



## Inspection Report

---

WuXi AppTec Inc.  
2540 EXECUTIVE DRIVE  
SAINT PAUL, MN 55120

Customer ID: **15690**  
Certificate: **41-R-0061**  
Site: 001  
WUXI APPTEC INC

Type: ROUTINE INSPECTION  
Date: 26-MAR-2025

---

### 2.31(c)(7)

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

Observational procedures outlined in the IACUC protocol were not performed as written on 101 rabbits. The IACUC protocol states that following a surgical procedure to test the safety of a brain implant, "(a)nimal health will be observed daily via cage side assessment on Day 1 (once, post-surgery), Days 2-7 (twice per day). Supplemental physical and observational assessments will be conducted once daily on Days 2, 4, and 6 for the week following surgery." The protocol goes on to say that there are several possible postoperative complications that may occur and observations for neurobehavioral deficits "will be monitored and evaluated as possible behaviors detrimental to welfare for determining when animals will be euthanized." The facility has a standard operating protocol (SOP) for animal observations that instructs technicians to remove the animal from the enclosure for additional examination and labels these observations "clinical observations," to differentiate them from cage side assessments.

Documentation of the cage side and clinical observations show one animal was noted to have abnormal neurological signs on the cage side assessment on the afternoon of Day 1 and was humanely euthanized that day. The cage side observations were documented as "normal" for the remainder of the animals in the study. No clinical observations were documented on Days 2-7. A single clinical health observation was documented for all study animals on Day 8.

This activity constitutes a significant deviation from the approved activities in the protocol. Making significant changes to protocols without IACUC review and approval deprives the IACUC of the opportunity to provide oversight of animal activities and compliance with the Animal Welfare Act. Failing to complete assessments as described in the IACUC protocol could result in unrecognized suffering in the affected animals.

Principal investigators are to follow the IACUC approved protocols, and any proposed changes shall be reviewed and approved by the IACUC prior to implementation. Those carrying out procedures in an IACUC-approved protocol must adhere to what was approved by the IACUC.

Correct by April 2, 2025

### 2.38(l)(3)

#### Miscellaneous.

---

Prepared By: SHOSHANA TANENBAUM  
USDA, APHIS, Animal Care  
Title: VETERINARY MEDICAL  
OFFICER

Date:  
02-APR-2025

Received by Title: Facility Representative

Date:  
02-APR-2025



## Inspection Report

---

The registrant did not train seven research technicians on the facility's contingency plan. These employees were hired between 2021 and February 27, 2025. The lack of training was discovered during inspection and was the result of a job categorization oversight.

Contingency plans and training for personnel are required to help ensure animal health and well-being in the event of an emergency or disaster. Research technicians may be directly involved in providing humane handling, treatment, transportation, housing, and care of animals in the event of an emergency or disaster. If Contingency Plan training is not provided, personnel may not be aware of their roles and responsibilities; animals may suffer illness, injury or death due to unpreparedness should an emergency or disaster strike.

The registrant must provide Contingency Plan training to employees regarding their roles and responsibilities as outlined in the Contingency Plan and ensure that that new hires receive this training within 30 days of their start date. Additionally, the registrant must conduct and document a review of the Contingency Plan at least once annually. Employees must be trained on any substantive changes made during this review within 30 days of making the changes. The registrant initiated training of the seven employees during the inspection.

To be corrected by April 11, 2025

This inspection and exit interview were conducted with facility representatives

---

**Prepared By:** SHOSHANA TANENBAUM  
USDA, APHIS, Animal Care  
**Title:** VETERINARY MEDICAL  
OFFICER

**Date:**  
02-APR-2025

**Received by Title:** Facility Representative

**Date:**  
02-APR-2025



**Species Inspected**

Cust No	Cert No	Site	Site Name	Inspection
15690	41-R-0061	001	WUXI APPTEC INC	26-MAR-2025

Count	Scientific Name	Common Name
000546	<i>Cavia porcellus</i>	DOMESTIC GUINEA PIG
000250	<i>Oryctolagus cuniculus</i>	DOMESTIC RABBIT / EUROPEAN RABBIT
000796	<b>Total</b>	