

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  06D2004180	<b>(X3) Date Survey Completed</b>  07/31/2020
<b>Name of Provider or Supplier</b>  Grace Health Clinic Laboratory	<b>Street Address, City, State</b>  3191 South Vaughn Way, Aurora, CO	
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>D2016</b>	<p><b>SUCCESSFUL PARTICIPATION</b> CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on routine desk audit of CMS-153 and 155 reports of proficiency testing performance and interview, the laboratory failed to achieve satisfactory performance for Chloride for two of three events, Event 3 of 2019 and Event 2 of 2020, resulting in unsuccessful proficiency testing performance. See D2096</p>
<b>D2096</b>	<p><b>ROUTINE CHEMISTRY</b> CFR(s): 493.841(f)</p> <p>Failure to achieve satisfactory performance for the same analyte or test in two</p>

consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on review of proficiency testing scores and interview, the laboratory failed to achieve a score of 80 percent for Chloride in two of three events, resulting in unsuccessful performance. The findings include: 1. During a review on 7-29-20, the CMS-153 Unsuccessful Proficiency Testing Report included Grace Health Clinic Laboratory with unsatisfactory proficiency testing scores for Chloride. 2. During a review on 7-29-20 of the CMS-155 report, the Chloride score for event 3 of 2019 was 60%. 3. During a review on 7-29-20 of the CMS-155 report, the Chloride score for event 2 of 2020 was 40%. 4. On 7-30-20 at 10:00 am, the laboratory director stated that there were issues with obtaining parts and service for the chemistry analyzer.