Your firm is producing sterile drugs under insanitary conditions.

A. Your firm is not using a sporicidal agent in the ISO 5 areas used for sterile operations.
B. Your firm is using non-sterile disinfectants in the ISO 5 areas used for sterile operations.
C. Your firm does not perform any contact sampling on the permanent equipment in the ISO 5 LAF hood. Your firm has not tested the dose calibrator and periphery equipment to determine your sanitization is effective.
D. Your firm does not measure the pressure differential between the ISO 5 hood used for sterile operations and the surrounding area.

*DATES OF INSPECTION
6/26/2017(Mon), 6/27/2017(Tue), 6/28/2017(Wed), 7/03/2017(Mon)