Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0405365	12/15/2022
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
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to ensure two of two Chemistry reportable ranges obtained during performance verification (PV) activities completed 2022 were adopted by the laboratory. In addition, the laboratory failed to verify reference intervals for one of one Hematology (Coagulation) analytes during PV activities completed in 2021. Findings are as follows: The laboratory performed Chemistry and Hematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 8:05 a.m. on 12/14/22. A. Chemistry 1. An Abbott Architect ci4100 chemistry analyzer was observed as present and available for use during the tour of the laboratory. The laboratory implemented Enzymatic Creatinine (CrEnz) testing on this analyzer in March 2022 as indicated by the GS during the tour. 2. PV activities were completed in March 2022 as indicated in laboratory records found in the March 2022 Enz. Creat. manilla folder. The Laboratory Director approved the PV on 03/29/22. 3. Verification of reportable range was required as established in the Laboratory Test Validation procedure found in the PolicyTech electronic procedure program. 4. The upper and/or lower reportable range limits adopted by the laboratory for CrEnz did not reflect the actual reportable range values obtained by the laboratory during the PV as indicated in the PV documents and Architect analyzer reporting limits for the analyte. See below.

	Analyte PV Adopted CrEnz urine 6.35-762.91 0.0-40.0 CrEnz serum 0.2-36.19 0.0-40.0 5. In an interview at 2:40 p.m. on 12/14/22, the GS confirmed the above finding. B. Hematology 1. A Stago Compact Max coagulation analyzer was observed as present and available for use during the tour of the laboratory. The laboratory implemented Heparin Xa testing on this analyzer in July 2021 as indicated by the GS during the tour. 2. PV activities for Heparin Xa accuracy, precision, and reportable range were completed on the Compact Max analyzer as indicated in laboratory records found in the Stago Compact Max Install manual. The Laboratory Director approved the PV with no date documented. 3. Verification of reference range was required as established in the Laboratory Test Validation procedure found in the PolicyTech electronic procedure program. 4. PV documentation did not include verification of Heparin Xa reference ranges (normal values). The laboratory was unable to provide this documentation upon request. 5. In an interview at 3:00 p.m. on 12/14/22, the GS confirmed the above finding. .
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the Technical Consultant failed to ensure comprehensive initial training, semi-annual competency assessments and annual competency assessment were performed for all testing personnel in 2021 and 2022. Findings are as follows: 1. The laboratory performed Immunology and Chemistry testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 8:05 a.m. on 12/14/22. 2. The following test systems or test kits were observed as present and available for use during the tour. i-STAT Troponin (back-up) Hologic TLiQ Fetal Fibronectin Amnisure ROM 3. Personnel competency evaluation encompassing all duties performed was required as established in the Competency Assessment procedure found in the PolicyTech electronic procedure program. 4. The i-STAT Troponin, Fetal Fibronectin, and Amnisure ROM tests were not included in the Self Assessment and Orientation Skills Checklist forms or Annual Competency forms completed between March 2021 and date of survey, 12 /14/22. Testing personnel (TP) were not assessed for competency on these tests. See below. 2021 - 5 of 5 tenured TP were not assessed annually 2022 - 6 of 6 new TP were not assessed initially 2022 - 1 of 1 new TP was not assessed semi-annually 5. The laboratory was unable to provide the missing training records and missing competency assessment documents upon request. 6. In an interview at 11:25 a.m. on 12/14/22, the GS confirmed the above finding. .