

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0936548	(X3) Date Survey Completed 06/07/2019
Name of Provider or Supplier Ascension Medical Group- Fox Valley Wisconsin Inc	Street Address, City, State 2725 Jackson St, Oshkosh, 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
D5793	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c)</p> <p>(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory proficiency testing evaluations, hematology corrective action logs, hematology analyzer service reports, hematology interlaboratory quality assurance program reports, and interview with the laboratory technical consultant, the laboratory did not review the effectiveness of the corrective actions taken to resolve the automated differential problems on the Beckman Coulter AcT 5 Diff hematology analyzer and prevent the recurrence of the problems. Findings Include: 1. Review of the American Proficiency Institute (API) proficiency testing evaluation reports showed: 2017 Hematology/Coagulation Event 2: Score of 20 % for Eosinophil Automated Differential; 2018 Hematology/Coagulation Event 3: Score of 40 % for Monocyte Automated Differential; 2019 Hematology/Coagulation Event 1: Score of 80 % for Eosinophil and Monocyte Automated Differential. Corrective action was documented after each event. 2. Random review of the Beckman Coulter Act Diff 5 hematology corrective action logs, instrument service reports, and hematology interlaboratory quality assurance program reports show that corrective action (CA) was performed on the following dates: August 18, 2017 August 23, 2017 March 13, 2018 June 11, 2018 June 14, 2018 July 31, 2018 August 16, 2018 November 27, 2018 December 20, 2018 Corrective action was performed to address failed proficiency, Diff Plot and database errors on the analyzer, and standard deviation index (SDI) outside of range on the interlaboratory quality assurance</p>

reports. Corrective actions also involved service representatives from Trimedx and Beckman Coulter performing instrument service. 3. Interview with the technical consultant on June 7, 2019 at 11:20 AM confirms that the laboratory did not address the effectiveness of the corrective actions taken to resolve hematology analyzer issues and to prevent the recurrence of the problems.