

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0696576	(X3) Date Survey Completed 09/14/2023
Name of Provider or Supplier Ucsb Student Health Services Laboratory	Street Address, City, State Bldg 588, Santa Barbara, CA	
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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's observation during the lab tour on the lack of calibrated thermometers in the refrigerators, freezers, heating blocks, etc. to verify digital temperature readings and interview with the laboratory's technical supervisors (TS) and testing personnel (TP); it was determined that the laboratory failed to monitor the digital temperature readings of equipment essential for proper storage of reagents and specimens that adversely affect patient test results. The findings included: 1. On the day of the survey, September 14, 2023, at approximately 2:35 p.m. based on the surveyors' observation and interview with the TS and TP; the laboratory failed to have up to date calibrated thermometers on the refrigerators, freezers, etc., that verify accurate digital thermometers readings which affect reagents and patients' samples testing. 2. The TS and TP confirmed on 9/14,/2023, at approximately 3:00 p.m. that the laboratory had no up to date calibrated thermometers in the refrigerators, freezer, heating blocks, etc. to verify digital temperature readings. 3. Based on the laboratory's submitted testing declaration volume, the laboratory tested and reported approximately 87,809 samples annually.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p>

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's procedure manual, lack of documentation, the surveyor's observation, and interview with the laboratory's technical supervisors (TS) and testing personnel (TP); it was determined that the laboratory failed to perform and document maintenance and calibration as defined by the manufacturer and with at least the frequency specified by the manufacturer for the laboratory's small equipment. The findings included: 1. The laboratory's standard operating procedure (SOP) indicated that preventive maintenance and calibration be performed on all equipment and instruments used in the laboratory. 2. The LD and TS confirmed on September 14, 2023, at approximately 3:00 p.m. that the laboratory failed to follow the manufacturer's instructions on preventive maintenance and calibration of small equipment such as timers, vortexes, microcentrifuges, mixers, and rotators. 3. According to the test volume declared by the laboratory on 9/14/2023 the laboratory performs approximately 87,809 diagnostic tests annually.

D6082

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(1)

The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's records for policies and procedures, patients' test results records, proficiency testing reports, direct observation by the surveyors during the lab tour, and interviews with technical supervisors and testing personnel on September 14, 2023; it was determined that the laboratory director failed to ensure that several aspects of the analytic phase of laboratory testing were monitored. See D5413 and D5429.