Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D1068770	11/21/2025
Name of Provider or Supplier	**Street Address, City, State**	
Dr Soos Pediatrics Pc	102 Bowling Lane, Dublin, 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 Clinical Laboratory Improvement Amendments (CLIA) Recertification Survey was completed on November 21, 2025. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D2130	HEMATOLOGY CFR(s): 493.851(f) (f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: A review of 2023 - 2025 AAB Proficiency Testing Records confirmed that the laboratory failed two out of three (2 out of 3) consecutive proficiency testing challenges. THE FINDINGS INCLUDE: 1. A review of 2023 - 2025 AAB Proficiency Testing Records confirmed that the laboratory received the scores below: - AAB-MLE M1 2025 event - Erythrocyte Count score of 60% - AAB-MLE M3 2025 event - Erythrocyte Count score of 40% 2. An exit interview, with Laboratory Staff, on November 21, 2025, at 1:00pm confirmed that the laboratory failed two out of three (2 out of 3) consecutive proficiency testing challenges.
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: A review of the current Laboratory Procedure Manual confirmed that the procedure manual failed to meet the regulation requirements stated in CLIA Regulation 493.1251 (b). THE FINDINGS INCLUDE: 1. A review of current Laboratory Procedure Manual confirmed that a Down Time Procedure, a Personnel Procedure, a Safety Procedure, and a Critical Values Procedure were not available on the date of survey. 2. An exit interview, with the Laboratory Staff, on November 21, 2025, at 1:00pm confirmed the procedure manual failed to meet the regulation requirements stated in CLIA Regulation 493.1251(b).
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: A review of the current Laboratory Procedure Manual confirmed that the procedure manual was not approved by the Laboratory Director prior to use. THE FINDINGS INCLUDE: 1. A review of current Laboratory Procedure Manual confirmed that the procedure manual was not approved by the Laboratory Director, prior to use, as required by CLIA Regulation 493.1251(d). 2. . An exit interview, with the Laboratory Staff, on November 21, 2025, at 1:00pm confirmed the procedure manual was not approved by the Laboratory Director prior to use.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

	This STANDARD is not met as evidenced by: A review of 2023 - 2025 Maintenance Records, 2023 - 2025 Temperature Records, 2023 - 2025 Personnel Records, 2023 - 2025 Quality Control Records, 2023 - 2023 Quality Assurance Records and current Procedure Manual confirmed that the Laboratory director failed to implement and to provide proper oversight of all laboratory operations. Refer to D2031, D5403, and D6028 for details.
D6028	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(10) (e)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart; This STANDARD is not met as evidenced by: A review of 2023 - 2025 Personnel Records confirmed that the Laboratory Director failed assure the ongoing competency for all individuals who perform clinical laboratory testing. THE FINDINGS INCLUDE: 1. A review of 2023 - 2025 Personnel Records revealed that training and competencies for Testing Personnel were performed by unqualified personnel. 2. An exit interview, with Laboratory Staff, on November 21, 2025, at 1:00pm confirmed that the Laboratory Director failed failed assure the ongoing competency for all individuals who perform clinical laboratory testing.