

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D2093483	<b>(X3) Date Survey Completed</b>  06/07/2022
<b>Name of Provider or Supplier</b>  Elite Urgent Care Inc	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D1002</b>	<p><b>REPORTING OF SARS-CoV-2 TEST RESULTS</b></p> <p>During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.</p> <p>This CONDITION is not met as evidenced by: Based on observation of three systems to test for SARS-CoV2, review of 2021-2022 laboratory test records, the lack of laboratory documents, and interview with the Laboratory Director (Owner), it was determined that the Condition for reporting COVID-19 test results to the Secretary of HHS was not met. Findings included: 1. The laboratory used three different tests for SARS-CoV2: Manufacturer Test name ----- Mesa Biotech Accula SARS-CoV2, PCR Quidel Sofia SARS Antigen FIA Quidel Sofia2 Flu + SARS Antigen FIA 2. Laboratory records selected randomly from 2021 - 2022 documented SARS-CoV2 testing and results, as follows: Date Time SARS-CoV2 Result 2/13/21 1:25 PM Positive 5/02/21 5:35 PM Negative 7/09/21 9:45 AM Negative 9/26/21 6:00 PM Positive 12/03/21 2:30 PM Positive 1/29/22 9:55 AM Negative 3/24/22 4:25 PM Positive 5/05/22 11:20 PM Positive 6/07/22 1:45 PM Negative 6/07/22 1:00 PM Positive 3. For 10 out of 10 tests from the timeframe February 2021 to June 2022, the laboratory failed to provide evidence of reporting COVID test results to public health. 4. The Laboratory Director/Owner affirmed (6/07/22 at 7:00PM) that no COVID test results had been reported to public health; and thus, the failure to report COVID test results to the Secretary of HHS. 5. The laboratory performed and failed to report to public health: 2,550 COVID tests results annually (Testing Declaration, 6/02/22). .</p>
<b>D2122</b>	<p><b>HEMATOLOGY</b> CFR(s): 493.851(b)</p>

Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

This STANDARD is not met as evidenced by:

Based on observation of the Sysmex XP300 hematology analyzer, review of 2021 - 2022 hematology tests records, proficiency testing reports from CMS (report 155D, Individual Laboratory Profile) and WSLH (Wisconsin State Laboratory of Hygiene); and interview with the Laboratory Director (Owner), it was determined that the laboratory failed to attain scores of 80% or better in hematology proficiency testing. Findings included: 1. For 2021 - Event 1, Hematology, CMS and WSLH reported scores of 0% for RBC, WBC, WBC Differential, Hemoglobin, Hematocrit and Platelets while the laboratory tested patients specimen. 2. For 2022- Event 1, Hematology, CMS reported no scores while the laboratory tested patients specimen. 3. The Laboratory Director affirmed (6/07/22 at 6:30PM) the aforementioned findings; and thus, the failure to attain satisfactory proficiency testing scores. 4. The reliability and quality of hematology results reported could not be assured when the laboratory failed to attain overall scores of at least 80% in proficiency testing. The laboratory reported 1,250 results during six months of testing (CLIA Application, 6/02/22). Hematology test reports randomly selected from the affected timeframes in 2021 and 2022 were, as follows: Test date Time specimen was tested 1/18/21 10:09 AM 2/22 /21 8:55 AM 3/13/21 10:17 AM 4/10/21 10:00 AM 5/19/21 14:17 PM 6/04/21 8:33 AM ... 1/03/22 1:27 PM 2/07/22 8:34 AM 3/01/22 12:59 PM 4/04/22 8:26 AM 5/04 /22 9:27 AM 6/06/22 6:05 PM . . .

**D2123**

**HEMATOLOGY**

CFR(s): 493.851(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 XP300 hematology analyzer, review of 2021 - 2022 proficiency testing reports from CMS (report 155D, Individual Laboratory Profile) and WSLH (Wisconsin State Laboratory of Hygiene) and laboratory records; the lack of proficiency test records, and interview with the Laboratory Director (Owner), it was determined that the laboratory failed to participate in hematology proficiency testing. Findings included: 1. 2021 - Event 1, Hematology a. Laboratory records documented proficiency samples were tested on 3/10/22, after the 3/05/21 deadline for reporting results. b. As a consequence of being unable to submit results for evaluation, the laboratory failed to participate. 2. 2022- Event 1, Hematology a. The laboratory failed to provide records of proficiency testing for the first event in 2022 (March) while continuing to test patients specimen. b. CMS reported no scores, indicating the laboratory had not participated in proficiency testing. c. The Order

Confirmation for 2022 revealed proficiency testing in routine hematology was not ordered until 6/03/22. 3. The Laboratory Director/Owner affirmed (6/07/22 at 7:00PM) the aforementioned findings; and thus, the failures to participate in proficiency testing for the first events of 2021 and 2022 while testing patients specimen. 4. The reliability and quality of hematology results reported could not be assured when the laboratory failed to participate in proficiency testing. The laboratory reported 1,250 results during six months of testing (CLIA Application, 6/02/22). Hematology test reports randomly selected from the timeframes of the first events in 2021 and 2022 were, as follows: Test date Time specimen was tested 1/18/21 10:09 AM 2/22/21 8:55 AM 3/13/21 10:17 AM 4/10/21 10:00 AM 5/19/21 14:17 PM 6/04/21 8:33 AM ... 1/03/22 1:27 PM 2/07/22 8:34 AM 3/01/22 12:59 PM 4/04/22 8:26 AM 5/04/22 9:27 AM 6/06/22 6:05 PM 5. This deficiency was previously cited on 10/06/20. .

**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 the serious nature and cumulative effects of the deficiencies cited, the Laboratory Director (Owner) is herein cited at the Condition level for deficient practice in providing overall management of the laboratory. Findings included: 1. The Laboratory Director was deficient in his practice of directing the laboratory to report COVID test results to public health. See D1002. 2. The Laboratory Director was repeatedly deficient in his practice of directing the laboratory to test proficiency testing samples as required and report results as required for participation in proficiency testing. See D6016. 3. This deficiency was previously cited on 10/06/20. .

**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 the deficiencies cited at D2121 and D2123, the Laboratory Director is herein cited for deficient practice in ensuring the laboratory tested and reported proficiency testing samples as required to participate in all proficiency testing events. 1. This deficiency was previously cited on 10/06/20. .