Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0975646	05/31/2024
Name of Provider or Supplier	**Street Address, City, State**	
Sandy Plains Pediatrics Pc	3225 Shallowford Rd Bldg 1300, Marietta, GA	

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 recertification survey was performed on May 24, 2024. The facility was found to be NOT in compliance with the CLIA conditions and standards for specialties /subspecialties for 42 CFR. CONDITION LEVELS: D5400 - Analytic Systems - 493.1250 D6000 - Moderate Complexity Laboratory Director - 493.1403 NOTE: The CMS-2567 (Statement of Deficiencies) is an official , legal document,. All information must remain unchanged except for entering the Plan Of Correction (POC), correction dates, and the signature space. Any discrepancy n the original deficiency citation(s) will be reported the the Georgia Regional Office (RO) for referral the Office of the Inspector General (OIG) for possible fraud if the information is inadvertently changed by the provide/supplier, the State Survey Agency (SA) should be notified immediately.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, 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 analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on the lack of room temperature logs, refrigerator/freezer temperature logs, humidity verifications, and the failure to perform Quality Control, the laboratory Director failed to monitor and evaluate the overall quality of the analytic systems or correctly identify problems as required. THIS IS A CONDITION LEVEL D5400 - ANALYTIC SYSTEMS - 493.1250 REFERENCE: D5413 - Test Systems, Equipment, Instruments, Reagent - 493.1252(a) D5441 - Control Procedures - 493.1256(a)(b)(c)(g)

D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on the lack of temperature and humidity documents and staff interview, the laboratory failed to provide documentation of the monitoring of the room temperature, refrigerator temperatures or humidity as required by the manufacturer. Findings: 1. Observation of laboratory documents confirmed the laboratory failed to monitor the temperatures of the refrigerators, room temperature or relative humidity, as required for storage of Quality Control reagents and performance of the Complete Blood Cell (CBC) analysis on the Sysmex Hematology Analyzer. 3. Interview with the Laboratory Director, on May 31, 2024 at approximately 12:30 pm in the laboratory area confirmed the statements above.
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 Sofia Quidel test kit (Flu and Sars Antigen FIA) package insert and staff interview, the test kit is classified as moderate complexity. The laboratory failed to provide any Quality Control (QC) documentation for the years 2022, 2023 thru the date of inspection. There was no QC performed on dates of patient testing to monitor the accuracy and precision of test performance for the Sofia Quidel RSV and Sars anigen test kit . FINDINGS: 1. The laboratory could not provide documentation that any QC was performed on the Sofia Quidel Flu and Sars Antigen FIA test kit for the years 2022, 2023 and thru May 2024. 2. Interfvew with the Laboratory Director on May 31, 2024, at approximately 1:30 pm in the laboratory confirmed the statement above.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403

	The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on the lack of temperature logs and humidity documents and the failure to provide documentation of open reagent and quality control dates, the Laboratory Director failed to provide overall management and direction of the laboratory. THIS IS A CONDITION LEVEL CITATION Findings: 1. Obervation in the laboratory confirmed there were no the room temperature logs, refrigerator/freezer temperature logs, or opened dates for quality control material. 2. Obervation in the laboratory confirmed there was no documentation of the performance of Quality Control for the Sofia Quidel Flu and SARS antigen FIA test kit. 2. Interview with the Laboratory Director, on 05/31/202, at approximately 1:30 pm, in the laboratory, confirmed the statements above.