



## Inspection Report

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Low Country Biosource Inc  
6133 MOUNT CARMEL RD  
WALTERBORO, SC 29488

Customer ID: **10055**

Certificate: **56-R-0110**

Site: 002

Low Country Biosource Inc

Type: FOCUSED INSPECTION

Date: 07-AUG-2023

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### 2.31(c)(7)

#### Institutional Animal Care and Use Committee (IACUC).

Dogs used on protocol #02-22 underwent a terminal anesthesia procedure and increased volume blood draw that were not defined in the IACUC approved protocol. The addition of the procedures were approved by the attending veterinarian rather than the IACUC. The facility does not have an IACUC approved policy in place for the attending veterinarian to approve changes to a protocol on behalf of the IACUC. The IACUC shall review and approve, require modifications to secure approval or withhold approval of proposed significant changes regarding the care and use of animals in ongoing activities. Correct by August 31, 2023.

### 2.31(d)(2)

#### Institutional Animal Care and Use Committee (IACUC).

Review of IACUC minutes disclosed that protocol #02-22 was reviewed and approved solely by email correspondence from the IACUC. Appropriate IACUC review is necessary to safeguard the use of all animals on study. The IACUC shall review proposed activities involving the care and use of animals and any member can call for a full Committee review. If not, the chairman can designate a member to review and have the authority to approve, modify or request full Committee review of any of those activities. No member may participate in IACUC review or approval of an activity in which that member is personally involved in the activity. Correct by August 31, 2023.

### 2.31(e)(2)

#### Institutional Animal Care and Use Committee (IACUC).

Protocol #02-22 did not contain a rationale for the number of animals to be used. The study stated they would use sixteen dogs total, dividing into subsets. This approach would 'balance achieving statistical significance while minimizing the number of dogs used'. No details such as statistical tests used or statisticians consulted were included to support the statement. An animal use proposal must include a rationale for the appropriateness of the numbers of animals to be used so that the IACUC can conduct a thorough review of the components of the activities related to the care and use of animals and determine that the proposed activities are in accordance with the Animal Welfare Act. The proposal to conduct an activity involving animals must contain a rationale for the numbers of animals to be used. Correct by August 31, 2023.

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Prepared By: CARLA THOMAS

USDA, APHIS, Animal Care

Date:

08-AUG-2023

Title: VETERINARY MEDICAL  
OFFICER

Received by Title: Authorized Person

Date:

08-AUG-2023



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### 2.35(c)(2)

#### Recordkeeping requirements.

The facility did not record the disposition information for sixteen dogs. Failure to maintain completed animal records hinders accurate tracking, identification, and tracing of animals upon their removal from the current facility. Every research facility shall keep and maintain records for live dogs which fully and correctly disclose the required information for the transporting, selling, or otherwise disposing of any live dog.  
Correct by August 31, 2023.

### 3.8

#### Exercise for dogs.

The registrant did not develop and document a written exercise plan for sixteen dogs used on study #02-22. Exercise is important for the well-being of the dogs. Research facilities must develop, document, and follow an appropriate plan to provide dogs with the opportunity for exercise. In addition, the plan must be approved by the attending veterinarian and available during APHIS inspections for review.  
Correct by August 31, 2023.

### 3.13(a)

#### Veterinary care for dogs.

The facility does not have a documented program of veterinary care. The facility completed a study, housing and using dogs in February 2023. The absence of a program of veterinary care disallows assurance that the preventive care and treatment is aligned with the veterinarian's authority and guidance. A written Program of Veterinary Care (PVC) for dogs must be established and maintained so that the facility has a current plan that provides for adequate preventative care and treatments as deemed necessary. The plan must include all required components as listed in the Animal Welfare Act and Animal Welfare Regulations, Part 3, Subpart A, Section 3.13.  
Correct by August 31, 2023.

This inspection and exit interview were conducted with authorized person.

Additional Inspectors:

SUSANNE BRUNKHORST, VETERINARY MEDICAL OFFICER

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Prepared By: CARLA THOMAS

USDA, APHIS, Animal Care

Title: VETERINARY MEDICAL  
OFFICER

Date:  
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**Species Inspected**

Cust No	Cert No	Site	Site Name	Inspection
10055	56-R-0110	002	Low Country Biosource Inc	07-AUG-2023

Count	Scientific Name	Common Name
000000	NONE	NONE
000000	Total	