

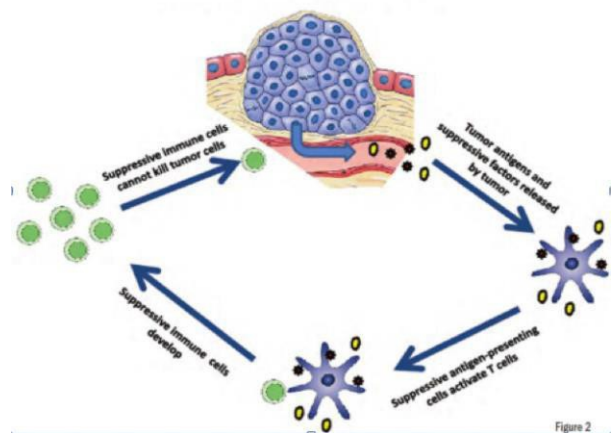
Dear Veterinarian,

Thank you for utilizing MediVet Biologics autologous prescription product service. This is an experimental vaccine service for canine cancer. Below you will find several FAQs that may be beneficial during your consultation and administration of the vaccine. Should you have any additional questions during the process please find our contact details below. We are happy to assist you.

## Basic Theory

Cancer cells can be recognized as foreign by the immune system if those cancer cells are presented to the immune system in a manner that “breaks immune tolerance.” Decades of research in mouse and human models have shown that tumor cells are very much like normal cells in that they express self-antigens that the body is taught to ignore early in development and throughout life. An immunosuppressive environment produced by growing tumors promotes an immune response toward the tumor that is ineffective, allowing the tumor to grow unchecked.

**Cycle of Tumor Immunosuppression**



An appropriately designed tumor vaccine, can break this cycle of tumor immunosuppression, generating tumor-specific immune cells that have effective anti-tumor reactivity, improving survival and quality of life in veterinary patients. Immunotherapy is specifically designed to make the patient’s tumor or disease appear foreign, thus inducing an effective anti-tumor immune response, like an immune response against viral or bacterial infections.

## How is this like other cancer vaccines?

Previous experimental cancer vaccines were designed to induce the generation of tumor-specific antibodies. Many newer cancer immunology studies have shown that while antibodies contribute to effective tumor immunity, development of tumor-specific T lymphocytes is critical for cancer immunotherapy. Newer antibody therapies appear beneficial because they enhance the function of T lymphocytes. Thus, future effective therapies will likely incorporate a dual approach. This experimental treatment is designed to induce both tumor-specific T lymphocytes and tumor-specific antibodies with an autologous vaccine approach. This we believe will lead to a stronger and more effective immune response to a patient’s tumor.



## Important Notes

This service is an experimental treatment option for canine patients only. **NOTE: The service is not available in all US states, contact us prior to consultation.**

We DO NOT accept feline, equine or tumors arising from other species. The patient must have a suspected survival of at least 90 days at the point of surgery to receive all three vaccine doses. There are additional inclusion/exclusion criteria to consider when speaking with owners.

## What types of cancer?

This service has been designed for all resectable canine tumors. To generate the vaccine a 3-5 cm in diameter sample will be sent next day air for processing. To date dogs with a variety of tumor types have received the experimental treatment including: oral melanoma, osteosarcoma, hemangiosarcoma, adenocarcinoma, nerve sheath tumors and mast cell.

## What Information Can I Share with the Owner?

MediVet Biologics has published data on the vaccine<sup>1</sup>. In the trial, greater than 85% of the dogs displayed an increased antitumor antibody response. Additional clinical assessment is described as well as a follow up trial is underway at a major veterinary university.

It should be communicated that the service is an experimental treatment for their pet.

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<sup>1</sup> <https://www.ncbi.nlm.nih.gov/pubmed/27863558>

## **What about histopathology of the sample?**

MediVet Biologics does not currently offer histological confirmation of the cancer. MediVet Biologics has selected the smallest volume of tumor tissue possible to process the vaccine. A minimum of 5 grams is required. If histopathology is required that still must be completed externally. Simply send us a 5 gram portion of the tumor. NOTE: this requires fresh tumor and needs to be sent the day of resection. **NO FORMALIN!!**

## **What if the tumor comes back non-cancerous from my histopathology lab?**

Should the report come back from your diagnostic lab as benign, please contact the help line immediately to suspend the service. Once notified the service will be suspended and no additional charges will be incurred beyond the processing fee. A new kit will be shipped ground back to your clinic at no cost.

## **What is the injection protocol?**

The injection protocol involves three administrations of a killed tumor vaccine derived from the patient's own tumor. Each dose is administered monthly as shown in the schedule provided. We ask that the entire 1 ml volume of each vaccine dose be administered intradermally equally distributed at 4 skin locations. The vaccine may appear cloudy, which is normal. The vaccine consists of cellular fragments obtained from 10 million cells from the tumor, which accounts for the cloudy nature of the vaccine. All vaccines are rigidly tested for sterility and are not released to your practice unless multiple sterility criteria are met.

## **What side effects should the owner be aware of?**

In similar human tumor vaccine studies, hundreds of vaccines have been administered on an out-patient basis. Following vaccination, patients are normally observed for roughly 1 hr. for development of any adverse event which in the experience of the investigators has been minor. Minor fever and minimal inflammation at the injection site may occur over the next 48 hours. Any adverse events should be reported via email [info@medivetbiologics.com](mailto:info@medivetbiologics.com) or via an adverse event reporting form.

## **Once the treatment protocol is underway what will my role be in the diagnostics to assist the patient?**

Once the vaccine is administered, your role will be to monitor the dog's health, behavior and quality of life. Assessment charts are available for the owner/veterinarian upon request.

## **Can I continue drug & other treatments in patients in that receive vaccine?**

The vaccine is experimental well being of the patient should be primary concern when evaluating concurrent medications. Immunomodulators, immune stimulants and steroids may interfere with vaccine effectiveness.

Additionally, chemotherapy may deplete myeloid precursor cells that may be detrimental to vaccine effectiveness. This experimental vaccine has not been studied in combination with chemotherapy or radiation.

**Need Help? Call us!**  
**(859) 885-7111**

**Email: [info@medivetbiologics.com](mailto:info@medivetbiologics.com)**