Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0877450	02/14/2018
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric Affiliates, Pa	400 Madison Ave, Lakewood, NJ	

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
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 surveyor review of Performance Specifications (PS) records and interview with the Nurse Manager (NM), the laboratory failed to verify accuracy and precision on Hematology tests performed on the Beckman AcT 2 Differential (Diff) analyzer before reporting patient test results from 12/6/16 to the date of survey. The NM confirmed on 2/14/18 at 10:50 am PS were not done.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on surveyor review of the Final Report (FR) and interview with the Nurse

	Manager (NM), the laboratory failed to include the Normal Reference Intervals (NRI) for Urine Culture tests from 12/1/15 to the date of survey. The NM confirmed on 2/14 /18 at 1:55 pm that the laboratory failed to include the NRI on the FR.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on surveyor review of the Performance Specification (PS) records and interview with the Nurse Manager (NM), the Laboratory Director (LD) failed to ensure that the PS procedure performed on the Beckman AcT 2 Differential (Diff) analyzer was adequate from 12/6/16 to the date of survey. The finding includes: 1. The LD did not review and sign the Reference Range verification record. 2. The NM confirmed on 2/14/18 at 11:15 am that the PS record was not reviewed.