

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0388401	(X3) Date Survey Completed 04/16/2019
Name of Provider or Supplier Aurora Health Center - Hubertus	Street Address, City, State 3055 Hubertus Rd, Hubertus, WI	
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
D6072	<p>TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3)</p> <p>Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of maintenance records and interview with testing personnel and the technical consultant, staff A did not adhere to laboratory policies by documenting maintenance and control activities days prior to performing the tasks. Findings include: 1. Review of the "Sysmex XS-1000i Maintenance Log" on Tuesday, April 16, 2019 showed staff A initialed entries showing performance of function checks, maintenance, and quality control activities on April 15, 16, 17, and 18. The log showed staff A performed daily start-up activities on April 15, 16, 17 and April 18, 2019, and daily shutdown and weekly maintenance activities on April 15 and 17, 2019. 2. Interview with staff A on April 16, 2019 at 9:15 AM revealed staff A completed the maintenance log on Monday, April 15, 2019 for the activities staff A expected to perform throughout the week. 3. Interview with the technical consultant on April 16, 2019 at 9:15 AM confirmed staff A did not adhere to the laboratory's policies by completing the maintenance log prior to performing the identified activities.</p>