

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0669515	(X3) Date Survey Completed 04/27/2022
Name of Provider or Supplier Illinois State University Student Health Service	Street Address, City, State 201 N University Street, Normal, IL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5433	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation, review of laboratory records, and interview with technical supervisor (TS), the laboratory failed to establish and perform a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting for one of one biosafety cabinets in use for microbiology testing. Findings Include: 1. On 4/27/2022 at 2:00 p.m., surveyor observed expired certification date 11-16-2020 on LABGARD ES Class II, Type A2 Biological Safety Cabinet (BSC). Serial NO. 201434100820. IL State University #331100. 2. Review of laboratory records found no documentation that the laboratory recertified the BSC by the next due date Nov - 2021, documented by CLEAN AIR FLOW, INC., P.O. BOX 725, Lincolnshire, IL 60069. 3. On 4/27 /2022 at 2:06 p.m., with TS confirmed the above findings.</p>