

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0405317	(X3) Date Survey Completed 04/06/2026
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
D0000	The Sanford Tracy 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 completed on 4/2/26. The following standard-level deficiencies were cited: 493.1251 Procedure manual 493.1291 Test report .
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>(b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel,</p>

the laboratory failed to include pertinent reference intervals in the procedure manual for one Hematology test and one Chemistry test in 2024 and 2025. Findings are as follows: 1. The laboratory performed Hematology and Chemistry testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 11:55 a.m. on 4/1/26. 2. The following test systems were observed as present and available for use during the tour: Cardinal Health HCG (Human Chorionic Gonadotropin) Combo Test Kit Alcor miniiSED Erythrocyte Sedimentation Rate (ESR) Hematology analyzer 3. A reference interval was not defined in the ESR miniiSED - Tracy procedure found in PolicyTech. Additionally, A reference interval was not defined in the HCG Combo Rapid Test - Tracy procedure found in PolicyTech. 4. In an interview at 10:07 a.m. on 4/2/26, the GS confirmed the above findings. 5. In an email received at 3:56 p.m. on 4/2/26, the GS indicated the laboratory performed the following test volumes on patient samples: HCG in 2024: 36 HCG in 2025: 10 ESR in 2025: 48 .

D5807

TEST REPORT
CFR(s): 493.1291(d)

(d) 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.

This STANDARD is not met as evidenced by:
. Based on observation, document review, and interview with laboratory personnel, the laboratory failed to ensure a single pertinent Chemistry reference interval was included on a patient test report in 2024. Findings are as follows: 1. The laboratory performed Chemistry kit testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 11:55 a.m. on 4/1/26. 2. A Cardinal Health HCG (Human Chorionic Gonadotropin) Combo Test Kit was observed as present and available for use during the tour. 3. A reference interval was not included on a patient test report from 4/16/24 reviewed on the date of survey. See Below. Patient Report from 4/16/26 Analyte Report Procedure* HCG --- --- *Additionally, A reference interval was not defined in the HCG Combo Rapid Test - Tracy procedure found in PolicyTech. See D5403. 4. In an interview at 10:07 a.m. on 4/2/26, the GS confirmed the above findings. 5. In an email received at 3:56 p.m. on 4/2/26, the GS indicated the laboratory performed 36 serum HCG tests on patient samples in 2024. .