

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D2077860	(X3) Date Survey Completed 02/14/2018
Name of Provider or Supplier Aurora Health Center - West Bend, Gateway Ct	Street Address, City, State 1100 Gateway Ct, West Bend, 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
D6093	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of quality control (QC) worksheets and laboratory procedures, and interview with the technical consultant, the laboratory director did not ensure that the quality control program for the Erythrocyte Sedimentation Rate (ESR) test was established and maintained to assure the quality of laboratory services. Findings include: 1. Review of ESR Auto Plus Control / maintenance log worksheets for November 2017 shows two acceptable QC ranges are listed, one identified as ACL (Aurora Clinical Laboratory) and a second identified as Manuf (Manufacturer). The worksheet also shows five QC results for the Level One control that are not in the ACL range but are identified as being within the manufacturer's range (November 2, 9, 10, 11 and 12). 2. Review of the procedure, Reference #3798 Version #3 ESR-Auto Plus Erythrocyte Sedimentation Rate, shows the acceptable range for control samples is not defined. 3. Further review of the procedure shows QC results are to be entered into AML for statistical analysis. 4. Interview with the technical consultant on February 14, 2018 at 12:00 PM confirmed the Quality Control program has not been specifically defined in the procedure and does not identify how the acceptable ranges for quality control samples are developed. Further interview confirms the laboratory does not enter QC results in AML or perform any other statistical evaluation of control results.</p>