Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0245583	02/18/2026
Name of Provider or Supplier	**Street Address, City, State**	
Sandhills Pediatrics Inc	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
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of 2024 and 2025 College of American Pathologist (CAP) proficiency testing (PT) records, lack of documentation and interview with technical consultant (TC) 02/18/26, the laboratory failed to review and perform corrective action for unacceptable PT results. Findings: Review of 2024 and 2025 CAP PT records revealed the following unacceptable PT results; 1. Urine Colony Count - Event MC3-A 2024 - Sample MC-01. 2. Neonatal Bilirubin - Event NB-B 2025 - Sample NB-09. 3. Hematology Auto Differential - Event FH3-A 2025 - Sample FH3-01 Hematocrit 4. Hematology Auto Differential - Event FH3-B 2025 - Sample FH3-06 Red Blood Cell Count and Hematocrit. 5. Hematology Auto Differential - Event FH3-C 2025 - Samples; FH3-11 Red Blood Cell Count and Hematocrit, FH3-12 Basophils, FH3-13 Absolute Basophils, FH3-14 Red Blood Cell Count, Hemoglobin, Hematocrit, White Blood Cell Count and Platelet Count. Review of 2024 and 2025 CAP PT records revealed no documentation of a review and corrective action for the unacceptable PT results. Interview with TC at approximately 12:30 p.m. confirmed the laboratory had not reviewed the unacceptable PT results and had not performed correction action for the unacceptable PT results. They stated they were unaware unacceptable PT results required a review and correction action.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) (b) The laboratory must verify the accuracy of the following: (b)(1) Any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or

	scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on review of 2024 and 2025 College of American Pathologist (CAP) proficiency testing (PT) records, lack of documentation and interview with technical consultant (TC) 02/18/26, the laboratory failed to review ungraded PT scores to ensure if corrective action was required. Findings: Review of CAP PT event FH3-A 2025 - Hematology Auto Differential revealed the laboratory received a Code 27 - "Lack of consensus" for Sample FH3-03 - Red Blood Cell Count and Hematocrit. The sample was ungraded due to lack of consensus. Review of 2024 and 2025 PT records revealed no documentation the laboratory had reviewed the participant summary for the ungraded PT results to determine if corrective action was required. Interview with TC at approximately 12:30 p.m. confirmed the laboratory had not reviewed the participant summary for the ungraded PT results. They stated they were unaware that ungraded PT results required any further action by the laboratory.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on surveyor observation, review of quality control (QC) reagent package insert and assay sheet, and interview with Technical Consultant (TC) 02/18/26, the laboratory failed to label QC reagents with new expiration dates after opening. Findings: At approximately 11:00 a.m. surveyor observed on a shelf in a small white refrigerator located in the main laboratory the following QC reagents labeled with an open date of 02/16/26. The 5 vials of QC reagent failed to be labeled with the new expiration date after opening. a. 3 vials of QC reagent; Cell-Dyn 22 Plus Control, Lot #'s L6012, H6012, and N6012. b. 2 vials of QC reagent; Liquichek Pediatric Control, Lot #'s 74961 and 74962. Review of QC reagent asset sheet for the Cell-Dyn 22 Plus Control revealed "8 Consecutive Day Open Vial Stability". Review of QC package insert for the Liquichek Pediatric Control revealed "Storage and Stability...Thawed Open: Once thawed, opened and stored tightly capped...this product will be stable as follows:...Bilirubin (Neonatal) and Bilirubin (Total); 7 days.". Interview with TC at approximately 11:00 a.m. confirmed the 5 vials of QC reagent were not labeled with the new expiration date after opening. They stated the QC reagent vials are always replaced with new vials on Mondays.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to

	verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of 2024 and 2025 calibration verification records, lack of documentation and interview with technical consultant (TC) 02/18/26, the laboratory failed to verify the calibration of the Neonatal Bilirubin at least every 6 months from 11/26/24 to 10/01/25, a period of approximately 10 months. Findings: Review of 2024 and 2025 calibration verification records revealed the laboratory verified the calibration on 11/26/24, 10/01/25 and 01/12/26. Review of 2024 and 2025 calibration verification records revealed no documentation of a verification of calibration for the Neonatal Bilirubin from 11/26/24 thru 10/01/25, a period of approximately 10 months. Interview with TC at approximately 3:00 p.m. confirmed the laboratory had no documentation of a calibration verification for the Neonatal Bilirubin from 11/26 /24 thru 10/01/25. They stated the calibration verification was performed but they were unable to find the documentation.