Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0877722	03/05/2019
Name of Provider or Supplier	**Street Address, City, State**	
Comprehensive Pediatric Care Pc	119 Prospect Street, Ridgewood, 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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual and interview with the Technical Consultant (TC), the laboratory failed to establish a procedure for imminently life-threatening test results, or panic or alert values for tests run on the Horiba Micros 60 analyzer at the time of the survey. The TC confirmed on 3/5/19 at 11:10 am that the laboratory did not establish the above procedure.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)

	(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with the Technical Consultant (TC), the laboratory failed to take Corrective Action (CA) when QC run on the Horiba Micros 60 analyzer was out of range from 2/8/18 to the date of the survey. The findings include: 1. A review of the QC records revealed the Normal (N) and High (H) control were out of range as follows: a. 2/8/18 - White Blood Cell Count (WBC) . b. 1/30/19 - Hemoglobin (HGB) and Red Blood Cells (RBC) c. 1/31 /19 - HGB and RBC 2. There was no documented evidence CA was taken. 3. Approximately ten patients per day were run and reported. 4. The TC confirmed on 3/5 /19 at 10:50 am that corrective action on failed QC was not performed.