United States Department of Agriculture
Animal and Plant Health Inspection Service

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# Inspection Report

Lampire Biological Laboratories Inc
P. O. Box 270
Pipersville, PA 18947

Customer ID: **369**
Certificate: **23-R-0122**
Site: 002
LAMPIRE BIOLOGICAL LABORATORIES

Type: ROUTINE INSPECTION
Date: 06-DEC-2016

**2.31(d)(1)**

**INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).**

Six Rabbits were directed to receive injections that were three times the maximum volume per site indicated in the IACUC approved "Core Rabbit Freunds" protocol. The subcutaneous injections of antigen and adjuvant are performed based upon a schedule provided by the client. There was no documentation available to indicate that the schedule, which included several modifications, had been reviewed or approved by the IACUC or facility veterinarian. The facility IACUC chair stated that the modifications were not discussed by the IACUC because he had determined that the client injection Schedule was within the guidelines of the approved "Core Rabbit Freunds" protocol. The printed Schedule directions did not include route and site for each of the injections and the volume per injection site was directed to be 0.5ml per site which is twice the 0.25ml maximum volume per site directed by the approved protocol. When antigen was provided by the client, facility staff recognized that the schedule directions would not fit the protocol with respect to Total Volume of injection per animal (3ml maximum). Facility staff corrected the Total Volume in discussion with the client before the injections were made. This change was not reported to a faclilty Veterinarian or the IACUC because the change brought the Total Volume within the guidelines of the approved protocol and staff did not realize that the volume per site was not within guidelines in the protocol. There is flexibility in the protocol regarding route of administration and concentration of the solution, and this flexibility was applied by the staff to correct the Total Volume. The volume of solution per site is stated in the protocol to be a maximum of 0.25 ml/site. The resulting volume of injection per site (after the correction for Total Volume) was directed to be 0.75ml per site for the injections performed 6 December 2016 instead of the 0.25ml per site maximum Indicated In the approved protocol. Based review of the documentation and discussion with faclilty personnel, the changes from the IACUC approved protocol in this case are considered significant. Proposed significant changes in ongoing activities must be reviewed by the IACUC to assure that the changes do not adversely affect the welfare of the animals. Correct by having the IACUC review all changes to approved protocols and maintain documentation of this review for future inspections. To be corrected before using animals under changes to any approved protocol.

**Prepared By:** [redacted] DAVID OELBERG, D V M

DAVID OELBERG USDA, APHIS, Animal Care

**Title:** VETERINARY MEDICAL OFFICER 1043

**Date:** 07-DEC-2016

**Received By:** [redacted] (b)(6), (b)(7)(c)

**Title:** ASSISTANT FARM MANAGER

**Date:** 07-DEC-2016