Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0306320	05/11/2021
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric Associates Of Auburn	2901 Corporate Park Drive, Opelika, AL	

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
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 the review of the API (American Proficiency Institute) Proficiency Testing (PT) records and an interview with Testing Personnel #1, the surveyor determined the laboratory failed to submit proficiency testing results by the submission deadlines for Hematology testing for Event #1 2021. The laboratory scored zero percent (0%) for this event, due to the failure to timely submit the results. This affected one of seven PT events reviewed by the surveyor. The findings include: 1. A review of the PT records revealed the due date to submit API proficiency testing results for the 1st Event 2021 was 03/31/2021. The API Performance Summary for 1st Event 2021 revealed zero percent (0%) for Hematology Complete Blood Count (CBC) failure to participate. 2. During an interview on 05/11/2021 at 12:15 PM, Testing Personnel #1 confirmed the 1st Event 2021 was not performed due to Testing Personnel #1 being off work for an extended period of time. Also, Testing Personnel #1 confirmed patient testing was still being performed during this time period by other Testing Personnel.
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory

	that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on record review and an interview, the laboratory failed to report SARS-CoV-2 (Severe Acute Respiratory Syndrome Coronovirus 2) test results for negative Coronovirus Disease 2019 (COVID-19) performed on the Quidel Sofia2 SARS Antigen FIA and COVID-19 IgG/IgM Rapid Test Cassette from January 8, 2021 [the date State Surveyors received CMS guidance for surveying on this deficiency] to May 11, 2021. The laboratory failed to report negative results for SARS-CoV-2 for the COVID-19 antigen and antibody test results to the Alabama Department of Public Health. Findings include: 1. A review of SARS-CoV-2 test results revealed patients were tested for SARS-CoV-2 using the Quidel Sofia2 SARS Antigen FIA, starting July 27, 2020 through May 11, 2021. A total of 1815 test were performed (87 Positives and 1728 Negatives) during this time period. A review of SARS-CoV-2 test results revealed patients were tested for SARS-CoV-2 using COVID-19 IgG/IgM Rapid Test Cassette, starting July 27, 2020 through May 11, 2021. A total of 25 test were performed (0 Positives and 25 Negatives) during this time period. 2. During an interview on May 11, 2021 at 10:40 AM, the Clinical Consultant #1 stated positive results were reported to the Alabama ALNBS Base system and negative results were not reported due to lack of manpower.
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 lack of laboratory procedures, and an interview with Testing Personnel #1, the laboratory failed to establish written policies and procedures to assess the competency of the employees. The findings include: 1. A review of the Laboratory Procedures revealed the laboratory had one procedure for performing Complete Blood Counts (CBCs) and no other policies and procedures. 2. During an interview on 05/11 /2021 at 12:20 PM, Testing Personnel #1 confirmed the procedure for performing Complete Blood Counts (CBCs) was the only policy and procedure the laboratory had.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

	This STANDARD is not met as evidenced by: Based on the review of the API (American Proficiency Institute) Proficiency Testing (PT) records and an interview with Testing Personnel #1, the surveyor determined the laboratory failed to submit proficiency testing results by the submission deadlines for Hematology testing for Event #1 2021 and verify the accuracy. The laboratory scored zero percent (0%) for this event, due to the failure to timely submit the results and did not perform a self evaluation when results were received. This affected one of seven PT events reviewed by the surveyor. The findings include: 1. A review of the PT records revealed the due date to submit API proficiency testing results for the 1st Event 2021 was 03/31/2021. The API Performance Summary for 1st Event 2021 revealed zero percent (0%) for Hematology Complete Blood Count (CBC) failure to participate. 2. During an interview on 05/11/2021 at 12:15 PM, Testing Personnel #1 confirmed the 1st Event 2021 was not performed due to Testing Personnel #1 being off work for an extended period of time. Also, Testing Personnel #1 confirmed patient testing was still being performed during this time period by other Testing Personnel and a self evaluation was not performed.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on the lack of the laboratory procedures, review of Quality Assessment (QA) records, and an interview with Testing Personnel #1, the laboratory failed to establish policies and procedures for an ongoing mechanism to monitor, assess, and correct problems identified. This was noted from 01/17/2019 to 05/11/2021. The findings include: 1. A review of the Laboratory Procedures revealed the laboratory had one procedure for performing Complete Blood Counts (CBCs) and no other policies and procedures. 2. A review of the Quality Assurance (QA) records revealed January 2019 to December 2019 QA forms covered Safety Policies, Proficiency Testing, and Preanalytic Systems. January 2020 to April 2021 QA forms covered Specimen Collection, Reporting Specimen Results, and Quality Control. 3. During an interview on 05/11/2021 at 1:50 PM, Testing Personnel #1 confirmed the Quality Assurance forms did not include all the practices/issues related to: Patient Confidentiality, Specimen identification and integrity, Complaint investigations, Communications, Personnel competency, and Proficiency testing performance. Testing Personnel #1 also confirmed the laboratory did not have an established procedure for QA.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document 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 a review of the Hematology Cell Dyn Emerald maintenance records, a

	review of the Cell-Dyn Emerald Operator's Manual, and an interview with Testing Personnel #1, the laboratory failed to document monthly maintenance. This was noted on 12 months out of 29 months for monthly maintenance reviewed by the surveyor. Also, for semi-annual maintenance this was noted from the previous survey 01/17 /2019 to 05/11/2021. The findings include: 1. A review of the Hematology maintenance records revealed that January 2019, February 2019, February 2020 - June 2020, August 2020, September 2020, December 2020, February 2021, and March 2021 the monthly cleaning was not documented on the Maintenance log. A review of the Hematology maintenance records also revealed the semi-annual maintenance was not documented from the pervious survey 01/17/2019 to 05/11/2021. 2. A review of the Cell-Dyn Emerald Operator's Manual revealed in section 9 page 9-11 under Monthly Maintenance the procedure for Bleach Cleaning to be performed monthly. A review of the Cell-Dyn Emerald Operator's Manual revealed in section 9 page 9-13 under Semi-Annual Maintenance the procedure for Lubricating the Pistons to be performed every six months. 3. During an interview on 05/11/2021 at 2:15 PM, Testing Personnel #1 confirmed monthly and semi-annual maintenance was not documented for the timeframe mention above.
D6017	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(ii) 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)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program. This STANDARD is not met as evidenced by: Based on the review of the API (American Proficiency Institute) Proficiency Testing (PT) records and an interview with Testing Personnel #1, the surveyor determined the Laboratory Director failed to ensure test results were submitted to API for grading for Hematology testing for Event #1 2021. The laboratory scored zero percent (0%) for this event, due to the failure to timely submit the results and did not perform a self evaulation when results were received. This affected one of seven PT events reviewed by the surveyor. The findings include: Refer to D2127.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on a review of personnel evaluation records and an interview with Testing Personnel #1, the Technical Consultant failed to assure annual evaluations were performed by a qualified personnel for Hematology Complete Blood Count (CBC). This was noted on two out of five employees since the previous survey, conducted 1 /17/2019. The findings include: 1. A review of the personnel records revealed that Testing Personnel #2 and # 3 had annual evaluations performed on 01/11/2019, 01/17

	/2020, and 10/13/2020. These evaluations were performed and reviewed by Testing Personnel #1, except Testing Personnel #2's evaluation on 01/17/2020 was not reviewed, as evidenced by lack of signature. 2. During an interview on 05/11/2021 at 11:40 AM, Testing Personnel #1 confirmed the above findings, and the Technical Consultant responsibilities were not delegated to Testing Personnel #1.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on a review of personnel records and an interview with Testing Personnel #1, the laboratory failed to have a diploma on file for Testing Personnel #4. This affected one of two new testing personnel reviewed by the surveyor. The findings include: 1. A review of personnel records revealed that Testing Personnel #4 had no education records on file. 2. During an interview on 05/11/2021 at 02:45 PM, Testing Personnel #1 confirmed the above finding.