Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0405365	11/30/2018
Name of Provider or Supplier	**Street Address, City, State**	
Sanford Worthington Medical Center	1018 6th Ave, Worthington, MN	

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 observation, document review and interview with laboratory personnel, the laboratory failed to ensure the reportable ranges of a Hematology analyzer were included in the procedure manual. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 11/29/18 at 8:05 a.m. 2. An Abbott / Cell-Dyn Ruby hematology analyzer was observed as present and available for use during the tour of the laboratory. 3. The reportable ranges for WBC*, RBC*, HGB*, and HCT* were not found in the Cell-Dyn Ruby Operation procedure located in the online procedure

	manual. The laboratory was unable to provide the information in another document upon request. 4. In an interview on 11/29/18 at 3:00 p.m., the GS confirmed the above findings. * WBC = White Blood Cell Count * RBC = Red Blood Cell Count * HGB = Hemoglobin * HCT = Hematocrit .
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) 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. This STANDARD is not met as evidenced by: . Based on observation, document review and interview with laboratory personnel, the laboratory failed to define, perform and document maintenance on a biological safety cabinet. Findings are as follows: 1. The laboratory performed Microbiology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 11/29/18 at 8:05 a.m. 2. A Nuaire Class II Type A2 biological safety cabinet was observed as present and available for use during the tour of the laboratory. 3. The Equipment Checks procedure, located in the on-line procedure manual, did not contain a requirement for maintenance or function checks for the biological safety cabinet. 4. Documentation of the maintenance or function checks for 2017 were not found in the laboratory maintenance records. The laboratory was unable to provide these records upon request. 5. In an interview on 11/29/18 at 11:15 a.m., the GS confirmed the above findings. .
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on observation, document review and interview with laboratory personnel, the laboratory failed to perform quality control (QC) at least once each day of patient specimen testing using an Immunology test kit. Findings are as follows: 1. The laboratory performed Immunology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 11/29/18 at 8:05 a.m. 2. Hologic Rapid fFN (Fetal Fibronectin) Cassette test kits were observed as present and available for use during the tour of the laboratory. 3. The Rapid Fetal Fibronectin (fFN) procedure, located in the on-line procedure manual, indicated that external QC was to be run with each new reagent lot number or shipment. 4. Review of QC records on the day of the survey revealed that external QC on reagent lot # A7024 had not been performed between 4/27/17 and 9/29/17. 5. An Individualized Quality Control Plan (IQCP) to reduce the frequency of QC performance from each day of patient testing was not

	found in laboratory records. The laboratory was unable to provide an IQCP upon request. 6. In an interview on 11/29/18 at 2:50 p.m., the GS confirmed the above findings. .
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: . Based on observation, document review and interview with laboratory personnel, the laboratory failed to test two levels of quality control (QC) material when preparing and placing new reagents into use on a Coagulation analyzer. Findings include: 1. The laboratory performed Coagulation testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 11/29/18 at 8:05 a.m. 2. A Sysmex CA-1500 coagulation analyzer was observed as present and available for use during the tour of the laboratory. 3. The Coagulation Quality Control procedure, located in the on-line procedure manual, did not indicate using 2 levels of control material when new reagents were prepared and placed into use for PT* or aPTT* 4. A review of QC records revealed that QC had only been performed every 8 hours. The laboratory was unable to provide evidence that QC had been performed when new reagents were prepared and placed into use. 5. In an interview on 11/29/18 at 2:35 p.m., the GS confirmed the above findings. * PT = Prothrombin Time * aPTT = Activated Partial Thromboplastin Time .