Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 34D0245583	**(X3) Date Survey Completed** 09/13/2023
Name of Provider or Supplier Sandhills Pediatrics Inc	**Street Address, City, State** 105 Pavilon Way, Southern Pines, NC	
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**
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and review of 2021, 2022, and 2023 CAP (College of American Pathologists) proficiency testing records, the laboratory failed to retain all proficiency testing records for at least two years. Review of the laboratory's "QUALITY ASSURANCE PROGRAM" revealed "... PROFICIENCY TESTING ... The results are maintained for a minimum of two years. ..." The laboratory's policy did not address retention of proficiency testing records other than results. Review of 2021, 2022, and 2023 CAP proficiency testing records revealed the laboratory failed to maintain all records for the following events for at least two years: 1. 2021 MC3-B test event - no signed attestation statement, no report form 2. 2023 NB-B test event - no signed attestation statement, no report form 3. 2023 MC3-A test event - no signed attestation statement 4. 2023 MC3-B test event - no signed attestation statement, no report form 5. 2023 FH3-B test event - no signed attestation statement, no report form, no instrument printouts.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The

	laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of 2021, 2022, and 2023 laboratory records, and interview with testing personnel 9/13/23, the laboratory failed to perform and document quality control each day of patient testing or establish an IQCP (Individualized Quality Control Plan) for the Uricult test. Review of the laboratory's "QUALITY CONTROL POLICIES FOR INDIVIDUAL TEST" procedure revealed "... URICULTS WHEN A NEW SHIPMENT IS RECEIVED, QC will be performed. If different lot numbers, each lot should be tested. ... Uri-Kit has provided a URICULT control kit. Follow package insert to perform QC. Results will be documented on the uricult QC log located in the QC manual. ... When opening a box, you must check all paddles for growth, cracks, and shrinkage. If you find any faults send box to lab coordinator or nursing supervisor for return to manufacturer. Document condition acceptable on insert, sign and store on designated sheet for urine slips. ..." Review of 2021, 2022, and 2023 laboratory records revealed the laboratory had not performed quality control for Uricult each day of patient testing. The laboratory had documented the condition of each lot number upon receipt and had retained documentation of the manufacturer's quality control testing for each lot number of Uricults. There was no documentation available to indicate that the laboratory had established an IQCP. During interview at approximately 1:05 p.m., TP #8 confirmed that the laboratory did not have an IQCP in place for the Uricult tests they perform.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of 2021, 2022, and 2023 laboratory records, and interview with TP (testing personnel) 9/13/23, the laboratory director failed to ensure maintenance of all quality assessment activities to assure the quality of laboratory services provided. Findings: 1. Review of the laboratory's "Calibrations and InterLaboratory Comparisons" procedure revealed "Twice a year the CBC and Neonatal bilirubin will be compared between offices. This will be performed by the lab coordinator or designated staff. ... Results will be evaluated and compared by the laboratory coordinator and the laboratory director. Results should fall within two standard deviations between all the offices. ..." Review of 2021, 2022, and 2023 laboratory records revealed the laboratory had not performed the comparisons as required by the laboratory's policy: a. In February 2021, the laboratory performed split sample testing with the local hospital. There was no documentation of comparisons with the laboratory's two sister laboratories, and there was no documentation of a second comparison in 2021. b. In 2022, the laboratory performed split sample comparisons for neonatal bilirubin in February and November. Split sample comparisons for CBC (complete blood count) were performed in

	February 2022, but there was no documentation that comparisons were performed a second time in 2022. During interview at approximately 1:05 p.m., TP #5, TP #8, and TP #34 stated that the 2021 and 2022 comparisons with the two other locations probably were not performed as they should have been due to staffing changes. They stated the 2023 comparisons have not been performed yet. 2. Review of the laboratory's "QUALITY ASSURANCE PROGRAM" policy revealed "CELL-DYN EMERALD QC will be uploaded monthly to Abbott EQC for review and the lab manager and director will review results for any problems..." Review of 2022 and 2023 hematology records revealed the laboratory installed a new Cell-Dyn hematology analyzer 8/18/22. The laboratory had retained daily quality control printouts, but had not printed summaries for each lot number to monitor for shifts and trends. There was also no documentation that the laboratory participated in the peer review program provided by Abbott.