Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0405465	07/16/2026
Name of Provider or Supplier	**Street Address, City, State**	
Sanford Canby Medical Center	112 St Olaf Ave S, Canby, 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 Canby Medical 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 July 16, 2026. The following condition-level deficiency was cited: 493.1290 Post Analytic Systems The following standard-level deficiencies were cited: 493.1251 Procedure Manual 493.1291 Test Report .
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (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. This STANDARD is not met as evidenced by:

	. Based on observation, document review, and interview with laboratory personnel, the laboratory failed to ensure six of thirteen pertinent Hematology reference intervals were included in the procedure manual at the time of survey. Findings are as follows: 1. The laboratory performed differential Hematology testing on patient samples as confirmed by the General Supervisor (GS1) during a tour of the laboratory at 12:45 p. m. on 7/15/26. 2. A Sysmex XN-550 analyzer, Hematology stains, and an Olympus BH-2 microscope were observed as present and available for use for differential testing during the tour. 3. Pertinent reference intervals for six of thirteen differential analytes were not included in the Hematology Reference Ranges - Canby procedure provided by the laboratory. See below: Analyte Procedure Neutrophils Absolute 1.8 - 8.0 K/uL Seg Neut Absolute 1.8 - 8.0 K/uL Band Absolute 0.0 - 0.7 K/uL Lymphocytes Absolute 0.8 - 4.1 K/uL Monocytes Absolute 0.0 - 1.0 K/uL Eosinophils Absolute 0.0 - 0.7 K/uL Basophil Absolute 0.0 - 0.2 K/uL Neutrophils Percent -- % Band Percent -- % Lymphocytes Percent -- % Monocytes Percent -- % Eosinophils Percent -- % Basophil Percent -- % 4. In an interview at 1:09 p.m. on 7/16 /26, the GS1 confirmed the above findings.
D5800	POSTANALYTIC SYSTEMS CFR(s): 493.1290 Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in 493.1291 unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7) that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the postanalytic systems and correct identified problems as specified in 493. 1299 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: . Based on document reveiw and interveiw with laboratory personnel, the laboratory failed to meet post-analytic systems requirements in 493.1291. Findings are as follows: 1. The laboratory failed to ensure the test report included pertinent reference intervals. See D5807. .
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 seven of thirteen pertinent Hematology reference intervals were included on a patient test report in 2024. Additionally, the laboratory failed to ensure one of six pertinent Chemistry reference intervals were included on a patient test report in 2025. Findings are as follows: A. Hematology 1. The laboratory performed differential Hematology testing on patient samples as confirmed by the General Supervisor (GS1) during a tour of the laboratory at 12:45 p.m. on 7/15/26. 2. A Sysmex XN-550 analyzer, Hematology stains, and an Olympus BH-2 microscope were observed as present and available for use for differential testing during the tour. 3. Pertinent reference intervals for seven of thirteen analytes were not included on a

	patient test report from 11/20/24 reviewed on the date of survey. See below: Analyte Procedure Report Neutrophils Abs 1.8 - 8.0 --- Seg Neut Abs 1.8 - 8.0 1.8 - 8.0 Band Abs 0.0 - 0.7 0.0 - 0.7 Lymphocytes Abs 0.8 - 4.1 0.8 - 4.1 Monocytes Abs 0.0 - 1.0 0.0 - 1.0 Eosinophils Abs 0.0 - 0.7 0.0 - 0.7 Basophil Abs 0.0 - 0.2 0.0 - 0.2 Neutrophils % -- % -- % Band % -- % -- % Lymphocytes % -- % -- % Monocytes % -- % -- % Eosinophils % -- % -- % Basophil % -- % -- % *Units for absolute count are K/uL Reference intervals were not defined in the Hematology Reference Ranges - Canby procedure provided by the laboratory. See D5403. B. Chemistry 1. The laboratory performed Venous Blood Gas (VBG) testing on patient samples as confirmed by the GS1 during the tour. 2. An Abbott iStat Chemistry device and CG4+ Blood Gas cartridges were observed as present and available for use during the tour. 3. One of six pertinent reference intervals were not included on a patient test report from 5/30/25 reviewed on the date of survey. See below: Analyte Procedure Patient Report pH 7.31 - 7.41 7.31 - 7.41 pCO2 35 - 50 mmHg 35 - 50 mmHg pO2 17 - 65 mmHg 17 - 65 mmHg BE -2 - 2 meq/L -2 - 2 meq/L HCO3 20 - 29 mmol/L 20 - 29 mmol/L O2 Sat % 60 - 80 % ---- 4. In an interview at 11:26 a.m. on 7/16/26., the GS1 confirmed the above findings. 5. The laboratory performed 29 VBG tests on patient samples in 2025 and 13 manual differential tests on patient samples in 2024 as indicated by the GS1 in an email received at 6:15 p.m. on 7/20/26. .