Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2108236	12/29/2025
Name of Provider or Supplier	**Street Address, City, State**	
24/7 Pediatric Care Centers Inc	1679 Eagle Harbor Parkway Suite B, Fleming Island, FL	

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	An announced CLIA recertification survey was conducted at 24/7 Pediatric Care Center on 12/29/25. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following Conditions were cited: D5200 493. 1230 Condition: General Laboratory Systems D6000 493.1403 Condition: Moderate Complexity Laboratory Director
D2014	TESTING OF PROFICIENCY TESTING SAMPLES (b)(6) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to ensure that instrument printouts for proficiency testing (PT) samples were retained and available for review for two of three testing events in 2025. The findings include: 1. A review of the laboratory's proficiency testing records for 2025 on 12/29/2025 revealed that original instrument printouts were missing for the second and third PT events of the year. 2. During an interview on 12/29/25 at 11:30 AM, the Office Manager confirmed that the laboratory was unable to locate or retrieve the instrument printouts for the second and third events of 2025. .
D2128	HEMATOLOGY CFR(s): 493.851(e)

	(e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to ensure that remedial action and training were performed and documented following an unsatisfactory proficiency testing performance for the white blood cell (WBC) differential in the first proficiency testing event of 2024. The findings include: 1. A review of the laboratory's proficiency testing records from the American Proficiency Institute (API) for the first event of 2024 showed that the laboratory received a score of 67% for the white blood cell differential and a score of 0% for Neutrophils. 2. The laboratory lacked documented evidence that any investigation, corrective action, or remedial training was performed to identify the cause of the failure or to prevent its recurrence. 3. During an interview on 12/29/25 at 11:30 AM, the Administrator confirmed that the laboratory had received the unsatisfactory results but could not provide any remedial action or training for the testing personnel involved.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, 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 general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory failed to ensure the overall quality of its general laboratory systems as evidenced by a systemic failure to evaluate the competency of testing personnel and a pervasive failure to review and evaluate proficiency testing (PT) performance. These collective failures in the quality assessment mechanism across all phases of testing resulted in the laboratory's inability to identify, evaluate, and resolve ongoing technical problems. The findings include: 1. The laboratory failed to follow its written policies and procedures to assess the competency of 80% of its testing personnel (4 out of 5) and ensured the only assessment performed was conducted by an unqualified individual. Refer to D5209. 2. The laboratory failed to review and evaluate proficiency testing results for eight consecutive testing events (2023-2025) to identify and correct performance problems, including a failed result for the white blood cell differential. Refer to D5211. 3. The laboratory failed to establish and follow a general laboratory systems quality assessment (QA) mechanism to review the effectiveness of corrective actions and ensure that systemic problems were communicated to appropriate staff to prevent recurrence. Refer to D5293.

D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review of personnel records and interview, the laboratory failed to follow its established written policies and procedures to ensure that competency assessments were performed for four out of five testing personnel in 2025. The findings include: 1. The laboratory's written procedure titled "Quality Assurance Program" states that "Personnel are evaluated semiannually during the first year of employment or when new methodologies are incorporated. Thereafter, evaluations are performed yearly". 2. The Form CMS-209, Laboratory Personnel Report, obtained at the time of the survey, listed five individuals as Testing Personnel. 3. A review of the personnel competency files on 12/29/25 showed that an annual competency assessment was documented for Testing Person 1 only. 4. The laboratory lacked documentation of competency assessments for Testing Persons 2, 3, 4, and 5 for the 2025 calendar year. 5. During an interview on 12/29/25 at 11:30 AM, the Administrator stated that the assessments were not performed at this laboratory. .
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 record review and staff interview, the laboratory failed to follow its quality assessment procedure by ensuring that proficiency testing results were reviewed and signed by the laboratory director (or qualified designee) for eight consecutive PT events between 2023 and 2025. The findings include: 1. Review of the laboratory ' s proficiency testing records on 12/29/25 revealed that signed reviews of PT results were missing for the following events: 2023: Second and Third events. 2024: First, Second, and Third events. 2025: First, Second, and Third events. 2. The laboratory lacked documented evidence that the Laboratory Director or a qualified Technical Consultant/Supervisor had reviewed and evaluated the scores and participant summary reports for these eight events to identify potential shifts, trends, or necessary corrective actions. 3. During an interview on 12/29/25 at 11:30 AM, the Clinical Manager confirmed that the laboratory did not have a signed review for the eight PT events across 2023, 2024, and 2025. 4. The laboratory policy titled "Quality Assurance Program" states "PT results are reviewed and retained for a period of at least two years." . .
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general

	laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to establish and follow a quality assessment (QA) mechanism to review the effectiveness of corrective actions or revise policies to prevent the recurrence of systemic problems in personnel competency and proficiency testing (PT) evaluation. The findings include: 1. The laboratory failed to follow its written policies for monitoring the competency of 80% of its Testing Personnel (4 out of 5) and allowed an unqualified "Manager" to assess the remaining staff member. The laboratory lacked documented evidence that it reviewed these failures or revised its policies to ensure that a qualified Technical Consultant performed these assessments to prevent recurrence. 2. The laboratory failed to review and evaluate its performance for eight consecutive PT events (2023-2025). There was no evidence of a QA review to identify why these reports were not signed or discussed with staff, nor were there any revised procedures implemented to ensure future PT reports were evaluated as required. 3. Following an unsatisfactory PT score of 67% for the white blood cell differential in 2024, the laboratory failed to document a review of the effectiveness of any remedial actions taken. The recurring nature of the PT review failures (spanning three years) demonstrates that the laboratory ' s QA mechanism was not effective in detecting or resolving these systemic communication and performance problems. 4. During an interview on 12/29 /25 at 11:30 AM, the Practice Manager confirmed the laboratory had not conducted or documented QA reviews related to general laboratory systems to discuss identified problems with the appropriate staff.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to ensure that scheduled preventive maintenance was performed and documented according to the manufacturer ' s instructions for the Sysmex XP-300 hematology analyzer. This failure to adhere to the required schedule occurred for weekly maintenance in 10 of 12 months in 2025 and for monthly maintenance in November 2024 and June 2025. The findings include: 1. The manufacturer's operating instructions for the Sysmex XP-300 hematology analyzer specify a maintenance schedule requiring the laboratory to "clean SRV (sampling valve) tray" on a weekly basis and to "Clean TD (transducer)" and "Clean waste chamber" on a monthly basis. 2. Review of the laboratory's maintenance logs for 2025 identified that the weekly SRV cleaning was not performed in January, March, April, June, July, August, September, October, November, and December. 3. The maintenance logs further showed that the monthly maintenance tasks (cleaning the transducer and waste chamber) were not performed in November 2024 and June 2025. 4. During the interview on 12/29/25 at 11:30 AM, the Office Manager confirmed the maintenance was not documented.
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 record review and interview, the Laboratory Director failed to provide effective direction over the operation of the laboratory as evidenced by pervasive failures in proficiency testing evaluation, personnel oversight, and the maintenance of the laboratory ' s analytical systems. The cumulative effect of these systemic problems resulted in the laboratory ' s inability to ensure the accuracy and reliability of patient test results. The findings include: 1. The Laboratory Director failed to ensure that proficiency testing (PT) reports received were reviewed by the appropriate staff to evaluate performance and identify problems requiring corrective action. Refer to D6018. 2. The Laboratory Director failed to ensure that an approved corrective action plan was followed when proficiency testing results were found to be unsatisfactory. Refer to D6019. 3. The Laboratory Director failed to ensure that policies and procedures were established and followed for monitoring the competency of testing personnel to assure they perform test procedures and report results promptly and proficiently. Refer to D6030.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) (e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratorys performance and to identify any problems that require corrective action; and This STANDARD is not met as evidenced by: Based on record review and staff interview, the Laboratory Director failed to ensure that proficiency testing reports were reviewed and evaluated for eight consecutive testing events across 2023, 2024, and 2025. This failure resulted in the laboratory ' s inability to identify and remediate technical problems, including a failed performance for the white blood cell (WBC) differential. The findings include: 1. A review of the laboratory ' s proficiency testing records on 12/29/25 revealed that signed reviews of PT reports were missing for eight consecutive events, including: 2023: Second and Third events. 2024: First, Second, and Third events. 2025: First, Second, and Third events. 2. The Laboratory Director failed to identify and evaluate an unsatisfactory performance during the first API testing event of 2024, where the laboratory received a score of 67% for the WBC differential and 0% for Neutrophils. Because the report was not reviewed by the director or a qualified designee, the laboratory failed to identify the need for mandatory corrective action (refer to D2128). 3. During an interview on 12/29/25 at 11:30 AM, the Clinical Manager confirmed that the Laboratory Director had not reviewed or signed the participant summary reports for any of the eight events identified above. 4. By failing to review these reports, the Laboratory Director failed to provide effective oversight of the laboratory ' s analytical systems, potentially compromising the accuracy and reliability of patient testing (refer to D5211).
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv)

	(e)(4)(iv) An approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory; This STANDARD is not met as evidenced by: Based on record review and staff interview, the Laboratory Director failed to ensure that a corrective action plan was implemented and followed after the laboratory received unsatisfactory proficiency testing results for the white blood cell (WBC) differential during the first event of 2024. The findings include: 1. A review of the laboratory ' s 2024 proficiency testing records from the American Proficiency Institute (API) showed that for the first event, the laboratory received an unsatisfactory score of 67% for the WBC differential and 0% for Neutrophils. 2. The laboratory lacked any documented evidence to demonstrate that the Laboratory Director had evaluated the failure or ensured that steps were taken to identify and correct the underlying technical problem. 3. During an interview on 12/29/25 at 11:30 AM, the Administrator confirmed that while they were aware of the unsatisfactory PT scores, they had not located a corrective action plan to address the Neutrophil and WBC differential failures. 4. By failing to ensure that a corrective action plan was followed, the Laboratory Director failed to meet their responsibility to ensure the ongoing accuracy and reliability of patient test results following a demonstrated performance failure (refer to D2128).
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to ensure that the laboratory ' s written competency assessment policies were followed for 4 of 5 testing personnel. The Laboratory Director further failed to ensure that the single competency assessment that was performed was conducted by an individual qualified to provide technical oversight. The findings include: 1. A review of the laboratory ' s personnel records for 2025 revealed that 4 out of 5 Testing Personnel (TP2, TP3, TP4, and TP5) lacked any documented competency assessments. 2. Review of the record for the remaining staff member (TP1) identified that a competency assessment had been completed; however, the assessment was performed by a "Manager", who lacked the regulatory qualifications of a Technical Consultant (TC). 3. During the interviews on 12/29/25 at 11:30 AM with the Administrator, Practice Manager, and Clinical Manager, it was confirmed that competency assessments were not available, and the person who signed them did not qualify as a technical consultant.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b)(8) Evaluating the competency of all testing personnel and assuring that the staff

	maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to-- This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to ensure that competency assessments were performed by a qualified Technical Consultant for the one Testing Person who was evaluated in 2024 and 2025. This failure resulted in the laboratory ' s inability to verify the technical accuracy and proficiency of its testing personnel. The findings include: 1. A review of the personnel competency file for Testing Person 1 (TP1) on 12/29/25 identified a completed competency assessment dated 06/18/2024 and 06/02/2025. 2. The assessment for TP1 was performed and signed by the Clinical Manager, an individual who does not meet the regulatory qualifications of a Technical Consultant (TC). 3. During an interview on 12/29/25 at 11:30 AM, the Practice Manager confirmed that the Clinical Manager and herself had been performing competency assessments for the laboratory but acknowledged that they did not possess the required clinical laboratory experience or education to qualify as a Technical Consultant. .