



Your prescription for improved
animal health vaccines.



PRESCRIPTION PLATFORM PRODUCT OVERVIEW



IMMUNOLOGICAL SERVICES PROVIDER (ISP)

A NEW APPROACH TO MAINTAINING HEALTHY ANIMAL POPULATIONS

Since the beginning of animal domestication, owners and producers have been dealing with the effects of animal diseases. Past efforts to combat them have included such things as herbal and antibiotic treatments, dietary modifications, alterations in management practices, and vaccination. Until recently, vaccination has been limited to the use of either commercial or autogenous vaccines, both of which have their own distinct advantages and drawbacks.

The USDA Center for Veterinary Biologics (CVB) has released guidance allowing for the development and licensure of Prescription Platform Vaccines (RxPP).

As an immunological services provider, Medgene Labs does more than produce state-of-the-art, precision vaccines. We help veterinarians and producers monitor their herd with diagnostic surveillance and data analytics to proactively provide treatment that is customized for each herd.

By partnering with veterinarians and producers, we create a system of checks and balances to provide tools resulting in healthier herds and improved production.

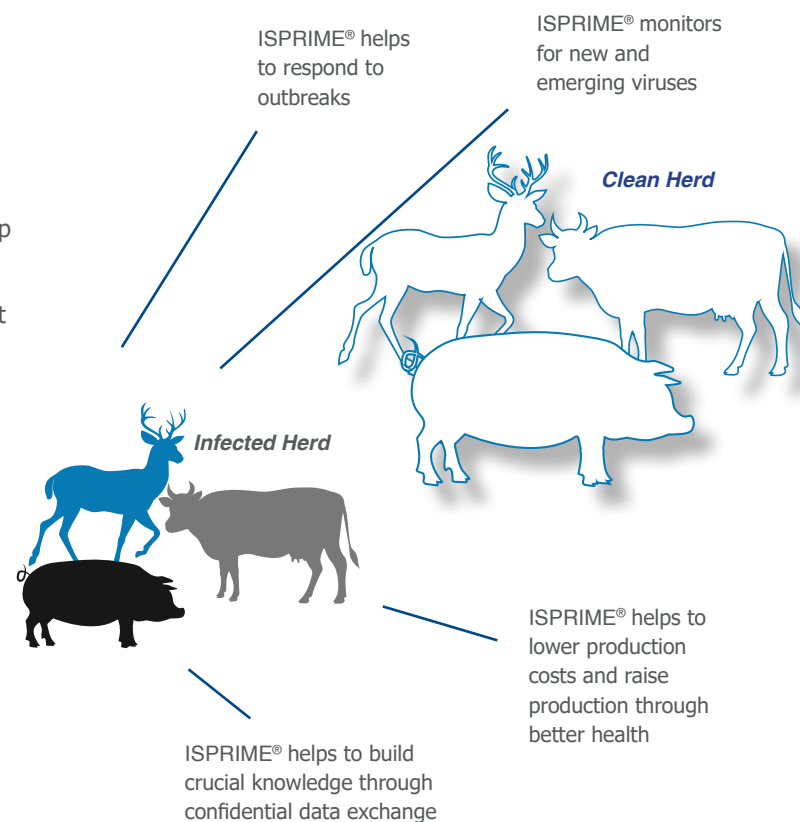
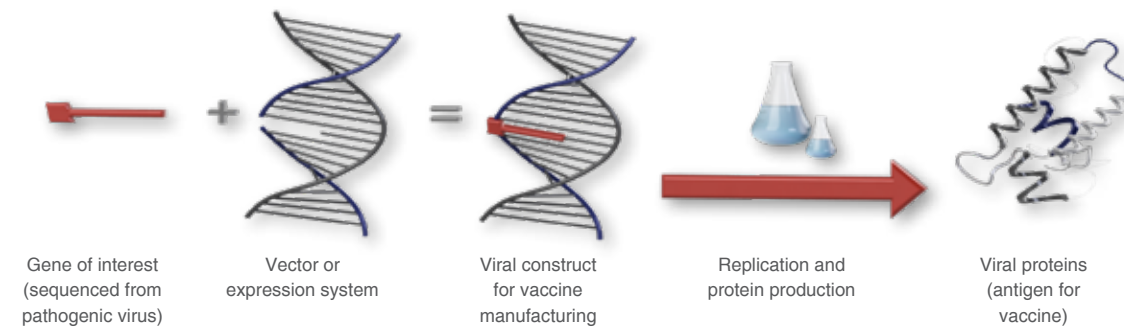


Illustration of RxPP Technology

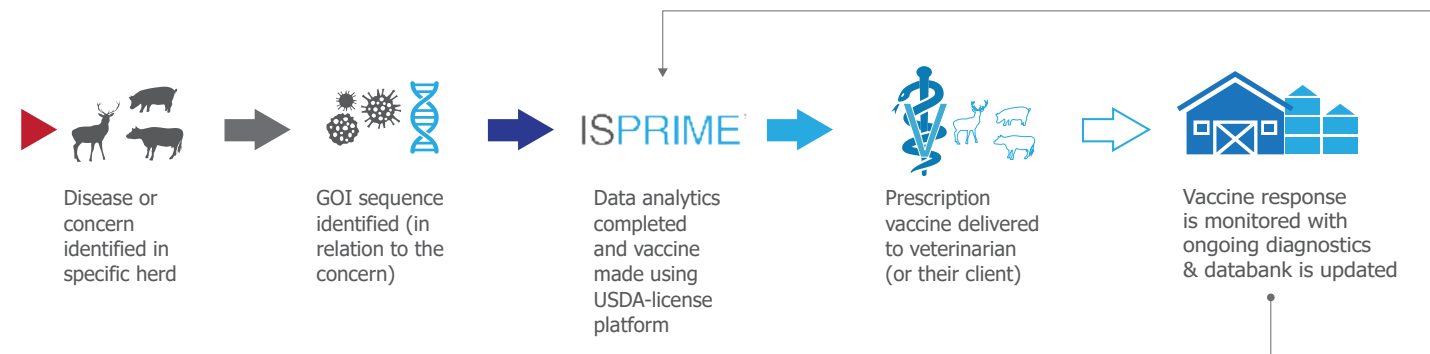


A Prescription Platform Vaccine is a platform-based, standardized vaccine that is nonviable and non-replicating (i.e., “killed”). By CVB definition, a production platform is a manufacturing process that relies on a single vector or expression system (“backbone”) and a standard process for inserting a gene or genes of interest (GOI) into the system to generate different recombinant master seeds or constructs, which are then used to produce product following a standardized method for manufacture. The GOI is selected to be one that codes for a protein that is known to convey immunity against the agent in question, so that the final product will be expected to produce disease coverage in vaccinated animals.

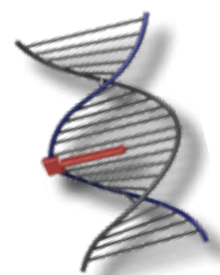


ISPRIME: SERVICE

The ISPrime Service was developed to rapidly respond to new and rapidly changing diseases. Through diagnostics and monitoring, we partner with our customers to rapidly rollout vaccines to protect and enhance the health of their herds. The process works by collecting a customer's sequence and comparing it to our construct library. If your sequence matches with one of our existing constructs, we will be able to deliver a precise vaccine in a matter of weeks. If one of our current constructs from our library is not a match, we develop a new construct and vaccine with 100% homology to the disease affecting your herd.



At the core of the ISPrime Service is a dedication to a dynamic and customized response for the health of your herd. Reliable and predictable response times are critical to managing herd health. With ISPrime services, you can count on on-time and on-budget delivery.



**CONSTRUCT BANK TO VACCINE
12 WEEKS OR LESS**



Currently Available Constructs for Future Vaccine Production

At Medgene, we are continually striving to develop and expand our construct library. Here is a list of our currently available constructs. If what you need is not listed below, please reach out to your representative to discuss available options. Additional constructs may be available or could be created based on your needs.

Pathogen	Target Protein	Variability
PCV	ORF2	Low
SIV	Single (Hemagglutinin)	High
Rota	VP4, VP7	High

Viral Homology

Viral homology is critically important to successful treatment of a herd. Viruses with a higher variability in homology need a more proactive approach to monitoring and responding to changes as the virus mutates and spreads. Prescription services help us to fulfill the monitoring and adaptation required to maximize the production of your herd.

Swine Production Pipeline:

IAV (H1, H3) TGEV
 PCV2 (a, b, d) APPV
 PEDV PPV (1, 2)
 Rota A, Rota B, Rota C Astrovirus
 PPIV
 PDCoV
 Sapovirus

Bovine Production Pipeline:

IDV
 BRSV
 BCV
 Rota A

Cervid Production Pipeline:

EHD (Experimental/Pre-License)





PRESCRIPTION VS COMMERCIAL VACCINES

Prescription

- Derived from a Gene of Interest (GOI) sequence. High success rate for viruses that are hard to grow.
- The subunit, targeted proteins are formulated with adjuvant and bottled.
- Conveniently available through a Veterinary Client Patient Relationship (VCPR).
- Recent target, GOI sequence only. Short development cycles.
- Safety proven, efficacy unproven (initial product is fully licensed with proven efficacy).

VS

Commercial

- Derived from a whole virus or a subunit. High success rate, but targets can be outdated as new strains emerge.
- Vaccines can be created as modified live or killed with an adjuvant.
- Mass produced and distributed.
- Long development cycles and approvals for new vaccines.
- Safety and efficacy proven.

Why and When to Choose Prescription Vaccines

When it comes to the health of your herd, it is important to consider a variety of variables to ensure the best outcome for your circumstances. At the top of the list, speed of delivery, safety, and cost of any vaccine should be high priorities for responsible veterinarians or producers during their evaluation.

Commercial vaccines have a long history. However, there are some viruses that cannot be isolated and others that mutate very rapidly, rendering vaccines ineffective. Prescription vaccines are designed to fill the gap left by commercial vaccines.

Sequencing your herd's pathogen can create exceptionally effective vaccines for herds affected by viruses that can not be isolated or that mutate very rapidly. Medgene Labs has produced a library of constructs to build a precise vaccine for the virus affecting your herd. In the event your herd is not a good match with one of our existing constructs, we are able to rapidly build and deploy a customized vaccine for your current situation.

Medgene is a leader in the new field of prescription vaccines. These are vaccines which are prescribed by a veterinarian to proactively target emerging diseases, such as viruses that change frequently or are difficult to grow. As an Immunological Services Provider™, Medgene monitors the production environment for new viruses, continuously updates its virus sequence and vaccine construct bank to rapidly counter production health risks, and serologically monitors vaccinated animals for effectiveness. Medgene provides these immunological services to its ISPRIME® community of leading livestock producers and their veterinarians in support of delivering consistent and reliable health management tools.

Additional general information regarding Prescription Product Vaccines can be found in Veterinary Services Memorandum Nos. 800.213 and 800.214. Medgene is licensed to provide RxPP vaccines and is in the process of licensing additional RxPP products for their ISPRIME service with the USDA. For more information on Medgene, please visit www.medgenelabs.com.

Disclaimer

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Medgene prescription platform vaccines allow us to be dynamic in our response to virus mutations and emergence of new strains. It is similar to commercial vaccines, in the original product is fully licensed, having passed the high standards for both efficacy and safety that are outlined by the USDA.

The manufacturing process is consistent from vaccine to vaccine, with the only change being the gene of interest that is inserted into the vector system to generate antigenic proteins in our lab.

Gary Bosch, DVM
Vice President, Medgene





"I started working with Medgene to help our clients address health challenges in various production areas. I was able to be part of a field trial with their prescription vaccine and had positive responses on several farms. Medgene's vaccine has helped me serve my clients, and the Medgene team has been very responsive to my needs."

Dr. Luke Strehle, DVM
Partner, Nebraska Veterinary Services



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animal health vaccines.

www.medgenelabs.com