

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 23D1012785	<b>(X3) Date Survey Completed</b> 02/19/2019
<b>Name of Provider or Supplier</b> Ascension St John	<b>Street Address, City, State</b> 28001 Harper Avenue, Saint Clair Shores, MI	
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>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: . Based on procedure review, record review, and interview with technical consultant #1 and #2 (TC1 and TC2), the laboratory failed to ensure competency policies were followed for one (#3) of three testing personnel (TP) performing the hematology complete blood cell count testing. Findings include: 1. Procedure review of the "Laboratory Manual" under the "Quality Control" section revealed competency is to be completed initially, at six months, and annually thereafter. 2. Record review of the TP competency assessments revealed their was no documentation to show the six month and annual review was completed for TP3 during their first year of employment. 3. During the interview on February 19, 2019 at 9:23 AM, TC1 confirmed the competency assessment had not been performed or documented as stated in the policy.</p>
<b>D5429</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: . Based on surveyor review of preventive maintenance logs and interview with</p>

technical consultant #2 (TC2), the laboratory failed to perform and document the weekly hematology analyzer maintenance according to the manufacturer's instructions during 2018 for 18 (January - March and July - December) of 36 weeks as required by the manufacturer. Findings include: 1. Review of the "XP-300 Maintenance Log" for 2018 showed the laboratory did not perform and document the weekly hematology analyzer maintenance for 18 of 36 weeks as follows: a. no week 1 - August, September, October, and December b. no week 2 - February, March, and August c. no week 3 - March, September, and December d. no week 4 - January, February, March, July, September, October, November, and December 2. During the interview on February 19, 2019 at 11:28 AM, TC2 stated the laboratory did not perform and document the weekly maintenance as required.