

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  13D0703662	<b>(X3) Date Survey Completed</b>  09/20/2022
<b>Name of Provider or Supplier</b>  Cascade Medical Center	<b>Street Address, City, State</b>  402 Lake Cascade Pkwy, Cascade, ID	
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>D5211</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records from American Proficiency Institute (API) and an interview with the laboratory manager on 9/20/2022, the laboratory failed to evaluate results that were less than 100% for 2021 and 2022. The findings include: 1. A review of chemistry 2021 event two PT records from API identified that the laboratory failed to evaluate the results for the following analytes; B-type natriuretic peptide (BNP) 60% and Creatine kinase-MB (CK-MB) 80%. 2. A review of hematology 2021 event two PT records from API identified that the laboratory failed to evaluate the results for the following analytes; urine sedimentation exam 50% and vaginal wet preparation (KOH) 0%. 3. A review of hematology 2022 event one PT records from API identified that the laboratory failed to evaluate the results for red cell count 80%. 4. An interview with the laboratory manager on 9/20/2022 at 10:30 am confirmed that the laboratory failed to evaluated PT results for the above analytes. 5. The laboratory reports performing 43,605 tests annually.</p>
<b>D5215</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p>

This STANDARD is not met as evidenced by:  
Based on a review of proficiency testing (PT) records from American Proficiency Institute (API) and an interview with the laboratory manager on 9/20/2022, the laboratory failed to evaluate the accuracy of analytes that were assigned an artificial score of 100% because it was ungraded by the PT provider. The findings include: 1. A review of Hematology 2021 event three PT records from API identified that the laboratory failed to evaluate an ungraded sample for vaginal wet preparation (KOH) that was given an artificial score of 100% due to lack of consensus. 2. A review of Hematology 2022 event two PT records from API identified that the laboratory failed to evaluate an ungraded sample for vaginal wet preparation that was given an artificial score of 100% due to lack of consensus. 3. An interview with the laboratory manager on 9/22/2021 at 10:30 am confirmed that the laboratory did not evaluate the accuracy of ungraded PT results that were given an artificial score of 100%. 4. The laboratory reports performing 43,605 tests annually.

**D5445**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(d)(1)(2)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--  
(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:  
Based on a review of the laboratory's policies and procedures, quality control (QC) records for the Siemens epoc and the Quidel triage and an interview with the laboratory manager on 9/20/2022, the laboratory failed to perform QC each day of patient testing. The findings include: 1. A review of the laboratory's policies and procedures identified that the laboratory failed to have an Individualized Quality Control Plan (IQCP) for testing performed on the epoc and the triage. 2. A review of QC for blood gas testing on the epoc and D-dimer, troponin and B-type natriuretic peptide (BNP) testing on the triage identified that the laboratory failed to test QC each day of patient testing. 3. An interview with the laboratory manager on 9/20/2022 at 12:32 pm confirmed that the laboratory did not have an IQCP for the epoc and the triage and only performed QC on new kit lots.