

Recombinant *Mycobacterium Avium* Subsp. *Paratuberculosis* Proteins Induce Immunity and Protect Against Infection

Johne's disease or paratuberculosis is caused by *Mycobacterium avium* subspecies *paratuberculosis* (MAP). The invention is a vaccine for paratuberculosis comprised of MAP proteins. Induction of the immune response significantly reduces or eliminates colonization of the animal by MAP, and consequently reduces or eliminates the symptoms of clinical disease in animals infected with MAP and reduces or eliminates fecal shedding of MAP.

Docket No: 161.12

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Benefits

- Vaccination with the compositions provides protection against clinical disease and reduces transmission of MAP infection within a herd

Applications

- A vaccine effective for stimulating a protective immune response in animals against paratuberculosis

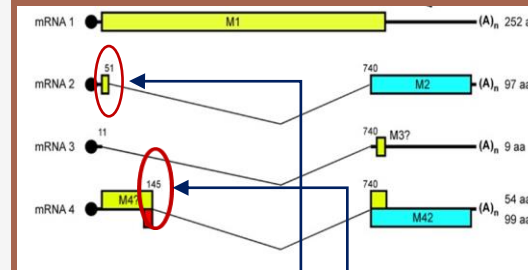
Live attenuated vaccine for avian influenza virus

Novel, attenuated H5 influenza vaccines have been developed that do not express either the M2 gene or the M42 gene found on viral segment 7. A single dose of either vaccine provides poultry with complete protective immunity against highly pathogenic avian influenza challenge. Following application, the live virus vaccine does not transmit to susceptible animals.

Docket No: 134.18

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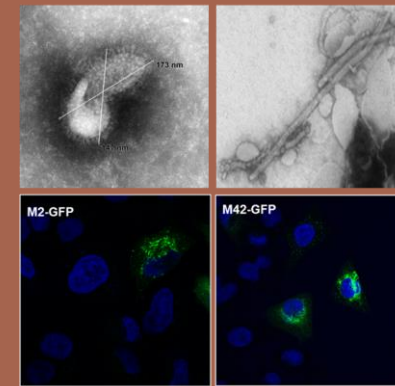
Segment 7



Generated deletion viruses with stop codons:
M2 @ position 52 = Δ M2
M42 @ position 145 = Δ M42

Δ M2

Δ M42



Benefits

- Provides broad protection against all H5 HPAI lineages and recent 2.3.4.4 clades
- Induces mucosal, humoral and cellular immunity in birds
- Can be applied to protect from other avian influenza subtypes, and mammalian influenza including swine, equine, canine and feline

Applications

- Safe and efficacious vaccine to combat influenza viruses to prevent disease in animal. Also, to reduce virus shedding that can be source of transmission, including humans

Recombinant vaccine against Marek's disease and Newcastle disease

A recombinant dual vaccine against Marek's disease and Newcastle disease has been developed using reverse genetics technology. This vaccine is safe and stable and can be lyophilized or stored and transported at an amble temperature. Vaccine generation and vaccination methods are included in the invention.

Docket No: 34.19

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Benefits

- Provides dual protection against Marek's disease and Newcastle disease
- Eliminates the "cold chain" requirement for Marek's disease vaccine production, storage, and transportation
- Can be delivered by mass immunization routes (e.g. aerosol, drinking water) to large chicken populations at an extremely low cost

Applications

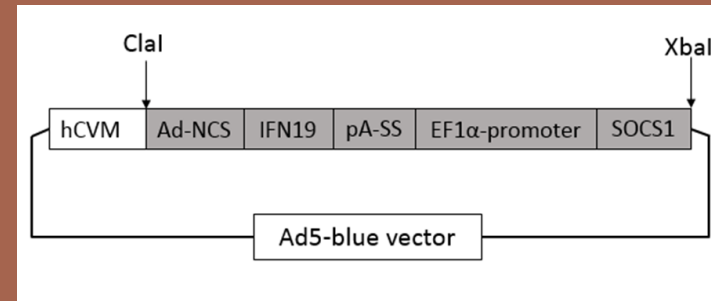
- Safe, stable and efficacious vaccine to prevent Marek's disease and Newcastle disease in chickens, and to reduce vaccination and poultry production costs

A New Gene-based Interferon Biotherapeutic

ARS constructed a new type I interferon gene expression system to increase interferon production and antiviral potency. This DNA construct can be inserted into gene-expressing vectors to be used as an antiviral biotherapeutic in pigs. The construct can be modified to be used in other animals.

Docket No: 115.17

Contact: Jim.Poulos@usda.gov



Benefits

- Uses the most potent porcine interferon gene to increase antiviral activity
- Uses a strong porcine promoter for high gene expression
- Includes another porcine gene to extend the duration of interferon production

Applications

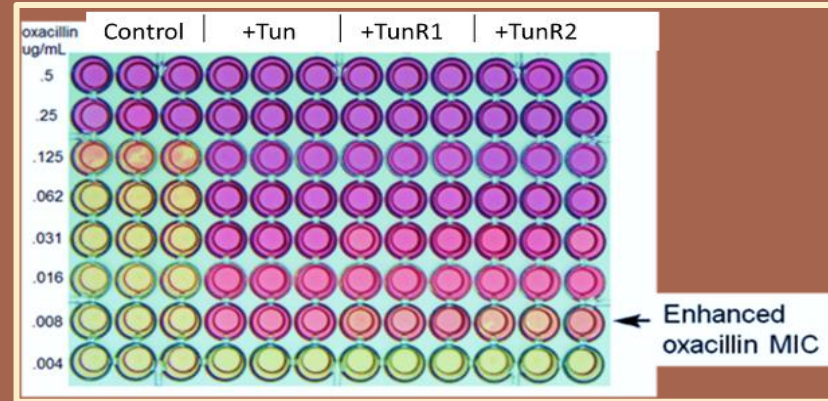
- Use alone for inducing rapid protection against virus infection
- Combine with vaccines for inducing rapid and long-lasting immune protection

Penicillin Enhancement by Modified Tunicamycins

The penicillins are the most commonly used antibiotics, with >60% utilized in agriculture, but resistance to penicillin is now widespread. The efficacy of penicillins are significantly improved by combining with modified tunicamycins, which are not toxic to eukaryotes. Modified tunicamycins (TunR1 and TunR2) enhance the penicillins efficacy by 32-64 fold, revitalizing penicillin's usage against resistant Gram-positive bacteria.

Docket No: 120.16

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Benefits

- Potent enhancement of medically-important penicillins
- Modifications drastically reduce the toxicity
- The combination of penicillin and modified tunicamycin are more efficacious than either penicillin or modified tunicamycin alone

Applications

- TunR1 and TunR2 are potent penicillin enhancers with new uses in antibiotic formulations for medicine and agriculture

Methods and Strains for Producing Bioproducts in *Aureobasidium Pullulans*

Methods for producing arabitol-containing liamocin and other bioproducts from novel modified strains of *Aureobasidium pullulans*. The *A. pullulans* strains contain genetic alterations to control the type of liamocin produced and decrease unwanted bio-products and bio-contaminants. Other useful bio-products produced include exophilins, massoia lactone, pullulan and liamocins with other head groups. The bioproducts can be produced melanin-free.

(Life Sciences, Medical-Health)

Docket No: 74.19 + 69.15

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Benefits

- The modified *A. pullulans* produce near 100% arabitol-containing liamocins on an inexpensive carbon sources such as glucose
- The liamocins and other bio-products produced are melanin-free

Applications

- Antibacterial activities of liamocins against certain gram-positive organisms may have potential applications as a veterinary treatment
- Potential chemical feedstock for the synthesis of a variety of products such as biosurfactants and polymers
- Antifouling agent, phytopathogen control agent

Recombinant *Eimeria Maxima* Protein Delivered as Nanoparticles for Poultry

A vaccine against avian coccidiosis has been developed that utilizes recombinant DNA technology and nanoparticles to stimulate an immune response in newly-hatched chickens against the causative agent *Eimeria maxima*. The recombinant protein, called EmaxIMP1 is purified and then conjugated to extremely small nanoparticles (20 nm in diameter) and orally given to newly-hatched chickens. This vaccine confers solid immunity against a challenge infection with the parasite *Eimeria maxima*. ARS scientists are now exploring the injection of embryonated chicken eggs as a practical means of delivering the nanoparticle-conjugated EmaxIMP1 protein to chicks prior to hatching just as vaccines against several viral pathogens are given.

Docket No: 94.17

Contact: Jim.Poulos@usda.gov



Benefits

- Delivering recombinant EmaxIMP1 as a conjugate to nanoparticles improves the level of production against *E. maxima* infection

Application

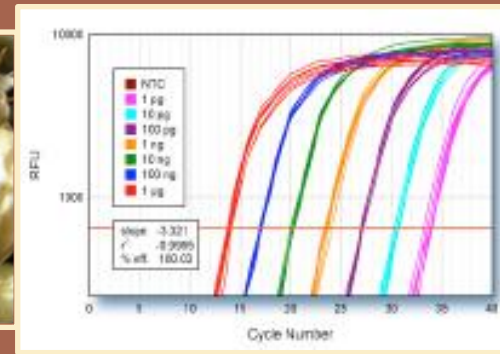
- Incorporating a recombinant *E. maxima* antigen, namely EmaxIMP1 into nanoparticles and using these to orally immunize newly-hatched broiler chicks

Advancing Tick-Borne Disease Diagnostics

Ticks and tick-borne diseases kill humans and animals. Enhanced pathogen detection is needed to improve the diagnosis of these diseases. The TickPath Layerplex is an innovative quantitative PCR (qPCR) assay to detect several tick-borne pathogens simultaneously. This assay aids in the diagnosis and treatment of human and animal tick-borne diseases.

Docket No: 68.16

Contact: Jeffrey.Walenta@usda.gov



Benefits

- Detects several groups of tick-borne pathogens in a sample simultaneously
- Distinguishes type of tick-borne pathogen in the sample simultaneously
- Guides decision for rapid and appropriate treatment
- Results obtained faster than with other types of assays

Applications

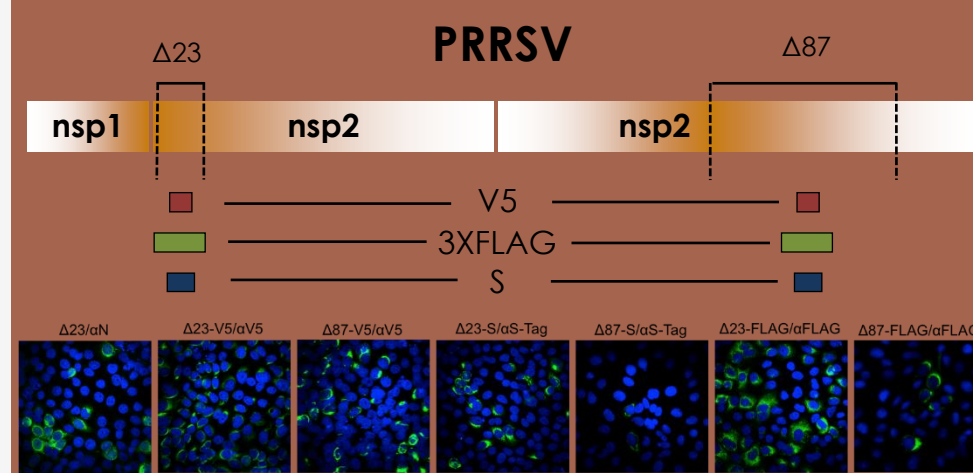
- Use during or after treatment of some tick-borne diseases as serologic titers can be persistent despite proper treatment of infection
- Replace serologic titer assays which are unable to determine if an active infection is occurring
- Can assay whole tick, tick fluid and serum from dogs, cats, cattle, etc.

Viable Viruses with Foreign Tags

An attenuated porcine respiratory and reproductive syndrome virus vaccine has been engineered to harbor either one of two deletions and/or one of three small immunogenic tags at the two deletion sites. The eight viruses efficiently replicate, maintain the parental virus phenotype, and are stable in cell cultures.

Docket No: 133.16

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Benefits

- The viruses are stable in cultured cells
- Allow efficient localization of nonstructural protein 2 (nsp2)
- Can be used to locate differently tagged nsp2 in co-infection studies

Applications

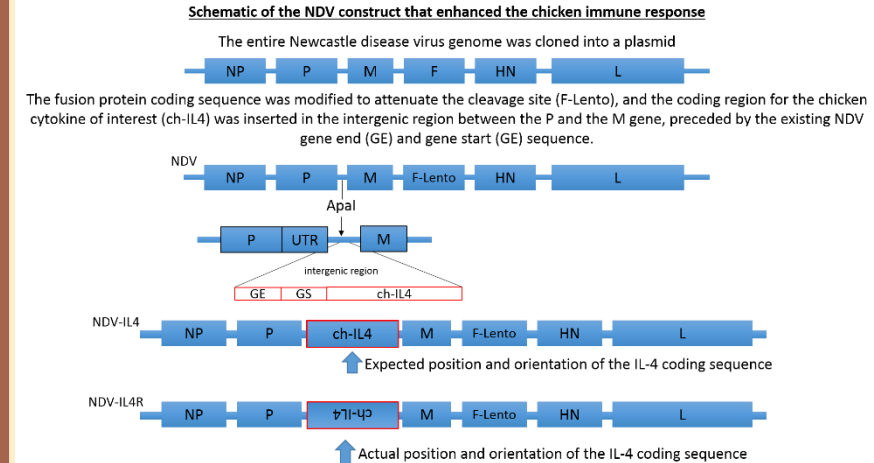
- Serves as a platform in developing new DIVA vaccines
- Molecular tool to study the role of nonstructural protein 2 in pathogenesis

Altered Avian Virus for *In-Ovo* Inoculation

Attenuated recombinant Newcastle disease virus (NDV) vaccines, containing an antisense coding region of the chicken interleukin 4 (IL4R) inserted into the NDV viral genome, were evaluated as candidates for *in-ovo* vaccination. ARS results indicate that these altered NDV-IL4R vaccines are a reliable *in-ovo* immunogenic composition that modulates the host animal's immune response and induces good protection in the host upon challenge.

Docket No: 46.16

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Benefits

- The vaccine can be administered safely *in-ovo* so that animals are protected at an early stage of life
- Antisense IL4 was used as an adjuvant to enhance the safety and protection induced by the vaccines and to create stronger immune responses

Applications

- Since Newcastle disease (ND) continues to be a threat to the poultry industry world-wide, this vaccine has the potential to be used as a novel, more effective *in-ovo* vaccine that elicits a strong immune response in hatchling chicks in order to decrease virulent virus replication and horizontal transmission

Animal Behavior Monitor

A system for monitoring ruminant animal foraging that utilizes a piezoelectric film sensor in communication with a computer processor to record and characterize jaw movement data for the foraging ruminant animal. The processor applies pattern algorithms to categorize the jaw movement data so that the jaw movements are categorized as at least chewing, biting, ruminating, and/or idling. Knowledge about livestock behavior and resource use can inform management decisions that influence outcomes in agricultural production, the environment, and rural prosperity.

Docket No: 125.17

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Benefits

- The system quantifies grazing behavior, including grazing time, ruminating time, resting time, bites/min and bites/day
- It has GPS tracking at a fix frequency of 5 minutes. It can track time spent in sensitive areas (e.g. riparian) and time spent in forage patches (diet selection)
- Other metrics can be added, including tail switch to track nutrient deposition, activity monitor for # of steps, and bites/feeding station
- Remote data access and troubleshooting

Applications

- This product would be of interest to grazing-based animal researchers
- It could be adapted for use for rangeland livestock, confinement livestock and for wildlife to monitor movement and grazing behavior

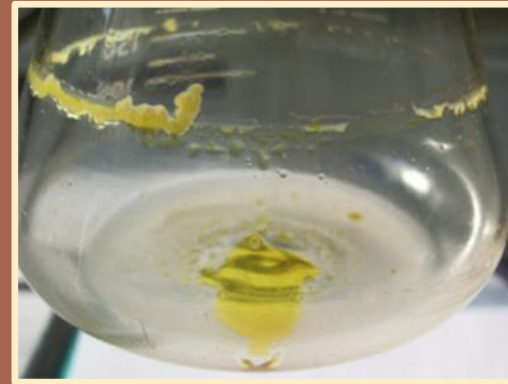
Novel Oil Having Antibacterial Activity

Liamocins produced by certain strains of the fungus *Aureobasidium pullulan* have anti-bacterial activity with specificity for *Streptococcus spp.*, *Enterococcus spp.*, and *Bacillus spp.* The invention includes methods of using the liamocins and compositions containing modified liamocins to kill bacteria. This invention also relates to methods to produce modified liamocins with specific head groups.

(Life Sciences)

Docket No: 107.13 + 51.18

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Benefits

- Liamocins are chemically different than conventional antibiotics, and cross-resistance should be minimal
- May be effective for Streptococcus infections that do not respond to conventional antibiotic therapy
- The liamocins are produced from low-cost agricultural biomass substrates, particularly pretreated wheat straw

Applications

- Dairy cattle dips for prevention of mastitis caused by Streptococcus sp.
- Topical antibacterial treatments
- In more refined forms, the pharmacologically active component(s) of the liamocins have potential to be incorporated into injectable or oral medicines

Compositions and Methods for Repelling Bloodsucking and Biting Insects, Ticks and Mites

Structures, activities and synthetic methods of chromenes and their analogs as repellents that can be used as personal protection against blood sucking and biting insects and arthropods such as mosquitoes, ticks, and fleas.

(Medical-Health)

Docket No: 73.16

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Benefits

- Long lasting natural products
- Biodegradable

Applications

- Plant derived Insect repellent that could potentially be applied to skin, hair and clothing. It could be applied as a spray, cream, ointment, paste or powder with a suitable medium or carrier

In Vitro Parasite Feeding System

The system includes a feeding vessel having an inlet, an outlet, and a membrane positioned across an opening in the vessel. Parasites (preferably ticks) are allowed to attach themselves to the membrane so that as a feeding fluid (preferably blood) is circulated through the vessel, the parasites feed on the feeding fluid through the membrane.

(Medical-Health)

Docket No: 116.15

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Benefits

- A simple, flexible, and economical tick feeding system that closely simulates a tick's preferred host throughout the entire tick life cycle
- Standardized, quality controlled vaccine production

Applications

- Full tick life cycle system for production of live pathogen stage specific vaccines or testing of anti-tick compounds

Genetically Modified *Babesia* Parasites Expressing Protective Tick Antigens

Methods for stable transfection of *Babesia* parasites with any heterologous DNA and genetically altered *Babesia* expressing heterologous DNA. One application can be for vaccines conferring immunity against parasitic arthropods. The method involves transfecting foreign DNA into *Babesia* resulting in genetically modified parasites that will be able to express foreign genes in animal hosts.

(Medical-Health)

Docket No: 35.16 + 116.05

Contact: David.Nicholson@usda.gov



Benefits

- Application would be a single dose of a bivalent vaccine
- Eliminates the need for recombinant protein production used in vaccines

Applications

- Facilitate control of both, ticks and tick-borne diseases in animals
- For expressing any desired antigen or other protein in animals that are infected with the genetically altered *Babesia*
- For vaccinating cattle in tropical areas of the world where gathering cattle could be a cumbersome procedure

Spontaneously Immortalized Avian Cell Line

A spontaneously immortalized avian cell line, designated ZS-1, derived from the primary chicken embryonic fibroblasts.

(Life Sciences)

Docket No: 87.13

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Benefits

- The immortal cell line is free of avian leukosis virus (ALV) and yet susceptible to all subgroups of ALV, including subgroup E
- Supports virus replication

Applications

- Production of viral agents, e.g., recombinant viral agents, expression of recombinant proteins, diagnostic assays of pathological specimens, etc.

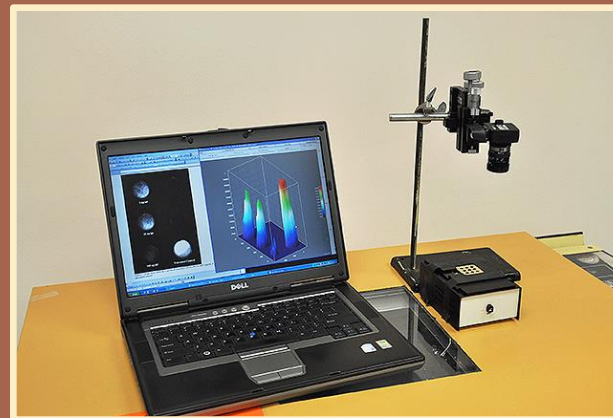
High Affinity Monoclonal Antibodies for Detection of Shiga Toxin 2 (STX2)

High affinity monoclonal antibodies against Shiga toxin strain Stx2 and hybridomas that produce such antibodies are described. The antibodies may be used in a kit for detecting Stx2 and variants thereof in a sample.

(Life Sciences, Medical-Health)

Docket No: 79.14 +186.11

Contact: David.Nicholson@usda.gov



Benefits

- The hybridoma cell lines produce monoclonal antibodies that detect all four variants of Stx2
- Immunoassays are rapid, highly specific and sensitive

Applications

- Basis for developing a sensitive immunoassays for detecting variants for Shiga toxin 2
- Immunoassays could be used for monitoring and source-tracking food supplies as well as monitoring contamination of clinical and environmental samples such as feces, soil, air, and water.