

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 27D0409879	(X3) Date Survey Completed 11/13/2019
Name of Provider or Supplier Fallon Medical Complex	Street Address, City, State 202 South 4th Street West, Baker, MT	
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
D6076	<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 routine desk audit of CMS-153 and 155 reports of proficiency testing performance and interview, the laboratory director failed to provide overall management and direction for preventing proficiency testing failures for three of four events (2018 event 3, 2019 event 1, and 2019 event 3) resulting in subsequent unsuccessful proficiency testing performance. See D2096.</p>
D6092	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv)</p> <p>The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing scores and interview, the laboratory director failed to achieve a score of 80 percent for chloride in three of four events in 2018 and 2019, resulting in subsequent unsuccessful performance. The findings include: 1. During a review on 3/18/19 at 11:30 a.m. of the CMS-153 Unsuccessful Proficiency Testing Report included Fallon Medical Complex with unsuccessful proficiency testing scores for chloride. 2. During a review on 3/20/19 at 8:00 a.m. of the CMS-155 report, the American Proficiency Institute (API) chloride score for event 3 of 2018 was 60%. 3. During a review on 3/20/19 at 8:00 a.m. of the CMS-155 report, the API</p>

chloride score for event 1 of 2019 was 40%. 4. On 3/20/19 at 9:00 a.m., the laboratory manager stated the failures occurred and corrective action is in progress. 5. During a review on 10/28/19 at 11:30 a.m. of the CMS-155 report, the API chloride score for event 3 of 2019 was 60%. 6. On 10/28/19 at 11:45 a.m., the laboratory manager stated the failures continue due to incompatibility between the proficiency sample matrix and the analyzer. The corrective action previously implemented failed to fix the problem.