

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  06D2004180	<b>(X3) Date Survey Completed</b>  04/04/2018
<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>D6076</b>	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on the deficiencies cited under the Laboratory Director's responsibilities and continued unsuccessful performance in proficiency testing, the laboratory director failed to provide overall management and direction for the laboratory. Refer to D6079.</p>
<b>D6079</b>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b)</p> <p>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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.</p> <p>This STANDARD is not met as evidenced by: Based on proficiency testing (PT) review and the laboratory's PT results, the</p>

laboratory failed to achieve satisfactory performance in the specialty of Chemistry for the analyte of Total Calcium and has sustained a subsequent occurrence of unsuccessful participation in PT. Findings include: a. Scores on the last 4 PT testing events: Analyte Year Event Score Total Calcium 2017 1 20% Total Calcium 2017 2 0% Total Calcium 2017 3 0% Total Calcium 2018 1 0%