



Newsletter

Spring/Summer2013



Providing Unique Technology for Animal Health

FEATURES

Regulations and Autogenous Biologics

What new!

Affect of changes

Hog Jog 2013

SIV News

Mycoplasma Testing

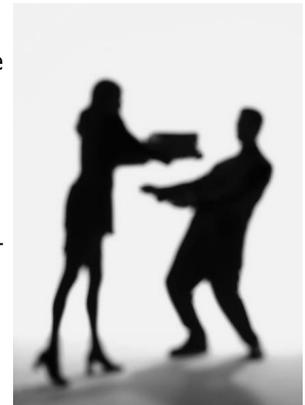
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Changes to Regulations Governing the Use Of Autogenous Biologics

The use of autogenous biologics– both bacterins and vaccines– is regulated by the Canadian Food Inspection Agency. Guidelines are available for review on their website at <http://inspection.gc.ca/animals/veterinary-biologics/guidelines-forms/3-13e/eng> During an inspection in October 2012 they informed us that there are going to be some changes to the requirements for the manufacturing of autogenous biologics in Canada. The key changes are as follows:

- 1.0 Isolates can be used for up to two years in an autogenous veterinary biologic, but the dating must now start at the day of isolation. Gallant will monitor the appropriate date and let you know on the Order Confirmation Form.
- 2.0 There is no longer a requirement to justify the use of the isolate after the first year, so you will no longer receive additional paperwork at the end of the first year.
- 3.0 Written justification for the use of more than 4 organisms in an autogenous veterinary biologic must be kept on file by the manufacturer. There is a section on the confirmation form to supply this information.
- 4.0 The use of an isolate beyond 24 months requires approval by CFIA. The application will include additional testing to determine identity, and purity of the isolate and an efficacy study of the biologic containing the isolate(s). Results may be confirmed by CFIA-CCVB. Any serials of biologic produced with the isolate(s) will be released for sale by CFIA-CCVB



What's New and Exciting



- * Gallant has begun development studies to adapt a poultry cell line for use in propagating poultry viruses. The goal is to use the cell line in isolating virus from samples and in the manufacturing of autogenous vaccines.
- * Hamid Haghighi has joined the team to work exclusively on research and development– to qualify the cells for vaccine manufacturing, study virus growth and vaccine design.

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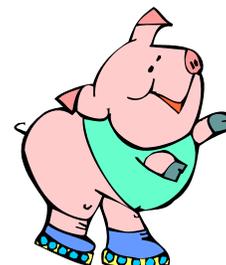
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Hog Jogging in Stratford 2013

Many of Gallant staff are training for the **2013 Hog Jog** run in Stratford on June 19. The cause this year is in support of Victims Services through Janet O'Rourke. Watch for our colourful T shirts and stop us to say "Hi!"

Last year saw a record number of jogger's out, so let's try to set a new record this year!!



How will new Guidelines change the autogenous biologics process in Canada?

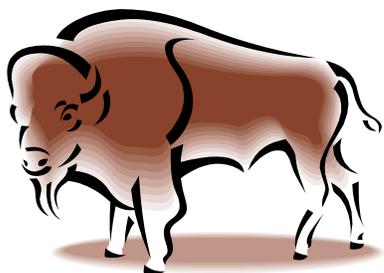
The staff at Gallant will ensure that each autogenous biologic order meets the regulatory requirements. We will continue our reminder system when isolates are expiring for each client, to give them the opportunity to make one last order, while they monitor for new cases to update the isolate. As of July 1, 2013 we will begin dating the time allowed for an isolate based on the date of isolation. We will take this as the last date on the diagnostic report or the date received by our lab, if submitted through another lab. This date will be shown on the confirmation form, as before. As of July 1, 2013 we will no longer require you to complete our "Extended Useage Form" after the first year of isolate use. The confirmation form will be expanded to provide adequate space to complete the information needed for our file.

SIV News

Gallant continues to isolate Swine Influenza virus, both H3N2 and H1N1, from submitted samples . As a follow-up to an autogenous vaccine programme we offer Haemagglutination Inhibition studies of serum from vaccinated animals. An excellent way to see a response to vaccina-



Mycoplasma Isolation and Bacterin Production



Gallant can successfully isolate *Mycoplasma bovis* from tissue samples from cattle. Isolates are sent to another lab to confirm the species and an autogenous bacterin can be manufactured from the isolate. We have made bacterins for cattle and bison.

We are currently studying various media preparations to allow for the isolation of swine strains of Mycoplasma, such as *M. hyosynoviae*, *M. hyorhinis* and *M. hyopneumoniae*.

We use a PCR based test to determine if the sample is positive and then proceed to isolate. We are working on a PCR based test that will identify the three swine Mycoplasma species in the sample- providing rapid results to identify species. The fastidious growth requirements of Mycoplasma provides a challenge to isolate a viable culture and it may

require an adaption period to lab media. The goal is to provide rapid identification using PCR, isolation of organism and the option to make an autogenous bacterin with the isolate.