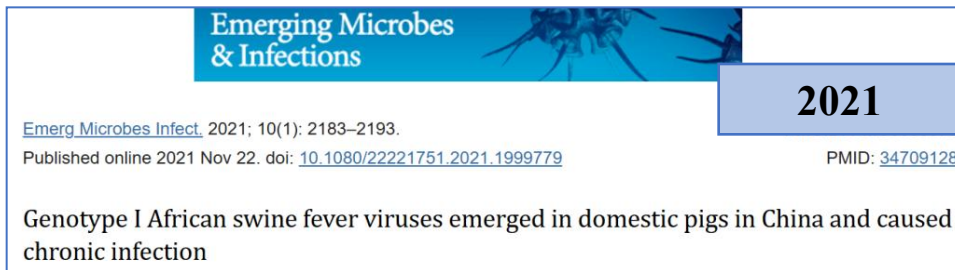
Types of ASFV strains circulating in China



The first outbreak was a **genotype II highly virulent strain** that caused acute clinical symptom in **2018**



Emergence and prevalence of naturally occurring **genotype II lower virulent strain** in domestic pigs in **China in 2020**



Genotype I strain 2021 (NH/p68-like strain) emerged in domestic pigs in China and caused chronic infection in



Highly lethal genotype I and II recombinant strain detected in pigs in **2021**



2. Establishment of Diagnostic System for ASF



Establishment of Diagnostic System for ASF

Manual of Diagnostic Tests and Vaccines
for Terrestrial Animals, thirteenth edition 2024



Figure 1. Test methods available and their purpose

Method	Purpose					
	Population freedom from infection	Individual animal freedom from infection prior to movement	Contribute to eradication policies	Confirmation of clinical cases	Prevalence of infection—surveillance	Immune status in individual animals or populations post-vaccination
Agent identification						
Virus isolation/ HAD test ¹	n/a	n/a	++	+++	++	n/a
FAT	n/a	n/a	++	++	+	n/a
ELISA for antigen detection	+	++	+	+	+	n/a
Conventional PCR	++	++	++	++	++	n/a
Real-time PCR	+++	+++	+++	+++	+++	n/a
Detection of immune response						
ELISA	+++	+++	+++	+	+++	n/a
IPT [*]	+++	+++	+++	+	+++	n/a
IFAT [*]	+++	+++	+++	+	+++	n/a
IBT [*]	++	++	++	+	++	n/a

Key: +++ = recommended method, validated for the purpose shown; ++ = suitable method but may need further validation; + = may be used in some situations, but cost, reliability, or other factors severely limits its application; n/a = not appropriate for this purpose; n/a = purpose not applicable.
HAD = haemadsorption; FAT = fluorescent antibody test; ELISA = enzyme-linked immunosorbent assay; PCR = polymerase chain reaction; IPT = indirect immunoperoxidase test; IFAT = indirect fluorescent antibody test; IBT = immunoblotting test.
^{*}Recommended method as confirmatory serological test.

National Standard of the People's Republic of China

ICS 11.220
B 41

GB

中华人民共和国国家标准

GB/T 18648—2020
代替 GB/T 18648—2002

National standard for
Diagnostic Techniques for ASF

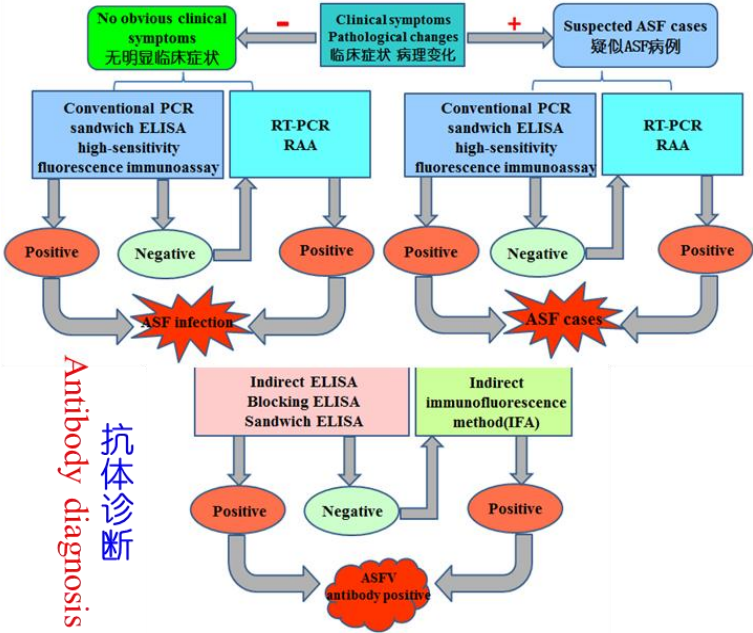
Diagnostic techniques for African swine fever

2020-12-14 发布

2020-12-14 实施

国家市场监督管理总局
国家标准化管理委员会 发布

病原诊断
Etiological diagnosis



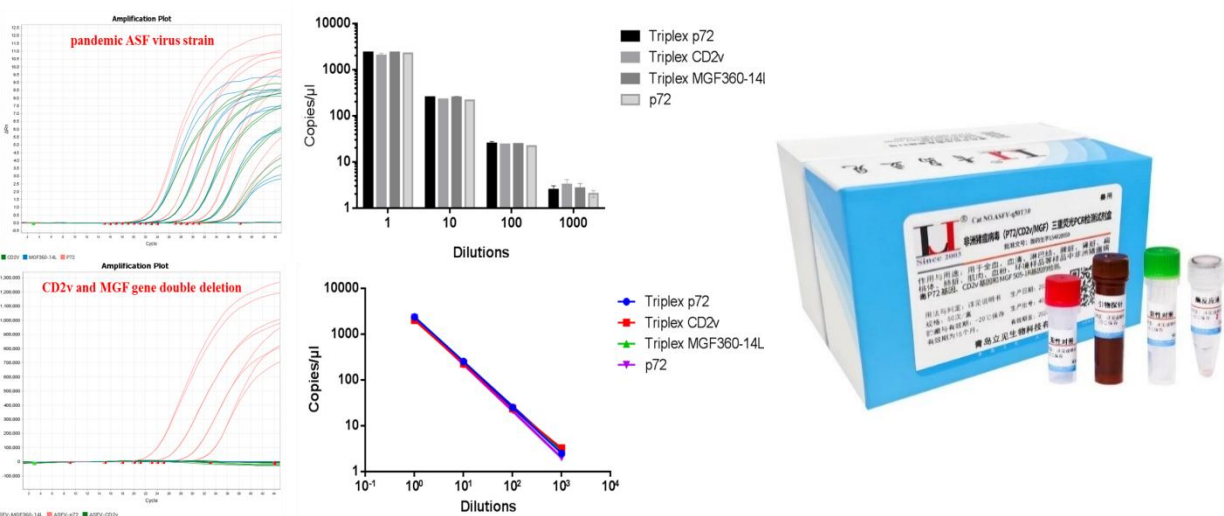
As of July 2025, **26 diagnostic kits** have been evaluated and approved by China Institute of Veterinary Drug Control of MARA, including **20 pathogen detection kits** and **6 ELISA antibody detection kits**.



Establishment of Diagnostic System for ASF

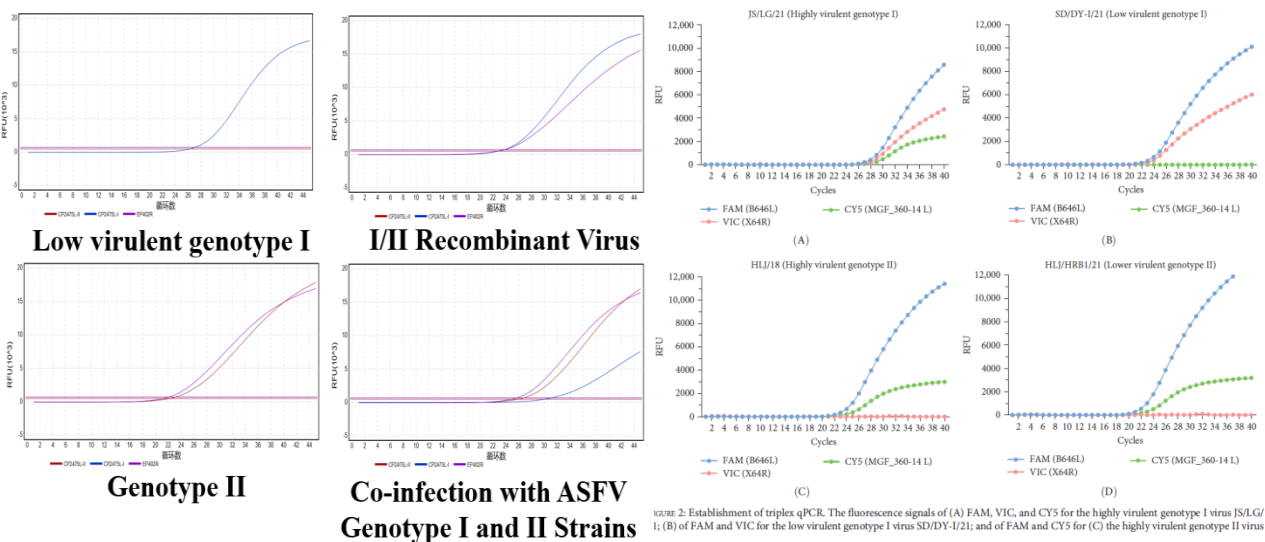
Testing Method for Differentiation of Unauthorized Vaccine-Derived Strains

WOAH Terrestrial Manual (2024, Chapter 3.8.5)



P72/CD2v/MGF360-14L Triplex qPCR Assay Kit, licensed as a novel veterinary medical product, was developed by CAHEC . The kit enables confirmatory diagnosis of the attenuated strain ASFV-7GD (seven-gene-deleted **Engineered** attenuated strains). It is currently the only licensed in vitro diagnostic (IVD) product for differential detection of engineered strains on the global market."

Testing Methods for Differentiation of three kinds strains circulating in China

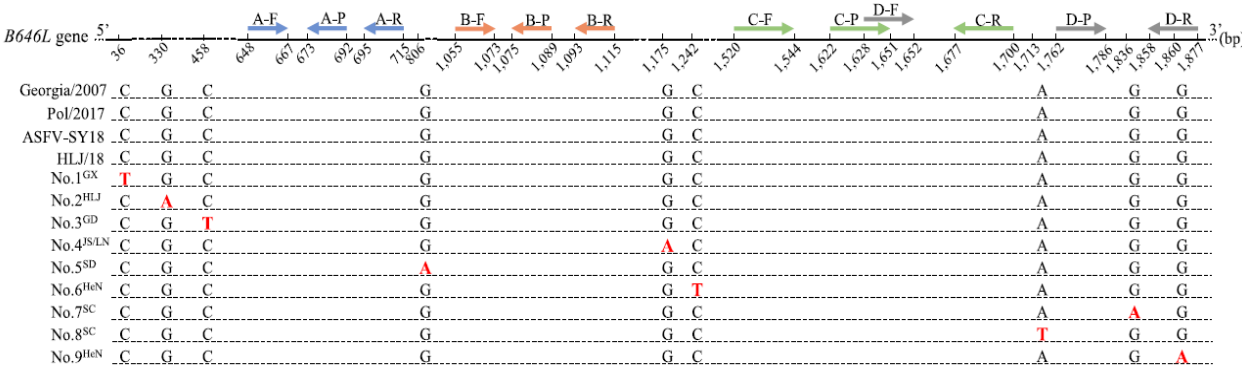


Transboundary and Emerging Diseases, 2024, 12, 1754.

Two Triplex qPCR methods were established for differentiating Genotype I/II Recombinant Virus from low-virulence genotype I and genotype II ASFV strains circulating in China by CAHEC and HVRI respectively. Specifically emphasized that the method by CAHEC enable definitive confirmation of co-infection with Genotype I and II strains

Establishment of Diagnostic System for ASF

Genomic Surveillance of ASFV Variants with Concurrent Validation of Current Diagnostic Assays



Journal of Infection 89 (2024) 106351

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journal homepage: www.elsevier.com/locate/jinf



Table 1. Effect of *B646L* mutations on the qPCR recommended by WOA and commercial ASFV detection kits in China

No.	qPCR detection kit	Ct value detected by using viral DNA with different mutations in the <i>B646L</i> gene						Positive control	Negative control	Result
		No mutation ^{&}	Mutation							
			No.2	No.3	No.4	No.5	No.9			
1	qPCR recommended by WOA ^H *	35.01	35.38	35.22	34.07	33.48	34.35	26.45	-	+
2	A	33.47	35.07	33.78	33.37	32.28	33.73	24.97	-	+
3	B	35.77	35.64	35.78	35.15	33.69	35.52	32.03	-	+
4	C	33.88	34.55	33.86	33.76	32.21	33.72	23.2	-	+
5	D	35.52	35.72	34.81	34.52	33.39	34.96	28.02	-	+
6	E	35.34	35.85	35.87	35.13	34.23	34.56	23.73	-	+
7	F	35.03	35	35.14	34.37	33.13	34.5	25.4	-	+
8	G	35.48	35.65	35.28	35.07	33.28	34.5	22.76	-	+
9	H	33.63	33.84	33.84	33.17	32.19	33.15	27.05	-	+
10	I	36.71	37.01	35.7	36.15	34.61	36.28	23.77	-	+
11	J	27.51	27.19	28.05	26.70	25.74	27.52	21.22	-	+

Nine mutations in the P72 gene from field samples and found that these mutations did not affect the qPCR methods currently used to detect ASFV in China.



3. Vaccine- Live attenuated Vaccines



China's Early Gene-Deleted Strains (2018-2020)

Represented by the Seven-Gene-Deleted Strain

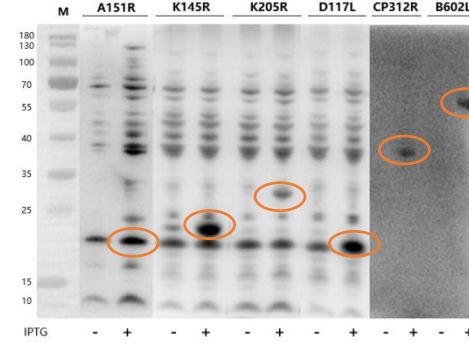
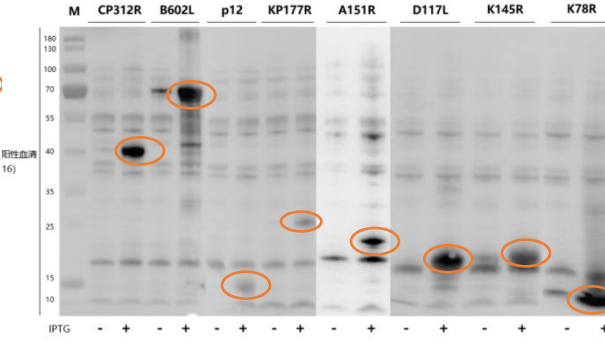
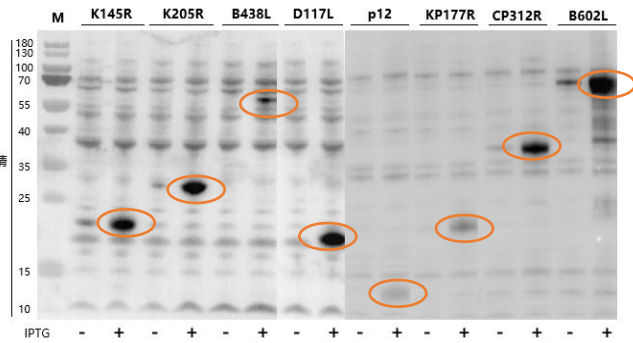
Deleted Genes	
MGF 505-1R, 360-12L, 360-13L, 360-14L, 505-2R, 505-3R	CD2V



Since 2021, Novel Genes/New Combinations Became the Primary Research Focus

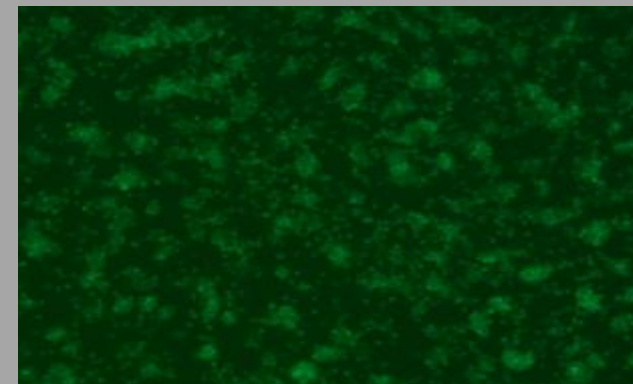
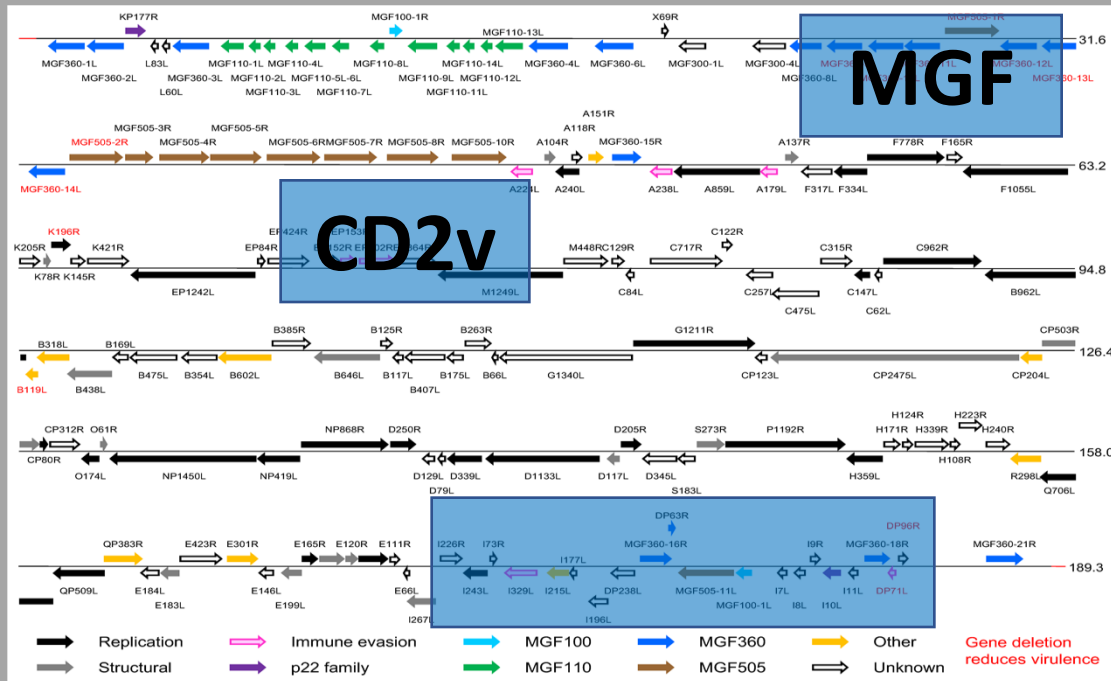
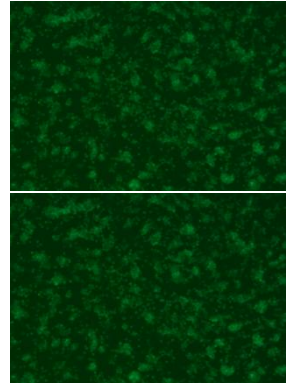
Time	Gene deleted	Inoculation dose	Survivors	Challenge dose	Survivors
2021	MGF360+CD2v+I177L	$10^3/10^5$ TCID ₅₀	10/10	50 HAD ₅₀	10/10
	I226R	$10^4/10^7$ TCID ₅₀	10/10	$10^{2.5}/10^4$ TCID ₅₀	10/10
	MGF 505-7R	10 HAD ₅₀	6/6	/	/
	MGF 110-9L	10 HAD ₅₀	3/5	/	/
	QP509L/QP383R	10^4 HAD ₅₀	6/6	10^2 HAD ₅₀	0/6
	E184L	$10^{2.2}$ HAD ₅₀	3/3	/	/
	MGF 360(9L-14L)+MGF 505(1R-3R)+I177L	10^5 HAD ₅₀	6/6	10 HAD ₅₀	2/2
	MGF 360(9L-14L)+MGF 505(1R-3R)+MGF 110-9L	10^5 HAD ₅₀	5/5	10 HAD ₅₀	2/2
	MGF360-9L	1HAD ₅₀	4/5	/	/
2022	I267	10 HAD ₅₀	1/6	/	/
	I73R	$10/10^4$ HAD ₅₀	12/12	10^2 HAD ₅₀	6/6
	MGF360-9L+MGF505-7R	10^4 HAD ₅₀	6/6	10^2 HAD ₅₀	5/6
	EP153R/EP402R+MGF 360-12L/13L/14L	10^5 TCID ₅₀	5/5	10^2 HAD ₅₀	5/5
2023	MGF110 / 360-9L	10^4 HAD ₅₀	6/6	10^4 HAD ₅₀	6/6
	I177L+CD2v	10^5 TCID ₅₀	5/5	10^5 TCID ₅₀	5/5
	I177L+CD2v+MGF	10^5 TCID ₅₀	5/5	10^5 TCID ₅₀	5/5





DIVA-1

DIVA-2



an ultra-attenuated
ASFV variant with
11-gene-deleted

A Large-scale Multigene family deletion strain

代表毒株	MGF110			MGF110	MGF100	MGF110					MGF360			MGF300						MGF505	MGF360			MGF505		
	4L	5-6L	7L	8L	1R	9L	11L	14L	12L	13L	4L	6L	X69R	1L	4L	8L	9L	10L	11L	1R	12L	13L	14L	2R	3R	4R
CN2018	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
CN2018-ΔLVR	+	+	+	+	+	缺失 Deleted region																	+	+	+	

The deleted region measures approximately **20 Kb, accounting for roughly one-ninth (1/9)** of the African swine fever virus genome.

No oral/nasal/anal viral shedding observed after immunization or virus challenge



Prospects for Marketing Authorization of Attenuated ASF Vaccines in China

- The likelihood of attenuated ASF vaccines obtaining marketing authorization in China is extremely **low**
- Primary concerns lie in **safety in sows** and the emergence of **vaccine-derived variants**.



Subunit vaccine



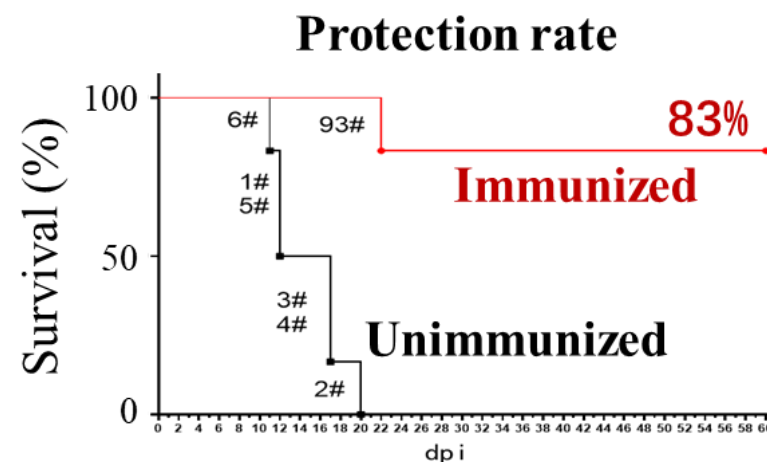
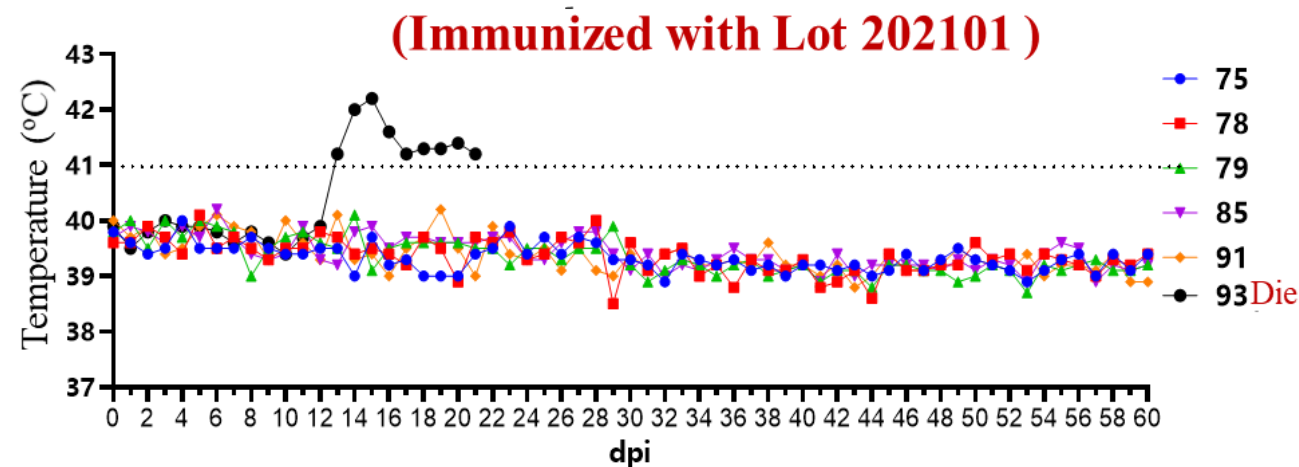
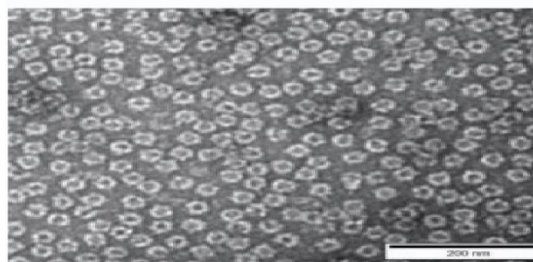
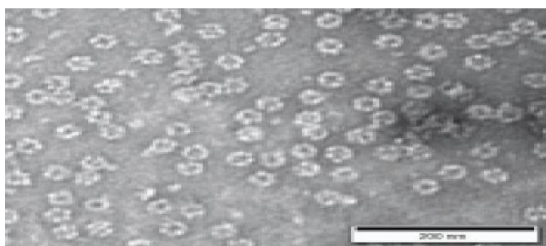
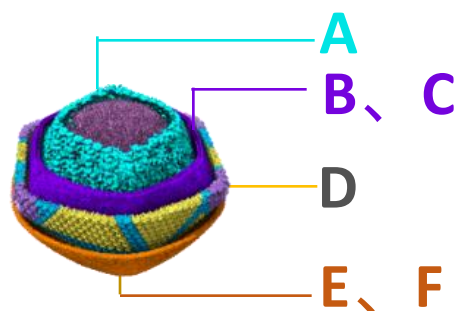
Subunit Vaccine -Lanzhou Veterinary Research Institute

Laboratory Research : After optimization, a seven-component formulation was finalized. Following two doses, the vaccine achieved a 100% protection rate against the prevalent virulent strain of Type II ASFV (ASFV/GS/2018) in China. The duration of immunity lasted over four months, proved safe for pregnant sows.

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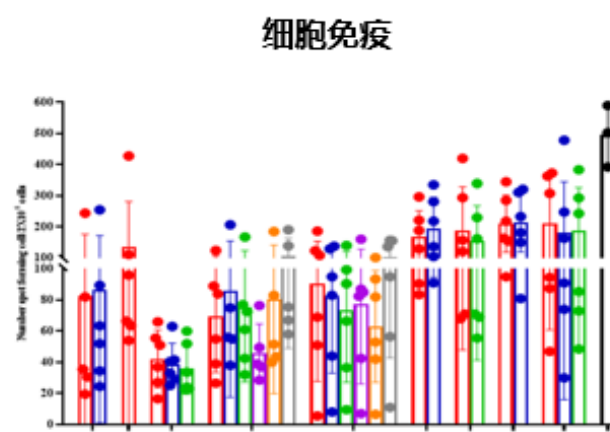
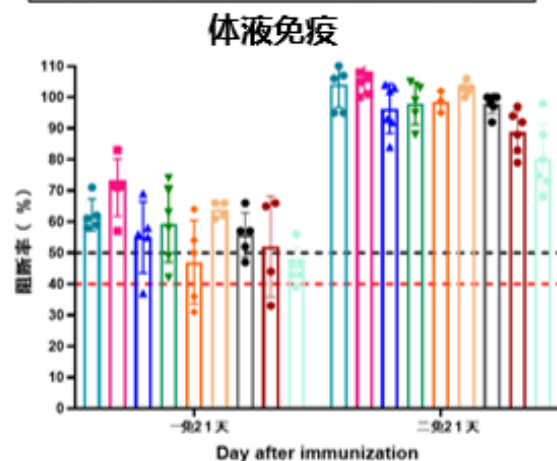
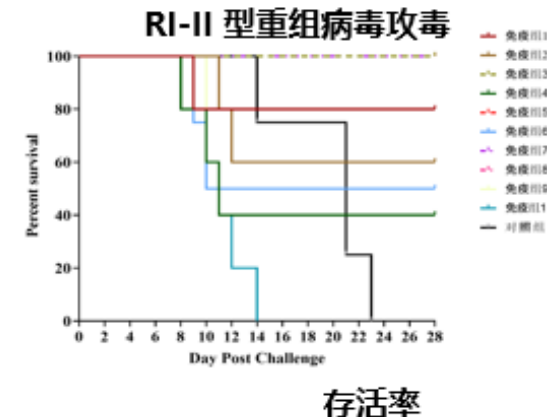
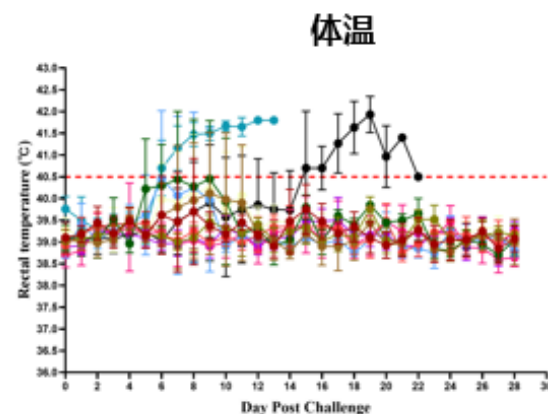
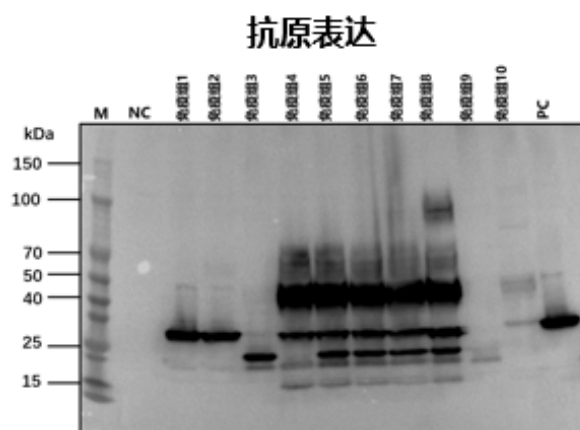
Nanoparticle Vaccine-Institute of Biophysics, Chinese Academy of Sciences



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mRNA vaccine- Jinyu Baoling Bio-Pharmaceutical Co., Ltd.



抗原	免疫数量	攻毒保护	存活率
免疫组1	5	(4/5)	80
免疫组2	5	(2/5)	40%
免疫组3	5	(5/5)	100%
免疫组4	5	(3/5)	60%
免疫组5	5	(5/5)	100%
免疫组6	4	(2/4)	50%
免疫组7	5	(5/5)	100%
免疫组8	5	(5/5)	100%
免疫组9	5	(2/5)	40%
免疫组10	5	(0/5)	0%
对照	5	(0/5)	0%

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Multiple institutions collaborate to advance clinical trials of African swine fever subunit vaccine

批件号:	2025058
项目名称:	非洲猪瘟亚单位疫苗临床试验
申请单位名称:	中国科学院生物物理研究所、国药集团动物保健股份有限公司、金宇保灵生物药品有限公司、中牧实业股份有限公司、广东蓝玉生物科技有限公司、中国科学院武汉病毒研究所
试制产品批号:	24681201、24681202、24681203、24681204、24681205、24681206
试制产品的数量:	3884瓶、3892瓶、3888瓶、3890瓶、3896瓶、3886瓶；50ml/瓶
拟临床试验地点:	1. 临床试验承担单位: 金宇保灵生物药品有限公司2. 试验地点: 麻城市和泰农业有限公司 (湖北省黄冈市麻城市歧亭镇戴家湾村)、全南现代牧业有限公司 (江西省赣州市全南县工业园三区)、唐山市路南丽平养殖场 (河北省唐山市路南区稻地镇刘东村)、肃宁县康达生猪养殖场 (河北省沧州市肃宁县肃宁镇西泽城村)、永靖县利旺养殖有限公司 (甘肃省临夏回族自治州永靖县盐锅峡镇盐集村方台三级)
有效期限:	2025/7/14-2027/7/13



Current Progress of Clinical Trials

- the first high-dose virus challenge test, **oral spraying** to simulate natural infection, with an ultra-high challenge dose of 8000 HAD50.
- within the **28-day observation** period, pigs in the immunized group reached qualified protection indicators. In contrast, all pigs in the non-immunized control group contracted the disease and died, registering a 100% mortality rate, which strongly confirmed the vaccine's protective effect.



Possibilities and Open Questions Regarding the Marketing Authorization of Subunit Vaccines in China

- Marketing authorization is possible.
- This vaccine targets Genotype II strains; data regarding recombinant strains remain unavailable.
- Whether the oral challenge model is standardized and can gain recognition from the expert panel.
- Biosecurity serves as the primary prevention and control measure in China. In addition, pork prices remain persistently low. Therefore, its future application prospects remain to be seen.



Tips- Critical Condition for the Deployment of African Swine Fever Vaccines

- Vaccines demonstrate excellent efficacy in physically robust experimental pigs, whereas protective efficacy against challenge declines markedly in pigs with suboptimal health status.
- **The health status of pigs is critically important.** It is also a key factor in resisting other diseases and achieving profitable production.



Future plans on prevention and control of ASF

- China will maintain implementation of the ASF zoning and compartmentalization policy while enhancing oversight of live pig transportation. At the production level, we are intensifying biosecurity management and expanding the establishment of ASF free compartments.
- Enhanced surveillance of circulating ASFV strains will be prioritized at slaughterhouses and bio-waste disposal facilities. This enables timely detection of emergent variants and facilitates pathobiological characterization studies.
- Vaccine, particularly live attenuated vaccines, requires judicious application. Indiscriminate use may exacerbate strain diversity and complexity within circulating viral populations.





•Thank you!



Shengqiang Ge
geshengqiang@cahec.cn

