



Inspection Report

Qed Biosciences Inc.
10919 Technology Place, Suite C
San Diego, CA 92127

Customer ID: **1707**
Certificate: **93-R-0389**
Site: 001
QED BIOSCIENCES, INC.

Type: ROUTINE INSPECTION
Date: 27-MAR-2017

2.31(d)(2)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

The umbrella rabbit antibody production protocol was submitted to the IACUC by the principal investigator and the same individual (PI) approved the protocol as the current IACUC chair.

With respect to activities involving animals, the IACUC, as an agent of the research facility, shall review protocols and amendments to protocols prior to approval. No member may participate in the IACUC review or approval of an activity in which that member has a conflicting interest (e.g., is personally involved in the activity).

Correct by 30 April, 2017

2.31(e)(3)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

The umbrella rabbit antibody production protocol describes that "rabbits will weigh at least 4 kg prior to blood collection" and "collecting 40-50ml whole blood per rabbit each time" and "rabbits are bled every two weeks", "Each rabbit will be used approximately 4 times".

There is not enough detail in the protocol to ensure that the animals are allowed to regenerate their blood volume between bleeds because there is no discussion of maximum volume per body weight, monitoring body weight or hematocrit to ensure that the animals are not in distress. The bleed schedules reviewed had two rabbits on every other week bleeds for 6 bleeds. The protocol says approximately 4 bleeds, and sometimes the course of the project is extended past that but there is no mention of monitoring the animal for additional bleeds.

There must be sufficient detail in the protocol for the IACUC to understand the use of the animals and evaluate the impact of the research projects on the animal in order to approve the protocol.

Correction by 30 May, 2017

Prepared By:

FRANK KATHARINE, D V M

FRANK KATHARINE, D V M USDA, APHIS, Animal Care

Title: VETERINARY MEDICAL OFFICER 6091

Date:
06-APR-2017

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Date:
06-APR-2017



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Exit briefing conducted with facility representative.

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