Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0448967	12/03/2024
Name of Provider or Supplier	**Street Address, City, State**	
Sunflower Medical Group Pa	5675 Roe Blvd, Ste 100, Roeland Park, KS	

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	A validation survey was completed December 3, 2024. Sunflower Medical Group PA-Mission Office laboratory was found not in compliance with the following CONDITIONAL LEVEL DEFICIENCIES: D6033 - 42 C.F.R. 493.1409 Condition: Technical Consultant Moderate Complexity
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 upon a review of laboratory procedures and interview with the laboratory director (LD), the laboratory failed to define by written procedure the reportable range for Sysmex XN-530 hematology analyzer, serial number 11523, for white blood cells

	(WBC), red blood cells, (RBC), hemoglobin (Hgb), hematocrit (Hct), and platelet (Plt). Findings: 1. Review of the procedure "ANALYTICAL MEASUREMENT RANGE (AMR) AND CLINICAL REPORTABLE RANGE (CRR)" and appendix "Analytical Measurement Range (AMR) and Clinical Reportable Range (CRR)" revealed no documentation of the reportable range for Sysmex XN-530 hematology analyzer, serial number 11523 for WBC, RBC, Hgb, Hct, and Plt. The laboratory reports approximately 114,615 Sysmex XN-530 hematology analyzer patient results annually. 2. Interview with the LD on 12/3/24 at 10:40 a.m. confirmed, the laboratory failed to define by written procedure the reportable range for Sysmex XN-530 hematology analyzer, serial number 11523, for WBC, RBC, Hgb, Hct, and Plt.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's Individualized Quality Control Plan (IQCP) documentation for the Cepheid Strep A test cartridge, Cepheid Flu A/B, RVS, and Sars CoV-2 4 plex test cartridge, lack of documented monitoring for test system performance, and interview with testing personnel (TP) #1, the laboratory failed to monitor over time the accuracy and precision of test performance within the Cepheid test system. Findings: 1. Review of the laboratory's IQCP for the Cepheid test system for the Cepheid Strep A test cartridge, and the Cepheid Flu A/B, RVS, Sars CoV-2 4 plex test cartridge revealed no documentation of review for 2022 and 2023. 2. Interview with TP #1 on 12/3/24 at 11 a.m. confirmed, the laboratory failed to monitor over time the accuracy and precision of test performance within the Cepheid test system.
D5813	TEST REPORT CFR(s): 493.1291(g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values. This STANDARD is not met as evidenced by: Based on review of the selected patient test reports with critical values for 2023 and to date of survey 2024, and interview with TP #1, the laboratory failed to document the immediate alert of the responsible individual or entity of the critical or panic test result value(s) in the test report. Findings: 1. Review of selected patient test reports with critical values revealed no documentation of: a. alerting the individual or entity

	responsible for using the test results of the critical or panic test result value(s) b. date and time of the critical alert. 2. Interview with TP #1 12/3/24 at 10:10 a.m. confirmed, the laboratory failed to document the immediate alert of the responsible individual or entity of the critical or panic test result value(s) in the test report.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on documentation of testing personnel (TP) competencies, Quality Control (QC) review signatures, and personnel qualifications, the laboratory failed to have a qualified person(s) performing duties as a technical consultant. See D6035.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

	This STANDARD is not met as evidenced by: Based on the review of the CMS 209 personnel report, documentation of TP competencies and QC review, personnel qualifications, and interview, the laboratory failed to have a qualified person(s) performing duties as a technical consultant (TC). Findings: 1. Review of the CMS209 revealed one TC and five TP for moderate complexity testing. Four of five TP had been employed for longer than six months. 2. Review of TP competency forms revealed: a. Competencies in 2023 and 2024 for TP #1, #2, #3, and #4 included direct observations that were performed by the LD, who did not qualify as a TC. 3. Review of QC documents revealed the signature of the LD. No signatures were present from a person who qualified as a TC. The laboratory reports approximately 602,445 patient test results annually. 4. Interview with the LD on 12/3/24 at 10 a.m. confirmed, the laboratory failed to have a qualified person(s) performing duties as a technical consultant.