



## Inspection Report

Ricerca Biosciences L L C  
7528 Auburn Road  
Concord Twp, OH 44077

Customer ID: **254**

Certificate: **31-R-0091**

Site: 001

RICERCA BIOSCIENCES LLC

Type: ROUTINE INSPECTION

Date: 26-APR-2017

No non-compliant items identified during this inspection.

This inspection and exit interview were conducted with facility representatives.

**Prepared By:**

NEAFSEY MICHAEL USDA, APHIS, Animal Care

**Date:**  
26-APR-2017

**Title:** VETERINARY MEDICAL OFFICER 6094

**Received By:**

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

**Title:** IACUC CHAIR  
19-04394\_000001

**Date:**  
26-APR-2017



Cust No	Cert No	Site	Site Name	Inspection
254	31-R-0091	001	CONCORD BIOSCIENCES LLC	26-APR-17

Count	Species
000022	CRAB-EATING MACAQUE / LONG-TAILED MACAQUE / CYNOMOLGUS MONKEY
000124	DOG ADULT
<b>000146</b>	<b>Total</b>



## Inspection Report

Concord Biosciences LLC  
10845 Wellness Way  
Concord Twp, OH 44077

Customer ID: **254**

Certificate: **31-R-0091**

Site: 001

CONCORD BIOSCIENCES LLC

Type: ROUTINE INSPECTION

Date: 18-SEP-2018

No non-compliant items identified during this inspection.

This inspection and exit interview were conducted with facility representatives.

**Prepared By:**

CROWLEY LACY, D V M USDA, APHIS, Animal Care

**Title:** VETERINARY MEDICAL OFFICER 6122

**Date:**

18-SEP-2018

**Received By:**

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

**Title:** IACUC CHAIR  
19-04394\_000003

**Date:**

18-SEP-2018



## Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
254	31-R-0091	001	CONCORD BIOSCIENCES LLC	18-SEP-18

Count	Scientific Name	Common Name
000235	<i>Canis lupus familiaris</i>	DOG ADULT
000021	<i>Macaca fascicularis</i>	CRAB-EATING MACAQUE / CYNOMOLGUS MONKEY
000003	<i>Sus scrofa domestica</i>	DOMESTIC PIG / POTBELLY PIG / MICRO PIG
<b>000259</b>	<b>Total</b>	



## Inspection Report

Frontage Labs  
10845 Wellness Way  
Concord Twp, OH 44077

Customer ID: **254**  
Certificate: **31-R-0091**  
Site: 001  
CONCORD BIOSCIENCES LLC

Type: FOCUSED INSPECTION  
Date: 29-MAY-2019

No non-compliant items identified during this inspection.

This inspection and exit interview were conducted with facility staff including the attending veterinarian and IACUC Chair.

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**Prepared By:**

CROWLEY LACY, D V M      USDA, APHIS, Animal Care

**Title:** VETERINARY MEDICAL OFFICER 6122

**Date:**  
29-MAY-2019

**Received By:**

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

**Title:** IACUC CHAIR  
19-04394\_000005

**Date:**  
29-MAY-2019



## Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
254	31-R-0091	001	CONCORD BIOSCIENCES LLC	29-MAY-19

Count	Scientific Name	Common Name
000164	<i>Canis lupus familiaris</i>	DOG ADULT
000061	<i>Macaca fascicularis</i>	CRAB-EATING MACAQUE / CYNOMOLGUS MONKEY
000029	<i>Sus scrofa domestica</i>	DOMESTIC PIG / POTBELLY PIG / MICRO PIG
<b>000254</b>	<b>Total</b>	

# Research Facility Protocol Selection Worksheet<sup>\*</sup>

Legal Name : Ricerca Biosciences, LLC

Customer Number: 254 Certificate Number: 31-R-0091

Inspection Date: 04/26/2017 Site Number: 001

Inspector: Michael Neafsey

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):	3
<b>Total Protocols Selected and Reviewed</b>	<b>3</b>

**\*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.

# Research Facility Protocol Selection Worksheet<sup>\*</sup>

**Legal Name:** Frontage Labs

**Customer Number:** 254

**Certificate Number:** 31-R-0091

**Site Number:** 1

**Inspection Date:** 5/29/19

**Inspection Type:** Routine ☐ Focused ☒ (list areas inspected) Animals

**Inspector:** Lacy Crowley DVM

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
<b>Total Protocols Selected and Reviewed</b>	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 2/11/19





April 21, 2017

Elizabeth Goldentyer, DVM  
Director – Animal Care, Eastern Region  
United States Department of Agriculture  
Animal and Plant Inspection Service  
920 Main Campus Drive, Suite 200  
Raleigh, NC 27606-5213

Dear Dr. Goldentyer:

SUBJECT: Appointment of Temporary Attending Veterinarian (31-R-0091)

Please be advised that Dr. (b) (6), (b) (7)(C) has left employment at Ricerca Biosciences. We have instituted a search for a new full time veterinarian and will notify you when we have filled the position. In the interim, Dr. (b) (6), (b) (7)(C) DVM, Ph.D., an existing member of the IACUC Committee, has been appointed by (b) (6), (b) (7)(C) IO, as temporary Attending Veterinarian.

If you have further questions or concerns, please don't hesitate to contact me.

Sincerely,

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

Ricerca Biosciences, LLC

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

cc: (b) (6), (b) (7)(C)

JUN 27 2017

Concord Biosciences  
10845 Wellness Way  
Concord, OH 44077

June 22, 2017

Elizabeth Goldentyer, DVM  
Director – Animal Care, Eastern Region  
United States Department of Agriculture  
Animal and Plant Inspection Service  
920 Main Campus Drive, Suite 200  
Raleigh, NC 27606-5213

Dear Dr. Goldentyer:

SUBJECT: New name and address – 31-R-0091

Please be advised Ricerca Biosciences, LLC has changed its name to Concord Biosciences, LLC. Although our physical location has not changed the address has changed to 10845 Wellness Way, Concord, OH 44077. The main telephone number has changed to 440-357-3200. These changes were made due to a split of our Chemical and Drug Safety Divisions.

If you have further questions or concerns, please don't hesitate to contact me.

Sincerely,

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

Concord Biosciences, LLC  
10845 Wellness Way  
Concord OH 44077

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

cc: (b) (6), (b) (7)(C)

\*Please note email address has not changed yet.

JUN 27 2017

Concord Biosciences  
10845 Wellness Way  
Concord, OH 44077

June 22, 2017

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

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

SUBJECT: New name and address - 000850

Please be advised Ricerca Biosciences, LLC has changed its name to Concord Biosciences, LLC. Although our physical location has not changed the address has changed to 10845 Wellness Way, Concord, OH 44077. The main telephone number has changed to 440-357-3200. These changes were made due to a split of our Chemical and Drug Safety Divisions.

If you have further questions or concerns, please don't hesitate to contact me.

Sincerely,

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

Concord Biosciences, LLC  
10845 Wellness Way  
Concord OH 44077

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

cc: Clifford Croley, IO.

\*Please note that email address has not changed yet.



United States  
Department of  
Agriculture

Marketing &  
Regulatory  
Programs Business  
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Plant Health  
Inspection  
Service

Animal Care

920 Main Campus  
Drive, Suite 200  
Raleigh, NC  
27606-5213  
Tel. 919-855-7100  
Fax: 919-855-7123

RE: ACKNOWLEDGE REMOVAL OF SITE

Certificate Number: 31-R-0091

Anniversary Date: 07/17/2017

July 12, 2017

Customer ID Number: 254

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

Concord Biosciences Llc  
10845 Wellness Way  
Concord Twp, OH 44077

Dear Registrant:

As you requested, site(s) number 001 has been removed from your Animal Welfare Act (AWA) registration. We understand that this site is no longer being used for activities covered under the AWA.

We appreciate your efforts in complying with the Animal Welfare Act. Contact this office at (919) 855-7100 if you have any questions regarding this letter or the Animal Welfare Act.

Sincerely,

Elizabeth Goldentyer, D. V. M.  
Director, Animal Welfare Operations  
USDA, APHIS, Animal Care

cc: Diane R Forbes

cc: Lacy Crowley



Safeguarding American Agriculture  
APHIS is an agency of USDA's Marketing and Regulatory Programs  
An Equal Opportunity Provider and Employer



Every research facility, exhibitor, carrier, and intermediate handler not required to be licensed under Section 3 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  
EASTERN  
920 Main Campus Drive  
Suite 200  
Raleigh, NC 27606-5210  
(919) 855-7100

**JUL 11 2017**

**CERTIFICATE NO./CUST NO:**

31-R-0091

254

**RENEWAL DATE**

17-Jul-2017

**17 Jul 2020 (83)**

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

Concord Biosciences LLC  
10845 Wellness Way  
Concord, OH 44077

COUNTY: LAKE TELEPHONE (440) 357 - 3200

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

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

Concord Biosciences LLC  
~~7528 Auburn Road~~  
Concord, OH 44077  
County: Lake

**10845 wellness way**

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

**31-R-0091**

**5. ARE YOU USING FEDERAL FUNDS TO CARRY OUT RESEARCH, TESTS, OR EXPERIMENTS**

☒ 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) \_\_\_\_\_

**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)

**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. SIGNATURE**

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

**11. NAME AND TITLE (Type or Print)**

**12. DATE SIGNED**

**5-July-2017**



United States  
Department of  
Agriculture

Marketing &  
Regulatory  
Programs Business  
Services

Animal and  
Plant Health  
Inspection  
Service

Animal Care

920 Main Campus  
Drive, Suite 200  
Raleigh, NC  
27606-5213  
Tel. 919-855-7100  
Fax: 919-855-7123

RE: ACKNOWLEDGE NEW SITE  
Certificate Number: 31-R-0091  
Renewal Date: 07/17/2017

July 12, 2017  
Customer ID Number: 254

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

Concord Biosciences Llc  
10845 Wellness Way  
Concord Twp, OH 44077

Dear Registrant:

Thank you for notifying us of your need for an additional site under your Animal Welfare Act (AWA) registration. The new Site(s) numbered 001 has been added to your current registration.

We appreciate your efforts in complying with the Animal Welfare Act. Contact this office at (919) 855-7100 if you have any questions regarding this letter or the Animal Welfare Act.

Sincerely,

Elizabeth Goldentyer, D. V. M.  
Director, Animal Welfare Operations  
USDA, APHIS, Animal Care

cc: Diane R Forbes  
cc: Lacy Crowley

Enclosures



Safeguarding American Agriculture  
APHIS is an agency of USDA's Marketing and Regulatory Programs  
An Equal Opportunity Provider and Employer



Every research facility, exhibitor, carrier, and intermediate handler not required to be licensed under Section 3 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**

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USDA APHIS ANIMAL CARE  
EASTERN  
920 Main Campus Drive  
Suite 200  
Raleigh, NC 27606-5210  
(919) 855-7100

JUL 11 2017

**CERTIFICATE NO./CUST NO:**

31-R-0091

254

**RENEWAL DATE**

17-Jul-2017

17 Jul 2020 (86)

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

Concord Biosciences LLC  
10845 Wellness Way  
Concord, OH 44077

COUNTY: LAKE TELEPHONE (440) 357 - 3200

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

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

Concord Biosciences LLC  
~~7528 Auburn Road~~  
Concord, OH 44077  
County: Lake

10845 Wellness Way

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

31-R-0091

**5. ARE YOU USING FEDERAL FUNDS TO CARRY OUT RESEARCH, TESTS, OR EXPERIMENTS**

☒ 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) \_\_\_\_\_

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)

**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.

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

DATE SIGNED

July 2017



August 1, 2017

Elizabeth Goldentyer, DVM  
Director – Animal Care, Eastern Region  
United States Department of Agriculture  
Animal and Plant Inspection Service  
920 Main Campus Drive, Suite 200  
Raleigh, NC 27606-5213

Dear Dr. Goldentyer:

SUBJECT: Appointment of New Attending Veterinarian (31-R-0091)

Please be advised that Dr. (b) (6), (b) (7)(C) has been appointed Attending Veterinarian of Concord Biosciences effective August 1<sup>st</sup>, 2017. Dr. (b) (6), (b) (7)(C) DVM, Ph.D., will step down as temporary AV but remain an existing member of the IACUC Committee.

If you have further questions or concerns, please don't hesitate to contact me.

Sincerely,

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

Concord Biosciences, LLC  
10845 Wellness Way

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

[www.concordbio.com](http://www.concordbio.com)

cc: (b) (6), (b) (7)(C)



**From:** [ACEAST](#)  
**To:** [Fausch, Emily R - APHIS](#)  
**Subject:** FW:  
**Date:** Monday, October 1, 2018 12:42:52 PM

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Thank you

William (Dan) Austin  
Inspection & Licensing Assistant

USDA-APHIS-AC  
2150 Centre Ave  
Building B, Mailstop 3W11  
Fort Collins, CO 80526-8117  
970-494-7463

**From:** Crowley, Lacy A - APHIS  
**Sent:** Wednesday, September 19, 2018 7:06 AM  
**To:** ACEAST <ACEAST@aphis.usda.gov>  
**Subject:**

Dear ACEast,  
Registrant 254 Concord Bioscience has had some changes to their IO and other contact personnel.

The new IO is:

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

Executive VP  
10845 Wellness Way  
Concord, OH

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

Also (b) (6), (b) (7)(C) and (b) (6), (b) (7)(C) are no longer with the company and should be removed.

Please let me know if there are any questions or concerns.

Sincerely,  
Lacy Crowley DVM  
984-209-9464

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February 13, 2019

Elizabeth Goldentyer, DVM  
Director – Animal Care, Eastern Region  
United States Department of Agriculture  
Animal and Plant Inspection Service  
920 Main Campus Drive, Suite 200  
Raleigh, NC 27606-5213

Dear Dr. Goldentyer:

SUBJECT: New name – 31-R-0091

Please be advised Concord Biosciences, LLC has been purchased by Frontage Laboratories in Exton, PA. and are changing our name to Frontage Labs effective with this communication. Our physical location and address remain the same. The main telephone number is still 440-357-3200. If you have further questions or concerns, please don't hesitate to contact me.

Sincerely,

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

Frontage Laboratories  
10845 Wellness Way  
Concord OH 44077

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

cc: Abdul Mutlib, IO.



Every research facility, exhibitor, carrier, and intermediate handler not required to be licensed under Section 3 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  
EASTERN  
920 Main Campus Drive  
Suite 200  
Raleigh, NC 27606-5210  
(919) 855-7100

**JUL 11 2017**

**CERTIFICATE NO./CUST NO:**

31-R-0091

254

**RENEWAL DATE**

17-Jul-2017

**17 Jul 2020**

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

Concord Biosciences LLC  
10845 Wellness Way  
Concord, OH 44077

COUNTY: LAKE TELEPHONE (440) 357 - 3200

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

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

Concord Biosciences LLC  
7528 Auburn Road  
Concord, OH 44077  
County: Lake

10845 Wellness Way

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

31-R-0091

**5. ARE YOU USING FEDERAL FUNDS TO CARRY OUT RESEARCH, TESTS, OR EXPERIMENTS**

☒ 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) \_\_\_\_\_

**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)

**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. SIGNATURE**

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

**11. NAME AND TITLE (Print Name)**

**12. DATE SIGNED**

5-July-2017



United States  
Department of  
Agriculture

Marketing and  
Regulatory  
Programs

Animal and  
Plant Health  
Inspection  
Service

Animal Care

EXPIRATION DATE: JULY 17, 2020

This is to certify that

CONCORD BIOSCIENCES LLC

is a registered  
under the

CLASS R RESEARCH FACILITY

## Animal Welfare Act

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

Certificate No. 31-R-0091

Customer No. 254

A handwritten signature in black ink, appearing to be "B. J. Long", is written over a horizontal line.

Deputy Administrator