Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0675960	03/15/2022
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric Associates Llpc	111 Medical Drive, Palestine, TX	

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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. .
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on the review of the laboratory's policy, American Proficiency Institute (API) proficiency records from 2019-2021, Laboratory personnel report, and confirmed in an interview found the laboratory failed to test the proficiency samples by personnel who routinely perform the testing in the laboratory. The findings were: 1. Review of the laboratory's policy titled Proficiency Testing revealed under General Guidelines, "... Testing of proficiency samples should be rotated among all laboratory staff performing patient testing...." 2. Review of American Proficiency Institute (API) proficiency records from 2019-2021 revealed eight of nine events were tested by the same TP#3. 2019 1st event 2019 2nd event 2019 3rd event 2020 1st event 2020 3rd event 2021 1st event 2021 2nd event 2021 3rd event 3. Review of Laboratory Personnel Report signed by the LD on 3/14/2022 revealed the laboratory has eight TPs. 4. An interview with the practice manager and TP#2 on 3/15/22 at 11:05 am in the breakroom confirmed the above findings. Key: LD=Laboratory Director TP=Testing personnel
D2123	HEMATOLOGY CFR(s): 493.851(c)

	Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on the review of the laboratory's American Proficiency Institute (API) hematology proficiency records from 2019-2021, and confirmed in an interview found the laboratory failed to participate in one of nine hematology testing event: 2020 hematology/Coagulation 2nd event. This failure to participate in the testing event resulted in a score of 0% for all analytes in the testing event. The findings were: 1. Review of American Proficiency Institute (API) hematology proficiency performance summary from 2019-2021 revealed the laboratory failed to participate 2020 hematology/coagulation 2nd event. 2. An interview with the practice manager and TP#2 on 3/15/22 at 11:05 am in the breakroom confirmed the above findings. Key: TP=Testing personnel
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on the review of the laboratory's policy, the laboratory's records, validation records, and confirmed in an interview found the laboratory failed to validate three of five performance specifications before reporting patient test results on one of one Sysmex XP300 hematology instrument. The findings were: 1. Review of the laboratory's policy titled Evaluation of Test Methods, signed by LD on 6/18/21, revealed under Quantitative Test Method, "The laboratory will verify the following manufacturer's stated performance specifications provided in the package insert before reporting patient results: Precision Accuracy Reportable range (Linearity study) Reference range Method comparison" 2. Review of the laboratory's records revealed the Sysmex XP300 hematology instrumnet (SN#: B5896) was put in use on 7/14 /2020. 3. Review of the laboratory's validation records revealed no documentation of accuracy, precision, and method comparison before reporting patient test results on one of one Sysmex XP300 (SN#:B5896) hematology instrument. 4. An interview with the practice manager and TP#2 on 3/15/22 at 2:30 pm in the breakroom confirmed the above findings. Key: LD=Laboratory Director TP=Testing personnel

D5461	CONTROL PROCEDURES CFR(s): 493.1256(d)(6)(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--Perform control material testing as specified in this paragraph before resuming patient testing when a complete change of reagents is introduced; major preventive maintenance is performed; or any critical part that may influence test performance is replaced. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the review of the laboratory replace reagent history logs from 12/28/20 to 2 /25/22 and confirmed in an interview found the laboratory failed to document a quality control run after a change in a reagent on one of one Sysmex XP-300 hematology instrument for four of 20 days reviewed. The findings were: 1. Review of the replace reagent history logs revealed two reagents are being used on Sysmex XP300 (SN#:B5896). Cellpack Stromatolyser-WH 2. Random review of the replace reagent history logs from 12/28/20 to 2/25/22 revealed four of 20 days reviewed with no documentation of the quality control run after the following reagent change on the Sysmex XP-300 (SN#B4821) hematology analyzer. 12/28/20 at 3:23 pm Stromatolyser-WH Lot#Y0001 Exp 1/9/21 04/09/21 at 12:22 pm Stromatolyser-WH Lot#Y1001 Exp 2/26/22 05/07/21 at 9:50 am Cellpack Lot#Y0125 Exp 6/10/22 08/09 /21 at 2:21 pm Stromatolyser-WH Lot#Y1001 Exp 2/26/22 3. Review of the patient test records for the above date revealed the laboratory performed four patient testing after the reagent change above with no documentation of the quality control run. 12/28 /20 at 3:24 pm Patient ID: 26789 04/09/21 at 1:53 pm Patient ID: 55409 05/07/21 at 2: 42 pm Patient ID: 55798 08/09/21 at 2:38 pm Patient ID: 55085 4. An interview with the practice manager and TP#2 on 3/15/22 at 11:50 am in the breakroom confirmed the above findings. Key: TP=Testing personnel
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) 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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on the review of the laboratory's records, the laboratory's validation records and confirmed in an interview found the LD failed to ensure the testing system validated for three of five analytical test performance specifications before reporting patient test results for one of one Sysmex XP300 hematology instrument. The findings were: 1. Review of the laboratory's records revealed the Sysmex XP300 hematology instrument (SN#: B5896) was put in use on 7/14/2020. 2. Review of the laboratory's validation records revealed LD failed to ensure the performance specifications of accuracy, precision, and method comparison validation completed before reporting

	patient test results on one of one Sysmex XP300 (SN#:B5896) hematology instrument. 3. An interview with the practice manager and TP#2 on 3/15/22 at 2:30 pm in the breakroom confirmed the above findings. Key: LD=Laboratory Director TP=Testing personnel