

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  16D0666773	<b>(X3) Date Survey Completed</b>  09/12/2019
<b>Name of Provider or Supplier</b>  Mercyone Ottumwa Family	<b>Street Address, City, State</b>  522 North Hancock Street, Ottumwa, 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>D5024</b>	<p><b>HEMATOLOGY</b> CFR(s): 493.1215</p> <p>If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on review of the ACL Elite coagulation reagent verification records from January 2019, observations of the coagulation analyzer and confirmed by laboratory personnel identifier #3 (refer to the Laboratory Personnel Report) at approximately 1:00 pm on 09/12/2019, the laboratory failed to meet the hematology (coagulation) requirements for test system/equipment/reagent verification as specified in the standard D5411.</p>
<b>D5411</b>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on review of ACL Elite coagulation reagent verification records from January 2019, observations of the coagulation analyzer and confirmed by laboratory personnel identifier #3 (refer to the Laboratory Personnel Report) at approximately 1:00 pm on 09/12/2019, the laboratory failed to program the correct normal patient mean for the current thromboplastin reagent in use (lot N0789332, expiration 07/2020) into the</p>

ACL Elite coagulation analyzer. The findings include: 1. The laboratory established a normal patient mean of 11.04 seconds for thromboplastin lot number N0789332 (expiration 07/2020) in January 2019. 2. At the time of the survey, observation of the ACL Elite coagulation analyzer revealed that the laboratory had programmed a normal patient mean of 11.55 seconds into the instrument. 3. Observation of thromboplastin reagent in the laboratory's refrigerator confirmed current use of lot N0789332 (expiration 07/2020). 4. Laboratory personnel identifier #3 confirmed that the laboratory did not have the correct established normal patient mean programmed into the coagulation analyzer.