

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2093483	(X3) Date Survey Completed 01/28/2026
Name of Provider or Supplier Elite Urgent Care Inc	Street Address, City, State 1524 Mchenry Ave, Ste 130, Modesto, 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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records, the lack of records, and interview with the Laboratory Director, it was determined the laboratory failed to test proficiency samples by personnel routinely testing patients samples. Findings included: a. Laboratory Personnel Report (CMS209 Laboratory Personnel Report (CLIA), 1/24/26) documented 5 Testing Persons (TP). b. Laboratory reports selected for this Survey documented the person testing the patient's sample [Lab Technician], as follows: Date Order TP ----- 9/02/25 440805017 TP -3 9/26/25 2202753734 TP -3 10/03/25 2207072444 AT 10/07/25 2209329389 CA 11/02/25 433653937 AT 11/03/25 2231152081 AT 12/19/25 2266655813 CA c. Laboratory proficiency testing records had no documentation for who tested the proficiency samples. d. The Laboratory Director affirmed (1/28/26 at 5PM) that all proficiency testing was performed by Testing Person-4. e. And thus, the reliability and quality of patients' hematology results reported by 4 out of 5 Testing Persons could not be assured during this Survey. The five Testing Persons reported 4,000 hematology results annually (CMS116 CLIA Application, 1/24/26). .</p>
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p>

This STANDARD is not met as evidenced by:
Based on review of 2023-2025 laboratory proficiency testing records, the lack of records, and interview with the Laboratory Director, it was determined the Testing Personnel and the Laboratory Director failed to Attest to the routine testing of proficiency testing samples. Findings included: a. Laboratory hematology proficiency testing records documented testing and reporting results to WSLH. b. For 5 out of 5 Events, laboratory records failed to include documents signed by the Testing Person /Analyst and the Laboratory Director attesting to the routine testing of proficiency samples. c. The Laboratory Director affirmed (1/28/26 at 5PM) the aforementioned lack of signed Attestation Statement documents. .

D2014

TESTING OF PROFICIENCY TESTING SAMPLES

(b)(6) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event.

This STANDARD is not met as evidenced by:
Based on review of laboratory proficiency testing records, the lack of records, and interview with the Laboratory Director, it was determined the laboratory failed to maintain complete records as required. Findings included: a. The laboratory proficiency testing records failed to identify the Testing Person. See D2007. b. The laboratory failed to have WSLH Attestation Statement documents signed by the Testing Person and the Laboratory Director. See D2009. c. And thus, the reliability and quality of 5 out of 5 proficiency testing events for preanalytic sample handling to analysis to postanalytic reporting could not be assured during this Survey. .

D2123

HEMATOLOGY
CFR(s): 493.851(c)

(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.

This STANDARD is not met as evidenced by:
Based on observation of the Sysmex XN330 hematology analyzer, review of 2023 - 2025 proficiency testing reports from CMS (report 155D Individual Laboratory Profile) and WSLH (Wisconsin State Laboratory of Hygiene) and laboratory records,

the lack of records, and interview with the Laboratory Director, it was determined that the laboratory failed to participate in 2025, Event 3. Findings included: a. The laboratory utilized the Sysmex XN330 to report hematology results, as follows: RBC (Red Blood Cell count) HCT (Hematocrit) HGB (Hemoglobin) WBC (White Blood Cell count) Platelets Automated WBC Differential (Types of WBC) b. CMS and WSLH reported the unsatisfactory scores of 0% for all 6 analytes due to not receiving any results from the laboratory in the 3rd Event of 2025. c. The laboratory had no records for testing and reporting hematology results to WSLH in the 3rd Event of 2025. d. The Laboratory Director affirmed (1/28/26 at 4:00 PM) the aforementioned findings and that the laboratory failed to participate in proficiency testing for the final event of 2025. e. The laboratory reported 4,000 hematology results annually (CMS116 CLIA Application, 1/24/26). The reliability and quality of patients' hematology results reported during the timeframe Septemeber 2025 - January 2026 could not be assured during this Survey. Several records selected for review are, as follows: . Date Order
----- 9/02/25 440805017 9/26/25 2202753734 10/03/25
2207072444 10/07/25 2209329389 11/02/25 433653937 11/03/25 2231152081 12/19
/25 2266655813 .