Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0670712	09/18/2018
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric Associates At Ridge Road	1200 East Ridge Road # 12, Mcallen, 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	The laboratory was found to be out of compliance based on the following CONDITION LEVEL DEFICIENCIES: D5400 - 42 C.F.R. 493.1250 Condition: Analytic systems; D6000 - 42 C.F.R. 493.1403 Condition: Lab Director, moderate complexity D6063 - 42 C.F.R. 493.1412 Condition: Testing Personnel; moderate complexity Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representative was given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, 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 analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of laboratory policy, review of manufacturer's instructions, review of quality control records, review of maintenance records, review of patient reports, and confirmed in interview of facility personnel, the laboratory failed to monitor the quality of its analytic systems as evidence by: 1. The laboratory failed to follow the

	manufacturer's instructions to ensure flags are resolved prior to their release to the healthcare provider (refer to D5411). 2. The laboratory failed to perform weekly maintenance according to the manufacturer's instructions (refer to D5429). 3. The laboratory failed to evaluate quality control in order to detect errors over time (refer to D5441).
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, review of laboratory policies, review of patient test results, and staff interview, it was revealed that the laboratory failed to provide documentation of following manufacturer's instructions to ensure CBC (complete blood count) samples with flags are verified prior to release to the healthcare provider. The findings were: 1. This is a repeat deficiency from the survey performed on August 24, 2016. 2. Review of the laboratory's policy titled, "Sysmex XP-300" (no approval date) stated, "Policy: CBCs displaying flag(s) will be verified prior to their release to the healthcare provider." 3. A review of the manufacturer's instructions for the Sysmex 300 (Code No. AU553517, Revised, July 2013) Section 8.3 "Histogram flags" states: "Flag AG - Presence of nucleated red blood cells, effects of fragmented red blood cells, increase of large platelets, platelet aggregation or agglutination, precipitation of fibrin, etc. Correction (reference): a. Check smear, etc. 4. A random review of patient results from September 2018 revealed the following patient test results failed to have documentation of any verification of flags prior to releasing the results to the healthcare provider: Date ID Flag 09-05-2018 201809050002 AG 09-05-2018 201809050004 AG 09-05-2018 201809050015 AG 09-05-2018 201809050020 AG 09-05-2018 201809050021 AG 09-05-2018 201809050022 AG 09-05-2018 201809050023 AG 09-05-2018 201809050026 AG 09-05-2018 201809050010 AG 09-06-2018 201809060002 AG 09-06-2018 201809060006 AG 09-06-2018 201809060011 AG 09-06-2018 201809060013 AG 09-06-2018 201809060014 AG 09-06-2018 201809060021 AG 09-06-2018 201809060023 AG 09-07-2018 201809070008 AG 09-07-2018 201809070009 AG 09-07-2018 201809100011 AG 09-07-2018 201809070014 AG 09-10-2018 201809100005 AG 09-10-2018 201809100013 AG 09-11-2018 201809110001 AG 09-11-2018 201809110007 AG 09-11-2018 201809110008 AG 09-12-2018 201809120001 AG 09-12-2018 201809120002 AG 09-12-2018 201809120003 AG 09-12-2018 201809120004 AG 09-12-2018 201809120005 AG 09-12-2018 201809120009 AG 09-13-2018 201809130012 AG 09-14-2018 201809140026 AG 09-17-2018 201809170003 AG 09-17-2018 201809170016 AG 09-17-2018 201809170017 AG 09-17-2018 201809170018 AG 09-17-2018 201809170020 AG 5. An interview with the technical consultant and the primary testing person on 09/18 /2018 at 1100 hours in the laboratory confirmed the findings.
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 review of laboratory job descriptions, review of instrument manufacturer's instructions, review of the laboratory's maintenance records, and confirmed in interview of facility personnel, the laboratory failed to provide documentation of performing weekly maintenance as defined by the manufacturer for the Sysmex XP 300 hematology analyzer. The findings included: 1. Review of the laboratory's job description for "Laboratorian" approved by the laboratory director with no date, stated, "The laboratorian is responsible of guaranteeing the test equipment is functional and maintained according to the maintenance schedules indicated by the manufacturer." 2. Review of the manufacturer's instructions for Sysmex XP 300 (Code No. AU553517) under the Cleaning and Maintenance section it stated, "Weekly: Clean SRV tray." 3. Review of maintenance records from January 2017 to August 2018 revealed the following occurrences when weekly maintenance was not documented as performed: July 2017 - week 3 July 2017 - week 4 August 2017 - week 4 October 2017 - week 3 October 2017 - week 4 August 2018 - week 2 August 2018 - week 4 4. An interview with testing personnel one (as listed on Form CMS-209) on 09/18/2018 at 14:30 hours in the office confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of the laboratory's quality control records, and confirmed in interview of facility personnel, the laboratory failed to monitor quality control over time. The findings were: 1. Review of the laboratory's policy titled, "The Quality Assurance Plan" (no approval date) stated, "Our laboratory uses and documents the use of an external quality control system to verify the performance and quality of the results generated." 2. The laboratory's policy did not address how to monitor quality control over time in order to detect errors over time. 2. Review of the laboratory's quality control records from July 2017 to August 2018 revealed the following lot numbers when quality control was not evaluated to determine if errors over time were detected: 708807 (expiration date: 07-05-2017) 717207 (expiration date: 09-27-2017) 725607 (expiration date: 12-20-2017) 4. An interview with the technical consultant on 09/18/2019 at 13:25 hours in the office confirmed the findings.

D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of laboratory records, review of instrument print outs, review of patient charts, and confirmed in staff interview, it was revealed the laboratory failed to have a policy in place to periodically verify the accuracy of the laboratory's LIS (laboratory information system). The findings were: 1. This is a repeat deficiency from the survey performed on August 24, 2016. 2. On September 18, 2018 at 15:00 hours in the office, the laboratory was asked to provide documentation of its periodic review of laboratory's LIS to ensure its accuracy. No records were made available for review. 3. Random review of patient printouts and patient charts revealed that when a patient had a platelet flag of "AG", testing persons would invalidate results on the printout, but the LIS report would still contain the result. There was no indication on the LIS report that the result had a flag. 3. An interview with the technical consultant on 09/18/2018 at 15:00 hours in the office confirmed the findings.
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 a review of proficiency testing records, review of manufacturer's instructions, review of the laboratory's quality control records, quality assessment records, review of patient test records, and staff interview, it was revealed that the laboratory director failed to provide overall management and direction of the laboratory services (refer to D6016, D6019, D6020, and D6029)
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

	This STANDARD is not met as evidenced by: Based on review of proficiency testing records and confirmed in interview of facility personnel, the laboratory director failed to ensure proficiency testing is performed as required. The findings were: 1. Review of the laboratory's American Association of Bioanalysts (AAB) proficiency testing records for 2017 (Non-Chemistry Quarter 3) revealed the laboratory documented the following: Combo Throat-Urine Specimen 3 Laboratory Comment: "There was no growth on the initial specimen. Asked for replacement specimen and still there was no growth - unable to perform testing." 2. Review of the AAB Data Summary for 2017 (Non-Chemistry Quarter 3) revealed the correct respons to Specimen 3 was "949 - No aerobic growth." The laboratory failed to identify that there was not a proficiency sample problem. 3. Review of the laboratory's AAB proficiency testing records for 2018 (Non-Chemistry Quarter 2) revealed the laboratory documented the following: Combo Throat-Urine Specimen 3 Laboratory Comment: "Unable to perform testing - no growth - too late for replacement specimen." 4. Review of the AAB DAta Summary for 2018 (Non-Chemistry Quarter 2) revealed the correct response to Specimen 3 from AAB was "949 - no aerobic growth." The laboratory failed to identify that there was not a proficiency sample problem. 5. An interview with the technical consultant on September 17, 2018 at 15:30 hours in the office confirmed the findings.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(iv) Ensure that 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 review of the laboratory's American Association of Bioanalysts (AAB) proficiency testing records from 2016 (event 3), 2017 (evetns 1, 2, and 3), and 2018 (events 1 and 2), and confirmed in interview of facility personnel, the laboratory director failed to ensure corrective action was completed when an unacceptable score was received on proficiency testing (PT) event. The findings were: 1. Review of the laboratory's AAB records for Non-Chemistry 2017 (event 1) revealed the laboratory received a score of "0" for specimen COMB T-U 3. 2. Review of the laboratory's submitted result was, "No aerobic Growth." 3. Review of the Patient Data Summary for 2017 (Non-Chemistry-event 1) revealed the correct response to extent the laboratory would result was, "Aerobe found." 4. As corrective action for the event the laboratory stated, "No growth in our lab." No other corrective action was performed. 5. An interview with the technical consultant on September 17, 2018 at 15:00 hours in the office confirmed the findings.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policy manual, quality control records and staff interview, it was revealed that the laboratory director failed to ensure that the quality control program was established and followed to ensure the quality of services provided. (refer to D5441)
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS-209, the laboratory's personnel records, and confirmed in interview of facility personnel, the laboratory director failed to ensure each testing person had the appropriate education and training to perform moderate complexity testing. The findings were: 1. Review of the laboratory's submitted Form CMS-209, approved by the laboratory director on September 17, 2018 revealed the laboratory identified 4 testing persons. 2. Review of the laboratory's personnel records revealed there were no education or training records on file for testing personnel one (as listed on Form CMS-209). 3. Review of the personnel records for testing personnel one (as listed on Form CMS 209) revealed she did not have documentation of a minimum of a high school diploma as required to perform moderate complexity testing. The records provided were for a medical assistant certificate and a background check. 4. An interview with the technical consultant on 09/18/2018 at 0930 hours in the office confirmed the findings.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of education to qualify 2 of 4 testing personnel (refer to D6065).
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 review of the laboratory's submitted Form CMS 209, review of laboratory policy, review of the laboratory's personnel files, and staff interview, it was revealed the laboratory failed to have documentation of education to qualify 1 of 4 testing personnel to perform moderate complexity testing. The findings were: 1. Review of the laboratory's policy titled, "Testing Personnel" approved by the laboratory director with no date, stated, "Must have earned a high school diploma or equivalent." 2. A review of the laboratory's submitted Form CMS 209 (signed by the laboratory director on 09/17/2018) revealed the laboratory identified 4 testing personnel. 3. A review of the laboratory's personnel records revealed 1 of 4 testing personnel did not have documentation of education to qualify them to perform moderate complexity testing. 4. Review of the personnel records for testing personnel one (as listed on Form CMS 209) revealed she did not have documentation of a minimum of a high school diploma as required to perform moderate complexity testing. The records provided were for a medical assistant certificate and a background check. 5. An interview with the technical consultant on 09/18/2018 at 0930 hours in the office confirmed the findings.