

Message from the President



As you are likely aware, the NovaVive line of immunotherapeutic products are manufactured in Athens, GA, USA.

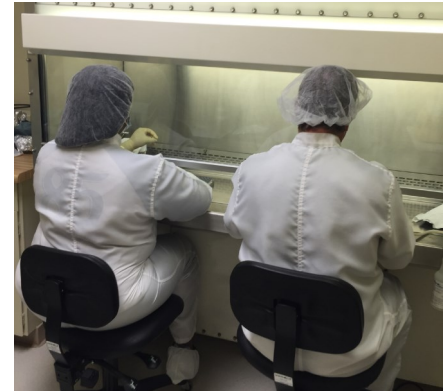
Our dedicated and capable manufacturing team of Lynn Bailes, Gordon Gilreath and Jolece Money do an exemplary job of staying on top of the production, packaging and shipping requirements for our 5 U.S. products. Some of these products are also approved and available in other countries around the world, so the production team must ensure that an appropriate level of inventory is available

at all times to satisfy various markets' requirements.

Our products are manufactured using a non-disease-causing mycobacterium. This organism is grown in our facility, harvested, purified, and broken into pieces. The processing involves numerous steps, resulting in the mycobacterium cell wall fraction (MCWF) active ingredient from which our products are made.

The cell wall fractions are mixed into a saline and lipid emulsion and filled into vials for distribution. The production process adheres to strict sterility standards, and each batch of product made undergoes testing to ensure purity, safety and potency.

As biologics, our products are regulated in the USA by the United States Department of Agriculture (USDA). Each serial of product must be reviewed by the USDA and



approved for release to the market. The USDA also performs random facility inspections to ensure compliance with manufacturing standards and procedures.

Thank you, Lynn, Gordon, and Jolece for your commitment to ensuring the highest quality products are available for our bovine, canine and equine "customers" - and their veterinarians.

Equimune a Valuable Tool in Competition Season

Equine influenza and other respiratory viruses or bacteria can be a major problem for horse owners and equine veterinarians, particularly during the competition season.

Transporting horses to/between events, housing them in new barns, and the stress of competition itself can all result in a compromised immune system and vulnerability to viral or bacterial infection.

After months (or years) of training, this is a serious concern.

Immunotherapy is designed to boost an animal's immune system to fight disease. NovaVive's line of regulator-approved immunotherapies includes Equimune[®], for the treatment of viral equine respiratory disease complex (ERDC). Equimune is approved and available in the USA, Australia and New Zealand.



A single dose of Equimune, when administered by IV injection, stimulates the horse's innate and specific immune responses for a number of days. It is a solo therapy, and an alternative to antibiotics.

Equimune activates immune system cells, thereby enhancing immediate production of interleukin 1 (IL-1). IL-1 then initiates both cell-mediated and humoral immunity cells. Cell-mediated immunity immediately seeks out virus-infected cells and destroys



them. Humoral immunity results in antibody production to provide a longer lasting protection against the particular viral invader.

It's often recommended that Equimune be administered to a horse at the onset of a disease challenge, which can be prior to shipping or on arrival at the competition site.

Amplimmune® Research Dataset Growing

NovaVive has had an ongoing development program with Amplimmune®, our immunotherapy for the treatment of calf scours. Our development program has generated a substantial amount of data supporting the use of Amplimmune as a natural immunotherapeutic for diseases of the calf. Here are some highlights (with links to publications/presentations for more details):

Reduction of severity of ETEC-induced diarrhea in calves - 1 ml administered by IV injection at first sign of clinical disease resulted in 90% of treated newborn calves surviving in this challenge study. [Acta Veterinaria-Beograd 2017, 67 \(2\)](#)

Improved performance of hutch-reared calves - 1 ml administered by IV, IM or SC injection in day-old calves resulted in a 15% increase in ADG over controls and 15% lower treatment costs. [AABP proceedings](#)

Reduced mortality and antimicrobial use in veal calves - 1 ml administered to veal calves on arrival at a feedlot resulted in 50% lower mortality, reduced incidence of clinical conditions, and significantly reduced use of antimicrobials and supportive therapies. [AABP poster](#)

Reduced risk of pneumonia in Jersey/cross calves in first month of life - 1 ml administered to 2- to 3-day-old Jersey and Jersey-cross heifers before or after transport reduced the number of calves treated for pneumonia in the first 30 days of life and improved morbidity and mortality outcomes. Those treated prior to transport had a 46% reduction in risk of being treated for pneumonia. [ADSA annual meeting](#).

Most recently, we've been collecting evidence of Amplimmune's applicability in the mature cow as an enhancement to reproduction:

Amplimmune in synchronized embryo transfer recipient Holstein heifers - A 5 ml by IM injection on the day of heat (approx. one week prior to embryo transfer) greatly improved pregnancy per synchronized recipient at day 60. [Reproduction, Fertility and Development](#) (<https://www.publish.csiro.au/RD/RDv33n2Ab75>)

Amplimmune impact on the incidence of disease and subsequent fertility of cows on an organic dairy operation - A 5 ml dose by SC injection 7 days before expected calving and a second dose within 24 hours after calving. In multiparous cows, the Amplimmune-treated cows outperformed the control animals with regard to pregnancy at first AI, 100 DIM and 150 DIM. [Journal of Animal Science](#) (<https://academic.oup.com/jas/article-abstract/99/9/skab191/6360969>)

What Dog Guardians are Saying About Immunocidin®



Sora is a 10.5-year-old Chow mix from Minnesota diagnosed with osteosarcoma. She has been receiving Immunocidin immunotherapy for more than 56 weeks.

"Sora was diagnosed with osteosarcoma last March. I had joined a FB group that mentioned the Immunocidin trial, and so I had my oncologist find out about this treatment. Sora has been on Immunocidin since May of last year, just before her forelimb amputation. She has done very well on it, and was able to return to competing in scentwork trials this past weekend where she earned a brand new title. I am so happy that it has been a part of her protocol, and has helped her regain her energy and love of sniffing."

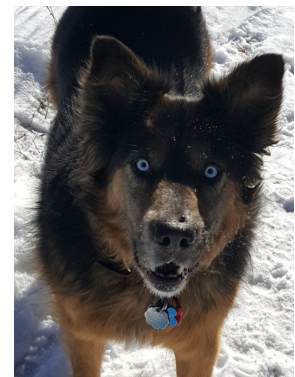
Hugo is a 6-year-old Dogue de Bordeaux from Springboro, OH who was diagnosed with osteosarcoma. He has been receiving Immunocidin immunotherapy for more than 31 weeks.



"Hugo was diagnosed October, 2021 with osteosarcoma. I was searching the Internet for an alternative treatment for him, hoping to keep him around as long as possible. By some miracle of fate, I was referred to

NovaVive and was accepted into a trial. Hugo had a partial front limb amputation on October 18th and we started Immunocidin treatments the next day. We have had holidays and special events I was afraid he would have missed. His birthday, snow, all of the big holidays and, his favorite of all, watching "his kids" in the pool. I am thankful for every day we have

with him, and look forward to him continuing to do well. Thanks so much for letting him take part in this trial."



Peace is a mixed breed dog from New Mexico who was diagnosed with oral melanoma and has been treated with Immunocidin for more than 118 weeks (more than two years)! She celebrated her 14th birthday on March 23rd!

"When Peace was diagnosed with cancer. I didn't know how long we'd have together. I only hoped that we could see her next birthday, when she would be 12. She has not only survived that birthday, but two more since then."

