

**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION**

DISTRICT OFFICE ADDRESS AND PHONE NUMBER FDA Atlanta Office 60 8th Street NE Atlanta, GA 0309 (404) 253-1161 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 01/30/2020-2/18/2020
	FEI NUMBER 1075523

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED  
**TO: Karen Spruill, Manager Pharmacy Automation**

FIRM NAME Piedmont Hospital, Inc. dba Phcy-Corp	STREET ADDRESS 1968 Peachtree Road NW
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CITY, STATE AND ZIP CODE Atlanta, GA 30309	TYPE OF ESTABLISHMENT INSPECTED Human Compounding Pharmacy
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THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS; AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.

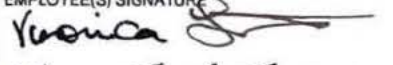
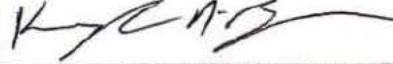
DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

**Observation 1**

Disinfecting agents and cleaning wipes used in the ISO 5 classified aseptic processing areas were not sterile.

Specifically, your (b) (4) and (b) (4) used (b) (4) for the disinfection/cleaning of your sterile compounding hood is not sterile. The hood is used for compounding sterile drug products.

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE  	EMPLOYEE(S) NAME AND TITLE (Print or Type) Veronica Fuentes, Investigator Kemejumaka Opara, Investigator	DATE ISSUED 02/18/2020
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