

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2093483	(X3) Date Survey Completed 10/06/2020
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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on review of the random patient test result records from 2018, 2019 and 2020, random comparisons of the patient samples test results from the split samples sent out to an outside CLIA certified laboratory, and lack of CMS approved proficiency testing (PT) test result reports, and interview with the laboratory director and the testing personnel, it was determined that the laboratory failed to meet the criteria in subpart I of this part and failed to participate a PT program approved by HHS for its hematology testing, CBC (complete blood cells count). The findings included: a. The laboratory performed CBC, a hematology testing by Sysmex XP-300 with serial # B0346 for the test results including WBC (white blood cell), RBC (red blood cell), Hgb (hemoglobin), Hct (hematocrit), and Platelet count, which are listed in the subpart I of 42 CFR part 493. b. The laboratory must enroll in an approved program or programs approved by CMS/HHS for which the laboratory seeks certification. c. On October 6, 2020 @ 11:05 am, the laboratory failed to present evidences of its participation of CBC testing with a PT program approved by CMS/HHS, see D-2123</p>
D2123	<p>HEMATOLOGY CFR(s): 493.851(c)</p>

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 review of the random patient test result records from 2018, 209 and 2020, random comparisons of the patient samples test results from the split samples sent out to an outside CLIA certified laboratory, and lack of CMS approved proficiency testing (PT) test result reports, and interview with the laboratory director and the testing personnel, it was determined that the laboratory failed to meets the criteria in subpart I of this part and failed to participate a PT program approved by HHS for its hematology testing, CBC (complete blood cells count). The findings included: a. The laboratory performed CBC, a hematology testing by Sysmex XP-300 with serial # B0346 for the test results including WBC (white blood cell), RBC (red blood cell), Hgb (hemoglobin), Hct (hematocrit), and Platelet count, which are listed in the subpart I of 42 CFR part 493. b. The laboratory failed to participate in a PT program approved by CMS/HHS from the years of 2018, 2019, and 2 parts of 2020. c. On October 6, 2020 @ 11:15 am, the laboratory failed to present records of its CBC PT result report records from 2018, 2019, and 1st and the 2nd part of PT participation. d. The laboratory director affirmed (10/06/2020 @ 11:25 am) that instead of participation of the CMS/HHS approved PT program, the laboratory had sent out split samples in 2018, 2019, and 2020 randomly to a CLIA certified laboratory for comparison of its CBC test results. e. The laboratory currently participated CBC PT program with WSLH (Wisconsin State Laboratory Hygiene) Proficiency Testing for the 3rd event. f. The laboratory performed CBC in approximately 85 patient samples each month.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

Based on review of the laboratory's patient test result records in 2018, 209 and 2020, random reports comparisons of the test results from the split samples sent out to an outside CLIA certified laboratory, and lack of CMS approved proficiency testing (PT) test result reports, and interview with the laboratory director and the testing personnel, it was determined that the laboratory failed to meets the criteria in subpart I of this part and is approved by HHS. The laboratory director failed to be responsible for the overall operation, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. The findings included: a. The laboratory performed CBC by Sysmex XP-300 with serial # B0346

for the test results including WBC (white blood cell), RBC (red blood cell), Hgb (hemoglobin), Hct (hematocrit), and Platelet count, which are listed in the subpart I of 42 CFR part 493. b. The laboratory failed to participate in a PT program approved by CMS/HHS in 2018, 2019, and part of 2020 see D-6016.

D6016

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(i)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:
Based on review of the laboratory's patient test result records in 2018, 209 and 2020, random reports comparisons of the test results from the split samples sent out to an outside CLIA certified laboratory, and lack of CMS approved proficiency testing (PT) test result reports, and interview with the laboratory director and the testing personnel, it was determined that the laboratory failed to meets the criteria in subpart I of this part and failed to participate a PT program approved by HHS. The laboratory director failed to ensure that the proficiency testing samples were tested as required under Subpart H of this part. The findings included: a. The laboratory performed CBC by Sysmex XP-300 with serial # B0346 for the test results including WBC (white blood cell), RBC (red blood cell), Hgb (hemoglobin), Hct (hematocrit), and platelet count, which is listed in the subpart I of 42 CFR part 493. b. The laboratory failed to participate in a PT program approved by CMS/HHS in 2018, 2019, and parts of 2020 and failed to test as required under Subpart H of this part, see D-2123.