



**VACCINE DEVELOPMENT TESTING**

Comprehensive suite of *in vivo*  
and *in vitro* services



# Partnerships with Labcorp

Access a comprehensive suite of discovery vaccine testing services, enabling the development of human and veterinary vaccines against viral and bacterial pathogens. With more than four decades of experience working with a variety of vaccine types within a full range of *in vivo* and *in vitro* services, we are the ideal partner for all your vaccine development needs.

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## Operational efficiency

- Effective study planning yields on-time execution and delivery
- Broad end to end service offering takes your vaccine from discovery to IND



## Cost & time savings

- Scientific expertise ensures studies are well designed to meet regulatory requirements, timelines and budgetary goals
- Efficient project management – integrating *in vivo* and *in vitro* services, as well as other Labcorp offerings – reduces study administration costs and tech transfer delays



## Flexibility

- Rapid study starts and focused operational team with 60,000 sq ft of vivarium space and priority access to a variety of host species
- Accommodate study design modifications quickly due to systems and procedures that are in place



## Vaccine development & solution-based discovery

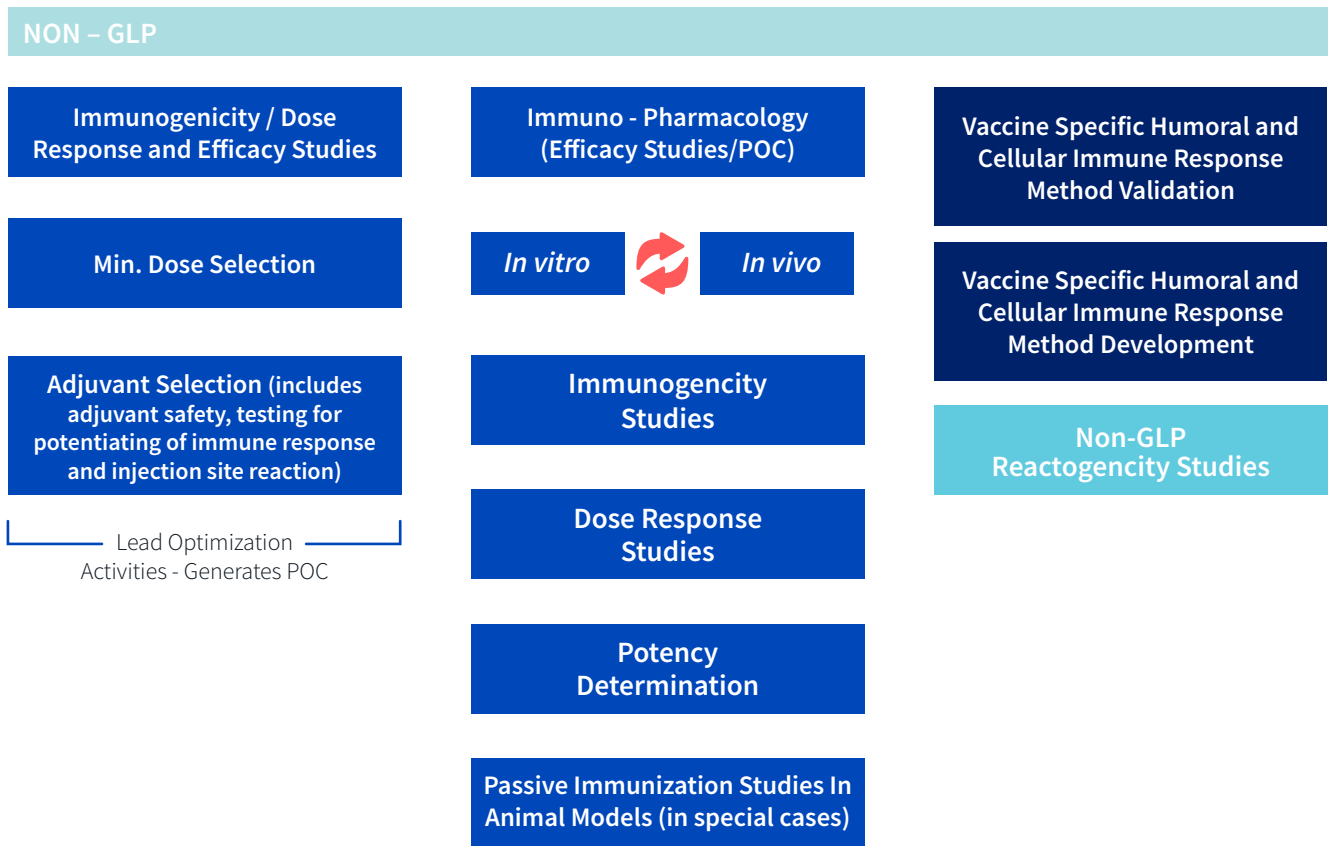
We work with all common vaccine types: subunit, live/attenuated, inactivated viruses and bacteria, DNA/RNA and toxoid.

### *In vitro* capabilities

- Humoral immune response analysis: Analyze various antibody response types by ELISA, neutralization assays, HAI and other tests in our well-equipped laboratories
- Cell-mediated immune response: Decipher Th1 and Th2 responses by ELISpot in a dedicated tissue culture facility

### *In vivo* capabilities

- Immunogenicity studies: Select from a variety of host species ranging from rodents to NHPs with rapid study starts and scalability from a few to a large number of animals
- Efficacy/challenge: Evaluate your vaccine's efficacy in our vivariums supporting up to BSL2 pathogens in custom-developed or standard research models

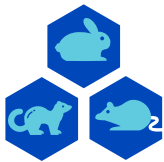


# Immunogenicity studies

Immunogenicity studies involve a combination of *in vivo* and *in vitro* services providing you with a complete evaluation of the immunogenicity of your test vaccines. We work with you as part of a comprehensive development plan to identify a suitable host species (based on the nature of the vaccine) and to recommend sample analysis methods.

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## Specifics



Host species selection



Dose response



Adjuvant selection



Dose optimization

## ***In vivo* testing**

- Broad experience and capabilities using common lab species
- Scalability ranging from 10 to >1,200 animals

## ***In vitro* testing**

- Humoral and cell-mediated immune analysis
- Flexibility to handle small to large sample sizes
- Rapid data generation thanks to colocation with vivariums

## Vaccine experience overview - Denver, PA

Indication	Vaccine Type(s)	Study Type(s)	Animal Model(s)	BSL Laboratory	ABSL Testing	ABSL Challenge
Influenza - Seasonal: Type A (H1N1, H3N2), Type B	Killed Virus, DNA, and Patch	Immunogenicity		1	1	-
		Reactogenicity		1	1	-
		Dose Response	Rabbit, Swine, Ferret, Mice	1	1	-
		General Safety Testing		1	1	-
		Real Time Stability (Immunopotency)		1	1	-
	Live Adeno-Vectored Vaccine	Immunogenicity	Rabbit, Mice	2	2	-
	Subunit, Recombinant	Reactogenicity	Rabbit	1	1	-
Dose Response		Rabbit, Mice	1	1	-	
Real Time Stability (Immunopotency)		Mice	1	1	-	
Influenza - Pandemic: H5N1 and Novel H1N1	Subunit, Recombinant	Immunogenicity	Rabbit, Ferret, Mice	1,2	1	-
		Reactogenicity	Rabbit	1	1	-
		Dose Response	Rabbit, Mice	1	1	-
		General Safety Testing	Guinea Pig, Mice	1	1	-
RSV	Virus-Like Particle, Recombinant	Immunogenicity		1	1	1
		Dose Response		1	1	1
		Virulent Challenge	Cotton Rat, Ferret	2	2	2
		Efficacy		2	2	2
		Potency		1	1	-
Anthrax - rProtective Antigen (rPA)	Subunit	Immunogenicity	Rabbit, Mice, Monkey	1	1	-
		Reactogenicity safety	Rabbit, Mice	1	1	-
		Dose response	Rabbit	1	1	-
		Potency	A/J Mice	1	1	-
		Real Time Stability (Immunopotency)	Rabbit	1	1	-
Dengue Virus	Subunit	Immunogenicity		1	1	-
		Potency	ICR Mice, Rabbits	1	1	-
Smallpox	Modified Live Virus	Vaccine Strain Safty	SCID Mice	2	2	2
	Modified Live Virus	Pathogenicity Challenge	Suckling Mice, Rabbit	2	2	2
Malaria	Subunit	Immunogenicity		1	1	-
		Dose Response	Rabbit	1	1	-
Plague - Yersinia pestis	Subunit	Immunogenicity	Mice	1	1	-
		Immunopotency	ICR Outbreak Mice	1	1	-
		Passive transfer - only pK study	ICR Outbreak Mice	1	1	-
Hepatitis B	Subunit	Immunopotency	C3H Mice	1	1	-
	Subunit	Adjuvant Safety	Mice	1	1	-
Hepatitis A	Subunit	Immunogenicity		1	1	-
		Dose Response	ICR Mice	1	1	-
		Adjuvant safety		1	1	-
Human Papilloma Virus	Subunit	Immunogenicity	ICR Mice, Rabbit	1	1	-
		Dose Response	ICR Mice, Rabbit	1	1	-
		Challenge (quazi virus)	Rabbit	2	2	2
		Adjuvant safety	ICR Mice, Rabbit	1	1	-
HIV - AIDS	Subunit	Immunogenicity	Rabbit	1	1	-
		Adjuvant Selection	Rabbit	1	1	-
		Dose Response	Rabbit	1	1	-
Staphylococcus aureus	Subunit	Immunogenicity	ICR Mice, Rabbit	1	1	-
		Dose Response	ICR Mice	1	1	-
		Efficacy	ICR Mice	2	2	2
		Challenge	Nonhuman Primate	2	2	2
Ricin	Subunit	Immunogenicity	Rabbit	1	1	-
		Dose Response		1	1	-
Human Rota Virus	Modified Live Virus	Safety Study: Single dose repeat dose and over dose	Rabbit, Rat	2	2	2
		Immunogenicity	Mouse	2	2	2

# Efficacy/Challenge studies

Following satisfactory immunogenicity results, efficacy or challenge studies can be conducted using a standard or custom animal model. Pathogens up to BSL2 can be tested in our state-of-the-art vivariums in studies ranging in size from small, pilot studies to larger, complex designs. Samples originating from these *in vivo* studies can be transferred to our *in vitro* laboratories for further analysis.

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## State-of-the-art facilities

- ABSL2 vivariums with large, multispecies capacity
- Option for individual, group and/or social housing (including EU style)



## Animal welfare

- AAALAC accredited
- Staffed by specialized and highly trained team members
- Animals monitored by on-site attending veterinarians
- On-site IACUC for rapid review and approval



## Institutional Biosafety Committee (IBC)

- On-site, NIH-registered IBC to review, edit and approve all studies involving infectious materials

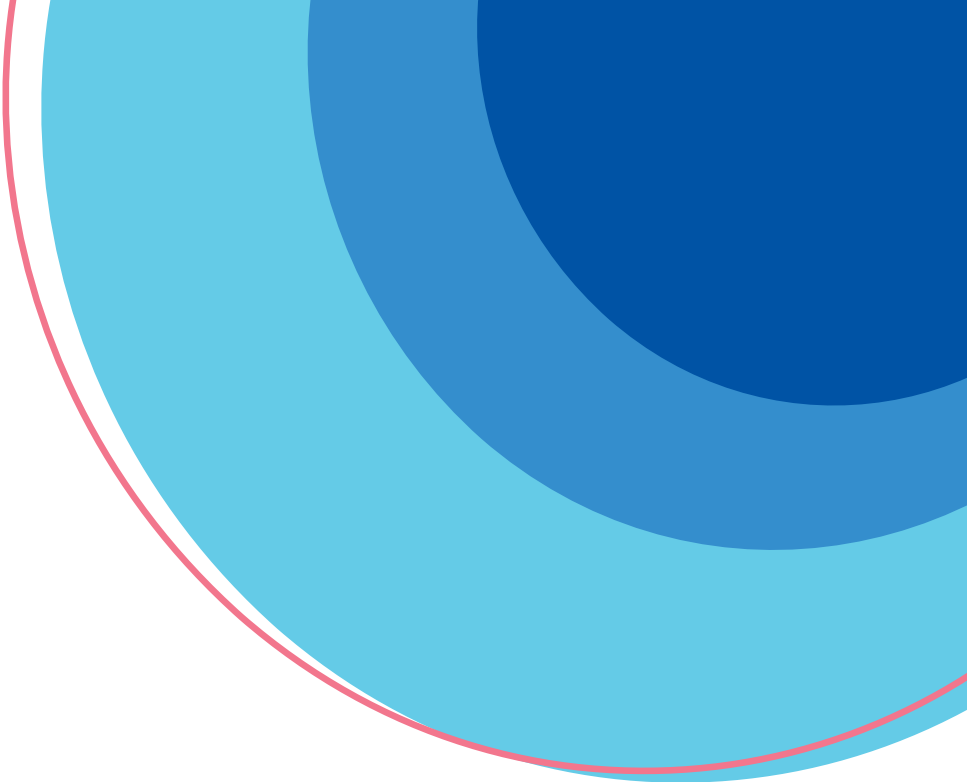


## Available animal models

Indication	Model	Study Type	Endpoints
<i>Clostridium difficile</i>	Hamster	Challenge and Efficacy	Clinical Symptoms/ Bacterial Load and Histopathology
<i>Influenza</i>	Ferret, Mouse	Challenge and Efficacy	Clinical Symptoms/Viral Load and Histopathology
<i>Rabies Virus</i>	Hamster, Mouse, Dog, Cat, Nonhuman Primate	Challenge and Efficacy	Clinical Symptoms/dFA/RFFIT Testing
<i>RSV</i>	Cotton Rat	Challenge and Efficacy	Clinical Symptoms/Viral Load and Histopathology
<i>Staphylococcus aureus</i> (MRSA)	Mouse Kidney Abscess	Challenge and Efficacy	Clinical Symptoms/ Bacterial Load

## Experience overview

Indication	Study Type(s)	Animal Model(s)	BSL Laboratory	ABSL Testing	ABSL Challenge
Bordetella bronchiseptica	Immunogenicity & Efficacy	Canine	2	1	N/A
	Safety - Single, Repeat & Overdose	Canine	2	2	N/A
	Efficacy/Challenge Study	Canine	2	2	2
<i>Clostridium difficile</i>	Bacterial Stock Preparation for Challenge	N/A	2	2	2
	Immunogenicity & Efficacy	Hamster	2	2	2
	Oral Gavage Challenge	Hamster	2	2	2
<i>Influenza</i>	Viral Stock Preparation for Challenge	Mice, Ferret	2	2	2
	Dose Optimization	Mice, Ferret	2	2	2
	Efficacy/Challenge Study	Mice, Ferret	2	2	2
<i>Rabies virus</i>	Immunogenicity, Immunotherapy and Efficacy	Hamster, Mouse, Dog Cat, Nonhuman Primate	2	2	2
<i>Staphylococcus aureus</i>	Bacterial Stock Preparation for Challenge	N/A	2	2	2
	Immunogenicity & Efficacy	Mouse, Rabbit	2	2	2
	Kidney Abscess Model (Efficacy)	Mouse	2	2	2
	Neutropenic Thigh Infection Model (Efficacy)	Mouse	2	2	2
<i>Streptococcus epidermidis</i>	Bacterial Stock Preparation for Challenge	N/A	2	2	2
	Immunogenicity & Efficacy	Mouse, Rabbit	2	2	2
	Efficacy/Challenge Study	Mouse	2	2	2
	Biofilm Preparation	Mouse	2	N/A	2
<i>Streptococcus pyogenes</i>	Bacterial Stock Preparation for Challenge	N/A	2	N/A	N/A
	Efficacy/Challenge Study	Rabbit	2	2	2



Whatever your niche, we can  
help to devise a solution

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Learn more at

[biopharma.labcorp.com/industry-solutions/by-product/vaccines.html](https://biopharma.labcorp.com/industry-solutions/by-product/vaccines.html)