



Inspection Report

Xenometrics L L C
17745 Metcalf Avenue
Stilwell, KS 66085

Customer ID: **321342**
Certificate: **48-R-0111**
Site: 001
Xenometrics, LLC

Type: ROUTINE INSPECTION
Date: 22-FEB-2017

2.31(d)(1)(iv)(A)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

The medical records for three Cynomolgus monkeys on one study documented that they experienced tremors during the study, but no treatment was given for the tremors. The Attending Veterinarian stated that she had discussed the clinical signs with the principal investigator; however, there was no written justification in the study protocol or from the principal investigator stating that treatment should be withheld for scientific reasons. Treatment is required for procedures that cause more than momentary or slight pain or distress to the animals unless the principal investigator documents in writing that withholding treatment is justified for scientific reasons. The IACUC must ensure that activities involving animals are documented in writing for review and approval purposes. TO BE CORRECTED FROM THIS POINT FORWARD.

This inspection was conducted with facility representatives on February 22 and 23, 2017. The exit interview was conducted on February 23 with facility representatives.

Additional Inspectors

Leisner Erika, Veterinary Medical Officer

Prepared By:

PLUMLEE KONNIE, D V M USDA, APHIS, Animal Care

Date:
28-FEB-2017

Title: VETERINARY MEDICAL OFFICER 6031

Received By:

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

Date:
01-MAR-2017

Title: SENT VIA EMAIL
19-04152_000001



Cust No	Cert No	Site	Site Name	Inspection
321342	48-R-0111	001	Xenometrics L L C	22-FEB-17

Count	Species
000019	DOMESTIC PIG / POTBELLY PIG / MICRO PIG
000021	DOMESTIC RABBIT / EUROPEAN RABBIT
000033	DOG PUPPY
000105	CRAB-EATING MACAQUE / LONG-TAILED MACAQUE / CYNOMOLGUS MONKEY
000124	DOG ADULT
000302	Total



Inspection Report

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17745 Metcalf Avenue
Stilwell, KS 66085

Customer ID: **321342**
Certificate: **48-R-0111**
Site: 001
Xenometrics, LLC

Type: --RESCINDED--
Date: 22-FEB-2017

2.31(d)(1)(iv)(A)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

The medical records for three Cynomolgus monkeys on one study documented that they experienced tremors during the study, but no treatment was given for the tremors. The Attending Veterinarian stated that she had discussed the clinical signs with the principal investigator; however, there was no written justification in the study protocol or from the principal investigator stating that treatment should be withheld for scientific reasons. Treatment is required for procedures that cause more than momentary or slight pain or distress to the animals unless the principal investigator documents in writing that withholding treatment is justified for scientific reasons. The IACUC must ensure that activities involving animals are documented in writing for review and approval purposes. TO BE CORRECTED FROM THIS POINT FORWARD.

Additional Inspectors

Leisner Erika, Veterinary Medical Officer

Prepared By:

PLUMLEE KONNIE, D V M USDA, APHIS, Animal Care

Date:
23-FEB-2017

Title: VETERINARY MEDICAL OFFICER 6031

Received By:

(b) (6), (b) (7)(C)
Title:
19-04152_000003

Date:
23-FEB-2017



Cust No	Cert No	Site	Site Name	Inspection
321342	48-R-0111	001	CITOLAB USA LLC	22-FEB-17

Count	Species
000019	DOMESTIC PIG / POTBELLY PIG / MICRO PIG
000021	DOMESTIC RABBIT / EUROPEAN RABBIT
000033	DOG PUPPY
000105	CRAB-EATING MACAQUE / CYNOMOLGUS MONKEY
000124	DOG ADULT
000302	Total

*

Research Facility Protocol Selection Worksheet

Legal Name : Xenometrics, LLC

Customer Number: 321342

Certificate Number: 48-R-0111

Inspection Date: Feb 22-23, 2017

Site Number: 001

Inspector: K. Plumlee & E. Leisner

Reasons Protocols Were Selected for Review :	How Many Protocols Were Selected
1. Protocols identified during inspection of concern (select all)	3
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):	5
Total Protocols Selected and Reviewed	8

*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.



Inspection Report

Citoxlab Usa Llc
17745 Metcalf Avenue
Stilwell, KS 66085

Customer ID: **321342**
Certificate: **48-R-0111**
Site: 001
CITOLAB USA LLC

Type: ROUTINE INSPECTION
Date: 10-SEP-2018

No non-compliant items identified during this inspection. The inspection was conducted 10-11 SEP 2018.
This inspection and an exit interview were conducted with facility representatives.

Prepared By:

OWENS AMANDA, D V M USDA, APHIS, Animal Care

Date:
11-SEP-2018

Title: VETERINARY MEDICAL OFFICER 6033

Received By:

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

Title:
19-04152_000006

Date:
11-SEP-2018



Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
321342	48-R-0111	001	CITOLAB USA LLC	10-SEP-18

Count	Scientific Name	Common Name
000157	<i>Canis lupus familiaris</i>	DOG ADULT
000032	<i>Canis lupus familiaris</i>	DOG PUPPY
000139	<i>Macaca fascicularis</i>	CRAB-EATING MACAQUE / CYNOMOLGUS MONKEY
000042	<i>Sus scrofa domestica</i>	DOMESTIC PIG / POTBELLY PIG / MICRO PIG
000370	Total	



United States Department of Agriculture
Animal and Plant Health Inspection Service
Teachable Moments

Legal Name: CITOLAB USA LLC

Customer Number: 321342 Certificate Number: 48-R-0111

Inspection Date: 10-SEP-18 Site Number: 001

Inspector: AMANDA OWENS, D V M

Section: _____

2.30(c)(1) REGISTRATION.

The facility did not notify the Animal Care Regional Director of its name change within 10 days of the change.

19-04152_000009



United States
Department of
Agriculture

Marketing and
Regulatory
Programs

Animal and
Plant Health
Inspection
Service

Animal Care

EXPIRATION DATE: MARCH 20, 2021

This is to certify that

XENOMETRICS L L C

is a registered
under the

CLASS R RESEARCH FACILITY

Animal Welfare Act

(7 U.S.C. 2131 et seq.)

48-R-0111

Certificate No.

321342

Customer No.

A handwritten signature in black ink, appearing to be "B. J. [unclear]", written over a horizontal line.

Deputy Administrator

Every research facility, exhibitor, carrier, and intermediate handler not required to be licensed under Section 2 of the Animal Welfare Act, shall register with the USDA (7 USC 2136). This application provides information for such registration.

OMB No. 0579-0036
FORM APPROVED

U.S. DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
APPLICATION FOR REGISTRATION
(TYPE OR PRINT)

REGISTRATION UPDATE

USDA USE ONLY

Applicant should send completed form to this address.
USDA APHIS ANIMAL CARE
WESTERN
2150 Centre Ave.
Building B, Mailstop 3W11
Fort Collins, CO 80526-8117
(970) 494-7478

CERTIFICATE NO./CUST NO:

48-R-0111

321342

RENEWAL DATE

20-Mar-2018

1. REGISTRANT (Name and permanent mailing address, including Zip Code)

Xenometrics L L C
17745 Metcalf Avenue
Stilwell, KS 66085

COUNTY: JOHNSON TELEPHONE (913) 850 - 5000

3. (A) PREVIOUS USDA REGISTRATION NUMBER (IF ANY)

2. LOCATION (S) OF BUSINESS, EXHIBITION SITE(S), OR RESEARCH FACILITIES
(Use additional sheets if necessary)

17745 Metcalf Avenue
Stilwell, KS 66085
County: Johnson

4. (B) ACTIVE USDA CERTIFICATE NUMBER(S) IN WHICH YOU HAVE AN INTEREST:

5. ARE YOU USING FEDERAL FUNDS TO CARRY OUT

RESEARCH, TESTS, OR EXPERIMENTS

(VARIES)

☒ Yes ☒ No

6. TYPE OF REGISTRATION:

☐ Class E - Exhibitor ☐ Class H - Intermediate Handler
☐ Class R - Research Facility ☐ Class T - Carrier

7. FEDERAL FUND TYPES:

☐ Award ☐ Contract ☐ Grant ☐ Loan

8. TYPE OF ORGANIZATION:

☐ Partnership ☐ Corporation ☐ Individual
☒ Other (Specify) LLC

9. IF INDIVIDUAL IDENTIFY EACH OWNER, IF PARTNERSHIP IDENTIFY EACH PARTNER OR OFFICER, IF CORPORATION, IDENTIFY PRINCIPAL OFFICERS FOR RESEARCH FACILITIES INCLUDE THE INSTITUTIONAL OFFICIAL (Use separate sheet if needed)

A. NAME B. TITLE C. ADDRESS (full address, including ZIP Code)

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

17745 METCALF AVENUE, BLDG #3
STILWELL, KANSAS 66085

CERTIFICATION

I hereby register as a Research Facility, Exhibitor, Carrier, or Intermediate Handler under the Animal Welfare Act, 7 U.S.C. 2131 et seq. and I certify that the information provided herein is true and correct to the best of my knowledge. I hereby acknowledge receipt of and agree to comply with all the regulations and standards contained in 9 CFR, Subpart A, parts 1, 2 and 3. I certify that all listed persons are 18 years of age or older.

10. (b) (6), (b) (7)(C)

11. NAME AND TITLE (Type or Print)

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

12. DATE SIGNED

09 FEB 2018

ACKNOWLEDGEMENT OF RECEIPT OF REGULATIONS AND STANDARDS

APHIS FORM 7011
(FEB 2009)

19-04152_000010

19 FEB 2018



United States Department of Agriculture

Animal and Plant
Health Inspection
Service

Animal Care

Fort Collins Office
2150 Centre Avenue
Building B, 3W11
Fort Collins, CO
80526
Phone: 970-494-7478

Raleigh Office
920 Main Campus Dr.
Suite 200
Raleigh, NC 27606
Phone: 919-855-7100

RE: REGISTRATION CANCELLATION

Certificate Number: 48-R-0111

Cancellation Date: 05/23/2019

May 23, 2019

Customer ID Number: 321342

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

Citoxlab Usa Llc
17745 Metcalf Avenue
Stilwell, KS 66085

Dear Sir/Madam:

As you requested, we are terminating your Registration under the Animal Welfare Act (AWA) effective the date shown above.

Should you decide to resume operations that require AWA registration, you will need to submit a new application. Please note that operating without a valid registration is a violation of the AWA and subject to legal action.

If you are a research facility, we wish to emphasize that all research facilities -- both active and inactive -- must file an annual report (APHIS Form 7023) with the Animal Care regional office documenting their activities and animal usage for the Federal fiscal year (October 1 through September 30) by December 1 of that year. Research facilities whose registrations were terminated during the fiscal year must also fulfill this requirement. Failure to do so constitutes a violation of the AWA and its regulations.

Accordingly, please complete the enclosed APHIS Form 7023 and return to it to the above address. Detailed instructions for completing the form are enclosed. All research facilities should complete items 4 through 13. Also required is the date, signature, and title of the Chief Executive Officer or other legally responsible official who attests to the accuracy of the report and to the assurance statements.

We appreciate your efforts in complying with the Animal Welfare Act. Contact this office at (970) 494-7478 if you have any questions regarding this letter or the Animal Welfare Act.

Sincerely,

Robert M. Gibbens, D. V. M.
Director, Animal Welfare Operations
USDA, APHIS, Animal Care

cc: Amanda J Owens

Enclosures



Elizabeth Goldentyer, D.V.M.
Director, Animal Welfare Operations
USDA, APHIS, Animal Care
EASTERN
920 Main Campus Drive
Suite 200
Raleigh, NC 27606-5213

May 7, 2019

RE: USDA Research Registration #48-R-0111
Change of ownership and cancellation request

Dear Dr. Goldentyer,

The purpose of this letter is to inform you that on April 29, 2019 Charles River Laboratories, Inc. purchased Citoxlab. The Citoxlab USA, LLC site located at 17745 Metcalf Avenue, Stilwell, KS 66085, and previously registered as Certificate number 48-R-0111 (customer number 321342 and site 001), is now a Charles River Company site. As a result of this change of ownership, we are requesting cancellation of the Citoxlab USA, LLC USDA Research facility registration (certificate number 48-R-0111, customer number 321342 and site 001).

A separate letter has been sent to your attention by Charles River requesting the addition of the Stilwell, KS site to their USDA registration (certificate number 14-R-0144, customer number 1799) due to the change in ownership.

All instructions regarding accessing the site through the posted visitor parking lot and visitor entrance, normal business hours and all contact telephone numbers remain the same as previously established by Citoxlab USA, LLC.

If we can provide any additional information or answer any questions, please contact me at Shannon.Colbern@us.citoxlab.com (913-850-5078) or Ryan Losson, (Scientist and IACUC Chairperson) at Ryan.Losson@us.citoxlab.com (913-850-5007).

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

Attending Veterinarian

CC: (b) (6), (b) (7)(C) – Stilwell site

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

Citoxlab USA, LLC
17745 Metcalf Avenue
Stilwell, Kansas 66085

Tel: (913) 850-5000
Fax: (913) 850-5101
Email: contact.northamerica@citoxlab.com

www.citoxlab.com

19-04152_000012

Animal Care Regional Director
USDA APHIS
Animal Care - Western Region
2150 Centre Aye, Bldg B
Mail Stop #3W1 1
Ft. Collins, CO 80526

10th September, 2018

Dear Valued Partner:

Class R Research facility name change
Registration Certificate #48-R-0111
Customer number: 321343

This letter is to notify you that Xenometrics, LLC has changed its name to **Citoxlab USA LLC**, and filed the necessary documents with the Kansas Secretary of State.

Please note that there has been no change in range of services we offer and the name change shall not impact our ongoing dedication to the Animal Welfare Act and our adherence to federal standards and regulations.

Our new name reflects our global presence as a full-fledged subsidiary of Citoxlab, allowing us to incorporate Citoxlab's corporate name recognition into our business activities, which include service lines beyond those we began with in 2006 as Xenometrics. The Citoxlab Group offers a comprehensive range of non-clinical services to meet the needs of pharmaceutical, biotechnology, medical device, chemical and agrochemical companies worldwide. Our commitment to our clients and partners remains our highest priority.

We would highly appreciate it if you could bring this information to the attention of your department(s) and/or persons responsible for any notices permitted under agreements, reviews, records, and obligations, by conveying to them a file with the enclosure of this letter. Our office location, your contacts and phone numbers here in Kansas will remain the same.

Should you have any questions regarding this name change, please feel free to contact me at +1 913 850 5005 or alternatively at abotchway@xenometricsllc.com

Yours Sincerely,

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

Citoxlab USA

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0036. The time required to complete this information collection is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB APPROVED
0579-0036
Exp. 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control
No. 0180-DOA-AN

Fiscal Year 2017

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NUMBER
48-R-0111

2. HEADQUARTERS RESEARCH FACILITY (Name, address, and telephone number as registered with USDA, include ZIP Code)

CITOLAB USA LLC
17745 Metcalf Avenue

STILWELL, KS 66085

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)

FACILITY LOCATIONS (Sites)

CITOLAB USA LLC

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets, if necessary, or use APHIS FORM 7023A.)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)	F. TOTAL NUMBER OF ANIMALS (Cols. C + D + E)
4. Dogs	0	454	49	0	503
5. Cats	0	41	0	0	41
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	6	0	0	6
8. Rabbits	0	95	0	0	95
9. Non-human Primates	5	109	54	3	166
10. Sheep	0	0	0	0	0
11. Pigs	34	112	60	0	172
12. Other Farm Animals					
13. Other Animals	0	0	102	0	102

ASSURANCE STATEMENTS

- 1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2.) Each principal investigator has considered alternatives to painful procedures.
- 3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.

NAME AND TITLE OF C.E.O. OR I.O. (Type or Print)

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

DATE SIGNED
23-JAN-2018

OMB APPROVED
0579-0036

Interagency Report Control
No. 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NUMBER
48-R-0111

CITOLAB USA LLC
17745 Metcalf Avenue

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use this form.)

ASSURANCE STATEMENTS

- 1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
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- 4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

NAME AND TITLE OF C.E.O. OR LO (Type or Print)

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

23-JAN-2018