Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D1014762	06/04/2019
Name of Provider or Supplier	**Street Address, City, State**	
Ascension Columbia St Mary's Milwaukee	375 W River Woods Pkwy, Glendale, 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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on surveyor review of hematology procedures and interview with the technical consultant, the procedures do not provide instructions for testing personnel to follow when a manual differential (diff) is indicated by the complete blood cell (CBC) results from the Beckman Coulter AcT Diff II hematology analyzer. Findings include: 1. Review of the hematology procedures revealed a procedure titled "CBC Criteria for Manual Diff / Slide Review, Effective 10/14; RW 8/15". The procedure identifies CBC results that require performance of a manual differential or slide review. The procedure includes instructions to "Order and perform a manual diff...", "Scan slide to

	verify count...", and "Send to the hospital lab if cells younger than bands are seen on the manual diff". Further review of hematology procedures revealed no instructions for scanning slides or the performance of a manual differential. 2. Interview with the technical consultant, staff B, on June 4, 2019 at 11:00 AM revealed testing personnel do not perform manual differentials or scan slides at this location. The interview also confirmed the procedures do not provide testing personnel with instructions to follow to refer a sample for a differential or slide review.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of quality control procedures and interview with the technical consultant, the laboratory has not established the same frequency of external control testing in the Individualized Quality Control Plans (IQCP) and the laboratory test procedures for the international normalized ratio (INR) and troponin test systems. Findings include: 1. Review of the IQCP for INR testing with the Hemochron Jr. Signature + analyzer showed the laboratory requires the testing of two levels of external liquid control material with each new lot of test cuvettes and every thirty days. Review of the laboratory test procedure, "INR Testing on the Hemochron Jr. Signature +" showed external "liquid controls are run with each new box of cuvettes and each eight hours of patient testing." 2. Review of the IQCP for Troponin testing on the i-STAT analyzer showed the laboratory requires testing of two levels of external control material with each new lot of cartridges and every thirty days. Review of the laboratory test procedure "Troponin I (cTNI) - Abbott i-STAT Meter Method" showed the laboratory requires testing of two levels of external control material each day patient samples are run. 3. Interview with the technical consultant, staff B, on June 4, 2019 at 11:00 AM confirmed the procedures and the IQCP do not require the same frequency of external control testing on the Hemochron Jr. Signature + or the i-STAT troponin test systems.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by:

	Based on surveyor review of hematology Interlaboratory Quality Assurance Program (IQAP) reports and corrective action records, and interview with the technical consultant, the laboratory did not assess or correct problems identified in the IQAP reports for the Beckman Coulter AcT Diff II between December 2018 and May 2019. Findings include: 1. Review of the Interlaboratory Quality Assurance Program (IQAP) reports for the Beckman Coulter AcT Diff II hematology analyzer showed reports from December 8, 2018 through April 5, 2019 included results identified by the manufacturer for review of potential precision issues. The reports directed the laboratory to "Refer to your IQAP manual for troubleshooting suggestions" for each of the following parameters: Control lot numbers: 068800, 078800, and 088800 December 8, 2018 through January 3, 2019 MCV (Mean Corpuscular Volume) flagged for Control Level 1 and Level 2 WBC (White Blood Cell) flagged for Control Level 2 December 8, 2018 through February 8, 2019 MCV flagged for Control Level 1 WBC flagged for Control Level 1 and 2 December 8, 2018 through March 8, 2019 WBC flagged for Control Level 1 and 2 Control lot numbers: 069500, 79500, and 089500 March 8, 2019 through April 5, 2019 MCV flagged for Control Level 1 and 3 WBC flagged for Control Level 1 and 2 Hemoglobin flagged for Control Level 3 Platelets flagged for Control Level 1 The technical consultant, staff C, initialed the reports but the reports show no evidence of corrective actions or assessment of the identified results. 2. Review of corrective action logs for March 2019 showed quality control was not acceptable on the first run for seven of thirty-one days. In May 2019, corrective action logs showed QC failed the first run on fourteen of thirty-one days. Laboratory staff initiated an instrument corrective action form to evaluate the analyzer on May 31, 2019. 3. Interview with the technical consultant, staff B, on June 4, 2019 at 11:00 AM confirmed the laboratory did not assess, and correct potential precision problems identified through the hematology quality control program from December 2018 until May 31, 2019.
D5821	TEST REPORT CFR(s): 493.1291(k) When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. This STANDARD is not met as evidenced by: Based on surveyor review of patient test reports and interview with the technical consultant, the laboratory did not issue a corrected report when laboratory staff changed the reported White Blood Cell (WBC) result for patient one. Findings include: 1. Review of patient test reports for patient one revealed a preliminary and a final hematology report. The preliminary report showed staff A performed hematology testing on a sample from patient 1. The laboratory faxed the results, including a WBC result of 6.8 thousand cells per microliter, to the urgent care area on April 1, 2019 at 3:37 PM. The final hematology report in the electronic medical record (EMR) showed the WBC result was 6.4 thousand cells per microliter. The report does not show the laboratory corrected the initial reported WBC result. The WBC result in the EMR included two comments, the first indicated, "WBC testing was performed at River Woods laboratory", the second indicated the "test was performed at Ascension CSM Milwaukee Lab". 2. Interview with the technical

	consultant, staff B, on June 4, 2019 at 12:45 PM confirmed the laboratory did not issue a corrected report when the laboratory changed the WBC result from 6.8 to 6.4 thousand cells per microliter.