Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2108236	05/29/2019
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
D2005	ENROLLMENT CFR(s): 493.801(a)(4) Authorize the proficiency testing program to release to HHS all data required to-- (i) Determine the laboratory's compliance with this subpart; and (ii) Make PT results available to the public as required in section 353(f)(3)(F) of the Public Health Service Act. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory testing personal, it was determined the laboratory failed to authorize American Proficiency Institute (API) proficiency testing program to release to the agency results for Hematology for 10 events reviewed (2016-2019). Findings included: Review of CASPER Report 0096D CLIA Application and Survey Summary Proficiency Testing Scores for previous 9 testing events showed that no routine proficiency testing scores were found for this provider. Review of API proficiency testing results on 5/29/19 at 9:00 a.m. showed that the laboratory was enrolled in proficiency testing with with successful and unsuccessful scores over the past three years. During an interview with the laboratory testing person #2 at 9:30 a.m. on 5/29/19, she was not aware that results were not being authorized to be released.
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by:

	Based on record review of API (American Proficiency Institute) proficiency test records and interview with testing personal, the laboratory failed to test hematology proficiency samples the same number of times that patient samples are tested for 4 testing events reviewed from 2017-2019. Findings Included: Review of the Complete Blood Count (CBC) Sysmex XP-300 instrument printout records for four API proficiency testing events from December 2017 through March 2019 showed the following: 1. The 2017 Hematology/Coagulation 3rd Event kit had two printouts for each of the five CBC samples tested (HSY-11 - HSY-15). 2. The 2018 Hematology /Coagulation 1st Event kit had two printouts for each of the five CBC samples tested (HSY-01 - HSY-05). 3. The 2018 Hematology/Coagulation 2nd Event kit had two printouts for each of the five CBC samples tested (HSY-06 - HSY-10). 4. The 2019 Hematology/Coagulation 1st Event kit had two printouts for each of the five CBC samples tested (HSY-01 - HSY-05). The tests performed were: White Cell Count, Red Cell Count, Hemoglobin, Hematocrit, Platelet Count, Mean corpuscular volume (MCV), Mean Corpuscular Hemoglobin (MCH), Mean Corpuscular Hemoglobin Concentration (MCHC), Red cell distribution width (RDW), Neutrophils, Lymphocytes, Monocytes. . Interview with testing person #2 on 5/29/19 at 9:37am confirmed hematology proficiency testing had been performed in duplicate.
D2127	HEMATOLOGY CFR(s): 493.851(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on record review of American Proficiency Institute (API) Hematology proficiency testing results and interview with laboratory testing personal, the laboratory failed to submit the proficiency testing results in the specified timeframe for the 3rd Hematology Event in 2018, resulting in a score of 0% for all Hematology analytes. Findings included: Review of the API Hematology proficiency testing results showed that the laboratory had obtained a score of 0% "Failure to Participate" for the following analytes: White Cell Count, Red Cell Count, Hemoglobin, Hematocrit, Platelet Count, Mean corpuscular volume (MCV), Mean Corpuscular Hemoglobin (MCH), Mean Corpuscular Hemoglobin Concentration (MCHC), Red cell distribution width (RDW), Neutrophils, Lymphocytes, and Monocytes. Interview on 5/29/19 at 9:30am with testing person #2 stated that they forgot to send in the API proficiency test results for the 3rd Hematology Event of 2018.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory staff, the facility failed to

	perform Hematology quality control (QC) each time patients were tested for 24 days of 36 patient testing days reviewed in 2019. Findings Included: The review of Hematology QC records on 5/29/19 showed that no QC was performed when patients were tested on the following days: March 1, 2019 - 1 patient , March 5, 2019 - 1 patient, March 8, 2019 - 1 patient, March 11, 2019 - 1 patient, March 17, 2019 - 1 patient, March 18, 2019 - 1 patient, March 20, 2019 - 1 patient, March 27, 2019 - 1 patient, April 10, 2019- 1 patient, April 13, 2019 - 1 patient, April 15, 2019 - 1 patient, April 16, 2019 - 1 patient, April 30, 2019 - 1 patient, May 2, 2019 - 2 patients, May 3, 2019 - 2 patients, May 7, 2019 - 1 patient, May 8, 2019 - 1 patient, May 10, 2019 - 1 patient, May 13, 2019 - 2 patients, May 14, 2019 - 1 patient, May 15, 2019 - 1 patient, May 18, 2019 - 1 patient, May 19, 2019 - 1 patient, and May 20, 2019 - 1 patient. The interview with the laboratory testing person #2 on 5/29/19 at 9:50am confirmed QC was not performed on all day patients were tested in 2019.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory staff, the laboratory failed to perform Hematology quality controls (QC) that were not expired prior to reporting patient results for 1 of 14 days of patient testing in May 2019. Findings Included: Record review of the laboratory's Hematology QC records for May 2019 showed on 5 /9/19 the QC used had lot number 90290710 and expired on 5/8/2019. Two patients were tested. During interview on 5/29/19 at 10:00am the testing personnel #2 confirmed the QC material was expired.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on record review of quarterly Qualtiy Assuarance (QA) documents and interview with testing personel, the laboratory failed to have an effective QA program that identified or corrected problems for quality control for four of four months reviewed (Septermber 2018, March 2019, April 2019 and May 2019). Findings Included: Review of the QA quarterly checklist showed the laboratory did not identify multiple quality control errors 2018-2019. Interview on 5/29/19 at 10:30am with testing person #2 confirmed that the QA checklist did not effectively identify and correct the quality control problems in the laboratory.