

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D0859649	(X3) Date Survey Completed 12/14/2023
Name of Provider or Supplier Campus Health Service	Street Address, City, State Arizona State University Health Services, Tempe, AZ	
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
D5205	<p>COMPLAINT INVESTIGATIONS CFR(s): 493.1233</p> <p>The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual and interview with the testing personnel (TP-1), the laboratory failed to have a system in place to document complaints and problems reported to the laboratory. Findings include: 1. The laboratory failed to provide evidence to indicate that it has a system in place to ensure that it documents all complaints and problems reported to the laboratory 2. The TP-1 interviewed on 12/14/2023 at 3:15 PM confirmed the laboratory did not have an established system in place to address complaints and problems reported to the laboratory. 3. The laboratory's reported annual test volume is 10,179.</p>
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:</p>

Based on lack of maintenance and function check documentation for the pipettes utilized by the laboratory and interview with the Testing Personnel (TP-1), the laboratory failed to establish a maintenance and calibration protocol for the pipettes that ensures equipment performance which is necessary for accurate and reliable test results and test result reporting. Findings include: 1. The laboratory performs patient testing in the specialties of Microbiology, Diagnostic Immunology, Chemistry and Hematology, with a reported annual test volume of 10,179. 2. The laboratory utilizes two pipettes in conjunction with patient testing, a 100 Microliter (L) pipette, serial# EH92326 and a 200 Microliter (L) pipette, serial# EH83600. 3. No documentation was presented for review during the survey conducted on 12/14/2023 to indicate the laboratory established a maintenance and function protocol for the pipettes listed above. 4. No evidence was provided for review to indicate the laboratory calibrated the pipettes from January 2021 through the date of the survey, 12/14/2023. 5. The TP-1 interviewed on 12/14/2023 at 3:02 PM confirmed the laboratory failed to establish a maintenance and calibration protocol for the pipettes, and confirmed the pipettes were not routinely calibrated during the timeframe indicated above.