

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0405238	(X3) Date Survey Completed 12/08/2022
Name of Provider or Supplier Sanford Jackson Medical Center	Street Address, City, State 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
D5807	<p>TEST REPORT CFR(s): 493.1291(d)</p> <p>Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.</p> <p>This STANDARD is not met as evidenced by:</p> <p>. Based on observation, document review, and interview with laboratory personnel, the laboratory failed to ensure Chemistry and Coagulation reference intervals were consistent between procedures, reference range tables, and patient test reports. Findings are as follows: A. Chemistry - Arterial Blood Gases 1. The laboratory performed Chemistry testing as confirmed by the Technical Supervisor (TS) during a tour of the laboratory at 7:05 a.m. on 12/08/22. 2. An Abbott i-STAT chemistry system was observed as present and available for use during the tour of the laboratory. The laboratory included the following analytes in the arterial blood gas test performed on this analyzer: pCO₂ - Partial pressure of Carbon Dioxide pO₂ - Partial pressure of Oxygen HCO₃ - Bicarbonate BE - Base Excess sO₂ - Oxygen Saturation pH - Potential of Hydrogen 3. Reference intervals listed in the i-STAT Procedure Manual procedure and the Sanford Jackson Medical Center Laboratory Test List spreadsheet, both located in the laboratory's electronic chemistry procedures folder, were not consistent with each other and/or those included on a patient test report (Female - 71 yrs) from 04/21/22 reviewed on date of survey as indicated below. Analyte Procedure Spreadsheet Report pH 7.35-7.45 7.37-7.44 7.37-7.44 pO₂ 80-100 85-100 85-100 HCO₃ 24-28 21-28 24-28 4. In an interview at 11:20 a.m. on 12/08/22, the TS confirmed the above finding. B. Chemistry - Basic Metabolic Panel 1. The laboratory performed Chemistry testing as confirmed by the Technical Supervisor (TS) during a tour of the laboratory at 7:05 a.m. on 12/08/22. 2. An Abbott i-STAT chemistry system was observed as present and available for use during the tour of the laboratory. The laboratory included the following analytes in the Basic Metabolic Panel</p>

performed on this analyzer: Na - Sodium K - Potassium Cl - Chloride BUN - Blood Urea Nitrogen Glu - Glucose Crea - Creatinine TCO2 - Total Carbon Dioxide 3. Reference intervals listed in the i-STAT Chem 8+ Basic Panel - Jackson procedure and the Sanford Jackson Medical Center Laboratory Test List spreadsheet, both located in the laboratory's electronic chemistry procedures folder, were not consistent with each other and/or those included on a patient test report (Female - 75 years) from 05/03/22 reviewed on date of survey as indicated below. Analyte Procedure Spreadsheet Report Na 135-145 136-148 136-148 K 3.5-5.3 3.6-5.0 3.6-5.0 Cl 99-110 98-106 98-106 BUN 6-22 8-23 8-23 Glu 70-100 70-105 70-105 Creat Age & Sex* 0.8-1.2 0.8-1.2 TCO2 23-32 23-33 23-33 * Age & Sex Creatinine reference intervals values table not found 4. In an interview at 11:20 a.m. on 12/08/22, the TS confirmed the above finding. C. Coagulation - Pro Time / INR 1. The laboratory performed Coagulation testing as confirmed by the Technical Supervisor (TS) during a tour of the laboratory at 7:05 a.m. on 12/08/22. 2. A Stago Satellite system was observed as present and available for use during the tour of the laboratory. 3. Reference intervals listed in the Sanford Jackson Medical Center Laboratory Test List spreadsheet, located in the laboratory's electronic procedures folder, were not consistent with those on a patient test report (Male - 76 yrs) from 09/15/22 reviewed on date of survey as indicated below. ProTime / INR - Prothrombin Time / International Normalized Ratio Analyte Procedure Spreadsheet Report ProTime Not given 8.8-12.9 12.0-14.5 INR Not given 0.89-1.29 0.9-1.1 4. In an interview at 12:40 p.m. on 12/08/22, the TS confirmed the above finding. .