

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D0664180	(X3) Date Survey Completed 07/24/2025
Name of Provider or Supplier Uscg Academy	Street Address, City, State 15 Mohegan Avenue, New London, CT	
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>(b) 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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 direct observation, temperature record review, and interview with the Laboratory Director (LD), the laboratory failed to monitor and document temperature conditions in laboratory draw room 128 where 104 blood collection tubes were stored. Findings: 1. During inspection of laboratory draw room 128 on July 24, 2025 at approximately 10:00 AM, the following blood collection tubes were observed: a. BD Vacutainer EDTA - 50 tubes Lot# 5015996 b. BD Vacutainer SST - 24 tubes Lot #5031305 c. Greiner Bio-One Red Top - 30 tubes Lot# C2411359 All tubes displayed manufacturer-printed storage temperature requirement of 4-25C (40-77F) on packaging. 2. Record review of room temperatures revealed no evidence the laboratory documented temperatures in draw room 128. 3. Interview with the LD on July 24, 2025 at approximately 11:00 AM confirmed that temperature monitoring and documentation procedures were not implemented for laboratory draw room 128.</p>
D5781	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken</p>

when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on review of humidity records and interview with the Laboratory Director (LD), the laboratory failed to document all corrective actions taken when humidity levels fell outside acceptable limits for 9 of 28 days reviewed in February 2025. Findings: 1. Humidity monitoring records revealed that during February 2025, there were 4 days (February 6, 15, 22, and 23) when humidity levels dropped to 18%, and 5 days (February 18, 19, 20, 21, and 24) when humidity levels dropped to 19%. The acceptable humidity range was 20-80%. Review of the corrective actions revealed one documented corrective action for February 2025 stating, "Humidifier ordered to help with humidity issues". No individual corrective actions were documented for each specific day humidity levels were out of range. 2. Interview with LD on July 24, 2025 at approximately 2:00 PM confirmed that the laboratory did not document corrective actions for each individual day when humidity levels were outside the acceptable range.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283.

This STANDARD is not met as evidenced by:

Based on review of humidity monitoring records for February 2025, Quality Assurance (QA) Laboratory Director (LD) Monthly Review form for February 2025, and interview with the LD, the laboratory failed to follow its written policy and procedure for an ongoing mechanism to monitor and correct problems identified in the analytic systems related to environmental monitoring. Findings: 1. Review of humidity monitoring records for February 2025 revealed the laboratory failed to document all corrective actions taken when humidity levels fell outside acceptable limits for 9 of 28 days. (Reference: D5781) 2. Review of the QA LD Monthly Review form for February 2025 revealed an oversight in QA procedures. The form included an environmental monitoring section with the QA parameter "All values within established range and corrective action documented?" which was marked "Yes" by the LD. The form was dated and signed by the LD on March 10, 2025. The LD failed to follow established procedures to properly assess the actual environmental conditions. Specifically, the LD did not identify that humidity levels were outside the established range during February 2025, nor did the review process detect that not all corrective actions were properly documented for out-of-range conditions. 3. Interview with LD on July 24, 2025 at approximately 2:30 PM confirmed that he failed to follow the QA Monthly Review checklist procedures to identify issues related to environmental monitoring for February 2025.