Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0405238	10/24/2024
Name of Provider or Supplier	**Street Address, City, State**	
Sanford Jackson Medical Center	1430 N Highway, Jackson, 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
D0000	The Sanford Jackson Medical Center laboratory was found to be out of compliance with the regulations of the Clinical Laboratory Improvement Amendments of 1988 (42 C.F.R. part 493) upon completion of the recertification survey performed on October 24, 2024. The following standard-level deficiency were cited: 493.1253 Establishment and verification of performance specifications .
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 three of four reviewed Chemistry reportable ranges obtained during twenty measured analyte performance verifications (PV) were adopted by the laboratory in 2024. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 8:10 a.m. on 10/24/24. 2. An Abbott i-STAT blood analysis system and an Abbott Architect ci41000 chemistry analyzer were observed as present and available for use during the tour of the laboratory. A. Abbott i-STAT 1. PV activities for i-STAT CG4+ (3 measured analytes), Chem8+ (9 measured analytes), and Troponin (1 measured analyte)cartridges were completed in August 2024 for a replacement i-STAT system as indicted in records found in the New i-STAT 2024 folder. The Laboratory Director approved the PV's on 08/22/24. The CG4+ data for

	measured analytes pH, pCO2, and pO2 was reviewed in depth during the survey. 2. The upper and/or lower reportable range limits adopted by the laboratory for 2 of 3 measured analytes in the CG4+ cartridge did not reflect the actual reportable range values obtained by the laboratory during the PV as indicated in PV records and the Laboratory Test List . See below. Analyte Obtained Adopted pCO2 18.50-94.20 15-110 pO2 46.00-404.00 15-450 3. The laboratory's New Method Verification Procedure for FDA Approved Non-Waived Assays found in the policy and procedure manager PolicyTech did not provide guidance on the adoption of the manufacturer's analytical measurement range (AM) when obtained values did not meet or exceed the AMR. 4. In an interview at 2:15 p.m. on 10/24/24., the GS confirmed the above finding and indicated the manufacturer's AMR for the analytes had been adopted. B. Abbott Architect ci41000 1. PV activities for the following analytes were completed in 2024 as indicted in individual folders for each analyte: Acetaminophen (ACE) Alanine Transaminase Aspartate Aminotransferase Lactic Acid Total Protein Uric Acid Phosphorus The Acetaminophen data was reviewed in depth during the survey. The Laboratory Director approved this PV on 05/16/24. 2. The upper and/or lower reportable range limits adopted by the laboratory for ACE did not reflect the actual reportable range values obtained by the laboratory during the PV as indicated in PV records and the Laboratory Test List . See below. Analyte Obtained Adopted ACE 11-354 3-377 3. In an interview at 4:45 p.m. on 10/24/24., the GS confirmed the above finding and indicated the manufacturer's AMR for Acetaminophen had been adopted.