



Inspection Report

Labcorp Early Development Laboratories Inc
3301 KINSMAN BOULEVARD
MADISON, WI 53704

Customer ID: **640**

Certificate: **35-R-0030**

Site: 004

Labcorp Early Development
Laboratories Inc

Type: FOCUSED INSPECTION

Date: 01-JUN-2022

No non-compliant items identified during this inspection.

This inspection and exit interview were conducted with facility representatives.

Prepared By: KERRY MCHENRY

USDA, APHIS, Animal Care

Date:

01-JUN-2022

Title: VETERINARY MEDICAL
OFFICER

Received by Title: Facility Representative

Date:

01-JUN-2022



Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
640	35-R-0030	004	Labcorp Early Development Laboratories Inc	01-JUN-2022

Count	Scientific Name	Common Name
000164	<i>Canis lupus familiaris</i>	DOG ADULT
000444	<i>Macaca fascicularis</i>	CRAB-EATING MACAQUE / CYNOMOLGUS MONKEY
000236	<i>Oryctolagus cuniculus</i>	DOMESTIC RABBIT / EUROPEAN RABBIT
000844	Total	



Animal and Plant
Health Inspection
Service

4700 River Road
Riverdale, MD 20737

June 6, 2022

(b) (6), (b) (7)(C)

Labcorp Early Development Laboratories Inc.
3301 Kinsman Boulevard
Madison, WI 53704

License No.: 35-R-0030
Customer No.: 640

Dear (b) (6), (b) (7)(C)

Your appeal of the citation on the USDA inspection report dated April 26, 2022 was thoroughly reviewed by an Animal Care appeal panel consisting of two Supervisory Animal Care Specialists, an Assistant Director, and me. The appeal is addressed below.

The citation for Section 2.33(b)(2) will remain on the report as written. Photographs taken at the time of inspection demonstrate that the hooves of these animals appear long, even when compared to the reference material included with your appeal.

All decisions made by the appeal panel are final and represent Animal Care's final determination for this appeal.

Sincerely,

Robert Gibbens, DVM
Director, Animal Welfare Operations
USDA, APHIS, Animal Care

USDA Animal Care. Ensuring humane treatment for animals covered by the Animal Welfare Act.

Labcorp Early Development Inc.
3301 Kinsman Boulevard
Madison, WI 53704

VIA EMAIL

17 May 2022

USDA Animal Care
2150 Centre Avenue, Building B
Mailstop #3W11
Fort Collins, CO 80526-8117
acwest@aphis.usda.gov

Re: Appeal of Citation for Noncompliance

Dear USDA Appeal Team:

We write regarding a recent inspection of the Labcorp Early Development Laboratories Inc. (formerly Covance Laboratories Inc.) site 011 license number 35-R-0030, that resulted in a citation for 2.33(b)(2), Attending veterinarian and adequate veterinary care. See Attachment 1

Background

Labcorp Drug Development is a leading contract research laboratory that has helped to assess thousands of innovative new medicines and medical devices in development by its clients. In accordance with FDA requirements, the (b) (7)(F) site provides in vivo surgical and evaluation for medical devices in development. (b) (7)(F) to house research animals that cannot be kept at the (b) (7)(F) long term.

On April 26, 2022, a Routine Unannounced Inspection resulted in a finding under Section 2.33(b)(2) that the two Yucatan pigs housed on site had overgrown hooves and the frequency of trimming was "not adequate to maintain the hooves at a normal length." As follow up to the inspection report, both animals were transported to the (b) (7)(F) facility for evaluation and hoof trimming. Measurements taken before and after trimming showed the hooves of each animal could only tolerate minimal trimming, of approximately 3-7mm of hoof wall removal per claw per animal without risking causing pain and or lameness.

Discussion

Yucatan pigs are a breed specific to research animals, and their hoof appearance is quite different from the typical domestic farm pig. The normal hoof length is significantly longer and the sensitive corium extends forward much further than other breeds. See Attachment 2 (showing Yucatan pigs and domestic pigs).

A brief literature search showed the average growth rate of farm pig's hooves, was approximately 6.3 - 11mm per 30 days (Van Amstel, 2010; Johnston, 1989). The American Mini-pig Association (www.americanminipigassociation.com) recommends that 6 months is a good hoof trimming schedule for most pigs. While some may need more frequent small trims but others may be able to go longer in between trims. Given the minimal amount of trimming that could be done on these animals we feel our frequency of trimming was appropriate. Overly aggressive trimming on these pigs can cause trauma, bleeding and lameness.

While the hoof appearance may have appeared slightly overgrown in comparison to domestic farm pigs, we have monitored and trimmed hooves regularly to maintain them at a normal length for this breed of pig. Accordingly, the hoof lengths or frequency of trimming here should not have resulted in a finding of a violation of Section 2.33(b)(2). Labcorp respectfully requests that the Appeals Team reverse the inspection finding.

Respectfully Submitted,

Labcorp Early Development Laboratories Inc.
(formerly Covance Laboratories Inc.)

By: _____

(b) (6), (b) (7)(C)

Attachments

References:

1. Johnston AM, Penny RH. Rate of claw horn growth and wear in biotin-supplemented and non-supplemented pigs. Vet Rec. 1989 Aug 5;125(6):130-2. doi: 10.1136/vr.125.6.130. PMID: 2773255.
2. Van Amstel, S. Claw horn growth and wear rates, toe length, and claw size in commercial pigs: A pilot study *J. of Swine Health and Prod.* 18 (5)
3. <https://americanminipigassociation.com/owners/helpful-owner-articles/hoof-trimming/#:~:text=In%20general%20every%206%20months,posture%2C%20joints%2C%20and%20ligaments.>



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3301 KINSMAN BOULEVARD
MADISON, WI 53704

Customer ID: 640

Certificate: 35-R-0030

Site: 011

Labcorp Early Development
Laboratories Inc

Type: ROUTINE INSPECTION

Date: 26-APR-2022

2.33(b)(2)

Attending veterinarian and adequate veterinary care.

Two Yucatan pigs (numbers 1123 & 4515) had overgrown hooves, and their hooves had not been trimmed since 3 February 2022. The previous hoof trim had been 4 November 2022, but this frequency is not adequate to maintain the hooves at a normal length. The failure to use appropriate methods to prevent, control, diagnose, and treat diseases or injuries may negatively impact the well-being and quality of life of the animals. The facility should ensure that all animals receive appropriate veterinary care, including hoof trimming as often as necessary.

Correct by 11 May 2022

This inspection was conducted with onsite manager and the exit interview was conducted over the phone with the AV.

Prepared By: KATHARINE FRANK

USDA, APHIS, Animal Care

Date:

27-APR-2022

Title: VETERINARY MEDICAL
OFFICER

Received by Title: Attending Veterinarian

Date:

27-APR-2022



Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
640	35-R-0030	011	Labcorp Early Development Laboratories Inc	26-APR-2022

Count	Scientific Name	Common Name
000004	<i>Canis lupus familiaris</i>	DOG ADULT
000002	<i>Sus scrofa domestica</i>	DOMESTIC PIG / POTBELLY PIG / MICRO PIG
000006	Total	

Attachment 2



Image 1. Yucatan https://nsrrc.missouri.edu/wp-content/uploads/2018/03/tie2catalase_pigs.jpg



Image 2. Yucatan <https://sinclairbioresources.com/miniature-swine-production/micro-yucatan-miniature-swine/>



Image 3. Domestic Pig



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USDA, APHIS, Animal Care

Date:

27-APR-2022

Title: VETERINARY MEDICAL
OFFICER

Received by Title: Attending Veterinarian

Date:

27-APR-2022



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000006	Total	

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Research Facility Protocol Selection Worksheet

Legal Name: Labcorp Early Development Laboratories Inc

Customer Number: 640

Certificate Number: 35 - R - 0030

Site Number: 004

Inspection Date: 01JUN2022

Inspection Type: Routine ☐

Focused ☒ (list areas inspected) Animals

Inspector: K. McHenry DVM VMO

Reasons Protocols Were Selected for Review :	How Many Protocols Were Selected
1. Protocols identified during inspection of concern (select all)	0
2. Column E protocols (select all)	0
3. Protocols with IACUC-approved exemptions/exceptions (select all)	0
4. Protocols cited as noncompliant and not corrected during the last inspection (select all)	0
5. Additional Protocols Selected: a. If <5 remaining protocols, select all remaining: b. If >5 remaining protocols, select 5 additional protocols: 1) Protocol for each regulated species and/or, 2) Protocols involving high risk procedures (see Chapter 7, Animal Welfare Inspection Guide for guidance):	0
Total Protocols Selected and Reviewed	0

*Note: Protocol selection guidance applies to protocols which have been initially approved, or have had significant changes approved, since the last inspection. For protocols reviewed by an Animal Care Veterinary Medical Officer within the last year, professional judgment should be used in determining whether another review is necessary.

Version 3/14/19