

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  16D0382576	<b>(X3) Date Survey Completed</b>  12/11/2018
<b>Name of Provider or Supplier</b>  Mercyone Ankeny Clinics	<b>Street Address, City, State</b>  800 East First Street, Suite 1700, Ankeny, IA	
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>D5217</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Laboratory Test List &amp; Annual volume form, proficiency testing (PT) records and confirmed by laboratory personnel identifier #7 (refer to the Laboratory Personnel Report) at approximately 2:00 pm on 12/11/2018, the laboratory failed to verify the accuracy of glycated hemoglobin testing at least twice annually for two out of two time periods from September 2017- September 2018. The findings include: 1. The Laboratory Test List &amp; Annual Volume form included the analyte, glycated hemoglobin. 2. The laboratory installed and began using a new chemistry analyzer (Dimension EXL) in September 2017. 3. Personnel identifier #7 stated that the laboratory forgot to enroll in PT after the new install and did not perform PT for the analyte, glycated hemoglobin, from September 2017- September 2018. 4. At the time of the survey, the laboratory did not have additional records indicating the verification of accuracy for the analyte, glycated hemoglobin.</p>