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DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION

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New Orleans, LA 70127  
504-252-4900

DATE(S) OF INS  
11/28/00 - 12/1/00

FD NUMBER  
1046595

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Terry B. Cummings, Director of Laboratory Services

FIRM NAME

Alpha Therapeutic Corporation

STREET ADDRESS

5700 Pleasant View Road

CITY, STATE AND ZIP CODE

Memphis, TN 38134

TYPE OF ESTABLISHMENT INSPECTED

Control Laboratory

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

1. An action item list of computer issues/projects kept by the information technology department indicates some proposed fixes and modifications for which there is no further documentation. The list references a fix for the LOG program, table hold, modification of the silent PAJR program, and block a center in the SPS1. There is no further documentation of the nature of the problem or investigation.

*Corrections promised by 3/6/01*

2. A discrepancy noted in a ~~exception~~ exception report on 8/17/2000 was not referred to the contract programmer for investigation until 11/29/2000. The exception report for HIV pipetting errors contained an ALT pipetting error. The exception reports are designed to be test specific.

*Corrected error fixed 12/5/00*

3. Personnel in the information technology department have not been consistently completing the daily checklist of operations performed as required by MIS SOP, Daily Startup Procedures for the ~~equipment~~ and ~~equipment~~.

*Corrections promised by 12/31/00*

# Therapeutic Corporation

**AW Rasmussen**



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