Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0670712	09/27/2022
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
D3033	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)(i) In addition, the laboratory must retain records of test system performance specifications that the laboratory establishes or verifies under 493.1253 for the period of time the laboratory uses the test system but no less than 2 years. This STANDARD is not met as evidenced by: Based on surveyor observation, review of laboratory records and confirmed in interview of laboratory personnel, the laboratory failed to retain the patient normal range verification for 1 of 1 Sysmex XN-330 hematology analyzer studies for the life of the instrument but no less than two years. The findings included: 1. Surveyor observation made on September 27, 2022 found one Sysmex XN-330 hematology analyzer in use. 2. Review of the laboratory's records found the laboratory failed to retain the patient normal range study portion of the verification study for the life of the instrument but no less than two years. 3. The findings were confirmed in interview with the technical consultant on September 27, 2022 at 11:00 hours in the office.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic 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 analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of laboratory policies, review of patient test results, and staff

	interview, it was revealed that the laboratory's quality assurance policy failed to identify and correct when CBC (complete blood count) samples with flags are released to the healthcare provider prior to the flags being resolved for 10 of 10 patient results reviewed from September 1, 2022 to September 22, 2022. The findings included: 1. Review of the laboratory's "Quality Assurance Plan" not signed or dated by the laboratory director stated, "1. Evaluate the effectiveness of our written policies and procedures. 2. Identify problems in our laboratory and apply corrective actions. 3. Assure that accurate and reliable test results are obtained and reporting to the physician in a timely manner. 4. Assure the laboratory personnel are adequately trained and their performance is periodically evaluated. 5. Revise our laboratory policies and procedures whenever necessary ..." 2. Review of the laboratory's policy titled, "Sysmex XP-300" signed by the laboratory director with no approval date stated, "It will be the policy of this laboratory to return [SIC] flagged CBC results. If the second run still shows flags, then lab will evaluate flagged differentials according to the procedures in the unit's operator manual. See that the sample requirements are met, that the unit is in good working order, and that the testing procedure is correctly followed. Sometimes the flags will disappear when the sample is allowed to equilibrate at room temperature for 15 to 20 minutes, or by re-drawing the patient. If the flags disappear, then report that result. If the flags persist, follow the manufacturer's instructions." 3. Based on random review of records from September 1, 2022 to September 22, 2022 the following 10 of 10 patient CBC results were released to the healthcare provider prior to abnormal flag resolution. Sample Number: 202209060023 Test Date: 09-06-2022 Flag: Abnormal Platelet Distribution Sample Number: 202209090022 Test Date: 09-09-2022 Flag: White Blood Cell Abnormal Scattergram, Lymphocytosis, Monocytosis, Blasts/Abnormal Lymphocytes Sample Number: 202209120020 Test Date: 09-12-2022 Flag: Lymphocytosis, Blasts /Abnormal Lymphocytosis Sample Number: 202209120029 Test Date: 09-12-2022 Flag: Platelet Clumps? Sample Number: 202209100010 Test Date: 09-19-2022 Flag: Atypical Lymphocytes Sample Number: 202209200014 Test Date: 09-20-2022 Flag; Left Shift? Sample Number: 202209200020 Test Date: 09-20-2022 Flag: Lymphocytosis, Blasts/Abnormal Lymphocytes Sample Number: 2022209210019 Test Date: 09-21-2022 Flag: White Blood Cell Scattergram, Monocytosis, Atypical Lymphocytes Sample Number: 202209220017 Test Date: 09-22-2022 Flag: Lymphocytosis, Blasts/Abnormal Lymphocytes? Sample Number: 202209220024 Test Date: 09-22-2022 Flag: Atypical Lymphocytes? 4. The laboratory was asked to provided documentation of the quality assurance plan identifying and correcting when abnormal patient results were provided to the healthcare provider. No documentation was provided. 5. An interview with the technical consultant and the primary testing person on 09/27/2022 at 1030 hours in the office confirmed the findings.
D6021	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 quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of laboratory policies, review of patient test results, and staff

	interview, the laboratory director failed to ensure the laboratory's quality assurance plan is maintained (refer to D5793).