Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0405317	(X3) Date Survey Completed 09/10/2020
Name of Provider or Supplier Sanford Tracy Medical Center	**Street Address, City, State** 251 5th St E, Tracy, 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 range value obtained during the performance verification on a new chemistry analyzer was adopted by the laboratory and included in the procedure manual. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 8:05 a.m. on 09/10/20. 2. An Abbott Architect Ci 4100 analyzer was observed as present and available for use during the tour of the laboratory. The laboratory completed performance verification (PV) activities and

	began testing patient specimens using this analyzer in April 2019 as indicated in laboratory records. 3. The reportable range indicated in the PV data summary table for Acetaminophen, the single analyte reviewed on date of survey, did not reflect the actual reportable range value obtained by the laboratory during the PV as indicated below. Analyte PV Table Acetaminophen 0.10-362.27 5-377 4. In an interview at 11: 05 a.m. on 09/10/20, the GS confirmed the above finding. The GS indicated the reportable range for the analyzer was standardized throughout the Sanford system.