Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0937556	01/31/2018
Name of Provider or Supplier	**Street Address, City, State**	
Abc Pediatrics Pc	735 Glynn Street, South, Fayetteville, GA	

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	Based on an Initial CLIA Survey performed on January 31, 2018 this facility was found to be non- compliant with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of proficiency test (PT) records and interview with the laboratory director (LD) , the LD failed to attest that PT samples were tested in the same manner as patient specimens. Findings include: 1. Review of the 2017 PT attestation statements revealed the LD did not sign the events of A & C. 2. Interview with the LD on 1/31/18 at approximately 330 PM in the back office, confirmed she did not sign the attestation forms mentioned.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of the procedure manual (SOP), lab documents, and an interview

	with the lab director (LD), the lab failed to establish and follow a written quality assurance (QA) plan to encompass and asses pre-analytical, analytical, and post analytical systems. Findings include: 1. Review of the SOP revealed no written QA plan to ensure quality patient results. 1. Review of the laboratory's records revealed no documentation of how the lab monitors, assesses, or when indicated, correct problems identified. 2. Interview with the LD on January 31, 2018 at 3:30 PM in the back office confirmed the laboratory did not have or follow a written QA plan.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on calibration document review and staff interview, the lab failed to calibrate the Cell-Dyn Emerald analyzer every six (6) months as required by the manufacturer. Findings include: 1. Review of calibration data revealed the Emerald was calibrated March 2016, October 2016 (a seven (7) month span); March 2017 (a 5 month span); and November 2017 (a 8 month span). 2. Interview with testing personnel #3 (CMS 209 form) on 1/31/18 at approximately 3 PM in the back office, confirmed the time spans.
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 document review and interview with the lab director (LD), the LD failed to ensure the lab was documenting corrective action plan when proficiency testing (PT) results are found to be unacceptable or unsatisfactory. Findings include: 1. Review of the 2017 PT attestation statements revealed the lab did not document corrective actions for failed results on 2017 PT events B & C (red blood cell score of 60 % for event B and red blood cell, white blood cell, hemoglobin, and hematocrit score of 60 % for event C). 2. Interview with the LD on 1/31/18 at approximately 330 PM in the back office, confirmed she did not sign the attestation forms mentioned.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of testing personnel (TP) documents and staff interview , the technical consultant failed to perform annual competency on all testing personnel. Findings include: 1. Review of testing personnel (TP) documents revealed 5 of 6 TP competency evaluations were performed by non-qualified personnel. 2. Testing personnel #3 (CMS 209 form) was the only TP evaluated by qualified personnel (LD). TP#3 evaluated the other 5 personnel. 3. An interview with TP #3 and the Lab director (LD) on 1/31/18 at approximately 3:20 PM in the back office, confirmed the TC did not perform annual competency on all TP.