

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 10-F-0003  
CUSTOMER NUMBER: 440

FORM APPROVED  
OMB NO. 0579-0036

**ANNUAL REPORT OF RESEARCH FACILITY**  
( TYPE OR PRINT )

Armed Forces Institute Of Pathology  
Div. Of Lab Animal Medicine  
6825 16th St. Nw  
Bldg 54 Rm 5016  
Washington, DC 20306

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

FACILITY LOCATIONS ( Sites ) - See Attached Listing

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 animal 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 an 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 wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals and the reast such drugs were not used must be attached to this report | F. TOTAL NUMBER OF ANIMALS ( COLUMNS C + D + E ) |
|--|--|---|--|---|--|
| 4. Dogs  |  |   |  |   |  |
| 5. Cats  |  |   |  |   |  |
| 6. Guinea Pigs                                       |  |   |  |   |  |
| 7. Hamsters  |  |   |  |   |  |
| 8. Rabbits   |  |   | 85   |   | 85   |
| 9. Non-human Primates                                |  |   |  |   |  |
| 10. Sheep  |  |   |  |   |  |
| 11. Pigs   |  |   |  |   |  |
| 12. Other Farm Animals                               |  |   |  |   |  |
| 13. Other Animals                                    |  |   |  |   |  |
| mouse  |  | 359   | 138  | 138   | 635  |

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 rese 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 ap 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 inc 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 provision 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 or Legally Responsible Institutional Official )

(b)(6), (b)(7)c

DATE SIGNED

14 Nov 08

### Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 10-F-0003
2. Number 138 of animals used in this study.
3. Species (common name) mouse of animals used in the study.
4. Explain the procedure producing pain and/or distress.

Inoculation of *Burkholderia* bacteria at high doses is expected to cause death within 2 weeks in unprotected mice.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below)

High performance MAbs for prophylaxis and treatment of infections of *B. pseudomallei* and *B. mallei* are needed to protect our troops in the event of biological warfare. MAbs specific to *B. pseudomallei* and *B. mallei* are developed and the neutralizing activities are evaluated using in vitro assays. This protocol is to evaluate the in vivo protective effects of the MAbs against lethal challenges by these 2 pathogenic bacteria in mice. First, determination of LD<sub>50</sub> is needed for each *Burkholderia* species. Death will be the study end point. The use of anesthetics will interfere with the interpretation of the study. In passive protective assays, mice receive individual or mixtures of MAbs, are then infected with *Burkholderia* bacteria and may show no symptoms, or infections of various degrees.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

Agency \_\_\_\_\_ CFR \_\_\_\_\_

NOV 26 2008