Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D0236407	05/30/2019
Name of Provider or Supplier	**Street Address, City, State**	
Upc-Pediatrics Associates	7 Chenoweth Drive Ste A, Bridgeport, WV	

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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of proficiency testing records and interview with testing personnel, the laboratory failed to ensure proficiency testing was rotated among all qualified testing personnel. Findings: 1. Review of proficiency testing attestation statements for event 3 of 2017, events 1, 2, and 3 of 2018, and event 1 of 2019 found that proficiency testing has only been performed by two of the five testing personnel (testing personnel 1 and 2). 2. Interview with Testing Personnel #1 (TP1) on 5/30/2019 at approximately 12:30PM confirmed that only two personnel have been performing proficiency testing.
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on a tour of the laboratory and interview with testing personnel, the laboratory failed to provide the necessary personal protective equipment (PPE) to guard the testing personnel from exposure to biohazardous materials. Findings: 1. A tour of the laboratory area found that there were no lab coats, face shields, or splash guards

	available to protect from splashing or aerosols when opening sample containers. 2. Interview with TP1 on 5/30/2019 at approximately 11:25AM confirmed that none of the required PPE was available or used.
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 review of the laboratory's procedure manual and interview with testing personnel, the laboratory failed to establish or document policies or procedures relating to the testing menu as required in (b)(1), (b)(9), (b)(13), and (b)(14). Findings: 1. The procedure manual did not meet all requirements under (b)(1). a. No policy or procedure was found for specimen labeling. b. No policy or procedure was found for specimen rejection guidelines. c. No policy or procedure was found for specimen referral. 2. The procedure manual did not meet all requirements under (b)(9). a. The manufacturer's instructions, in regard to flagged specimens, states that "If any flag appears, review the results according to your laboratory ' s protocol." A protocol for reviewing flagged results could not be found. b. Interview with TP1 on 5/30/2019 at approximately 11:45AM determined that "results [are] released with flags as long as there is a number." 3. The procedure manual did not meet all requirements under (b)(13). a. No policy or procedure was found for reporting patient results, including critical result notification. 4. The procedure manual did not meet all requirements under (b)(14). a. No policy or procedure was found for courses of action to take during a downtime or inoperable conditions in the testing system. 5. Interview with TP1 on 5/30/2019 at approximately 11:45AM confirmed the findings.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by:

	Based on review of the laboratory's procedure manual, the laboratory director did not sign or date all procedures or changes in procedure. Findings: 1. The only signed and dated procedure was from 2001; the procedure had been discontinued. 2. Dates that procedures were put into use and dates of discontinuation were not present. 3. The manufacturer's instructions were being used for each testing system or kit. None of the manufacturer's instructions were signed or dated by the laboratory director.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a tour of the laboratory and interview with testing personnel, the laboratory failed to monitor the conditions essential for proper storage of reagents and test system operation. Findings: 1. The Subzero refrigerator that contained hematology quality control materials was being monitored by an NIST-traceable thermometer. However, the calibration for said thermometer had expired on 9/26/2018. 2. There was no monitoring and recording of the room temperature, as required by the Flu, Mono, and Strep package inserts. Each kit requires storage from "2-30 degrees Celsius." TP1 confirmed that the room temperature is not being monitored on 5/30 /2019 at approximately 11:20AM. 3. Two timers were found during the lab tour. Neither had been tested or calibrated to ensure accuracy. Each kit test requires the result to be read within a specified period of time.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on a laboratory tour, the laboratory failed to label all reagents for the AcT-diff hematology instrument with the date of expiration. Findings: 1. The reagent kit, containing a buffered electrolyte solution and lysing reagent, was not dated when opened. Per TP1, there is no log kept for tracking reagent open dates. 2. None of the Coulter 4C ES control vials (3 levels) were dated when put into use. 3. The shutdown diluent inside the instrument was not dated when opened.
D5813	TEST REPORT CFR(s): 493.1291(g)

	The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with testing personnel, the laboratory failed to establish and maintain a critical result reporting policy. Findings: 1. During review of laboratory records, no documentation of critical result notification could be found. Additionally, no policy for critical result notification could be found. 2. Interview with TP1 on 5/30/2019 at approximately 11:45AM confirmed that no critical result notification policy was established and that critical result notification is not documented.
D6011	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(2) 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)(2) and provide a safe environment in which employees are protected from physical, chemical, and biological hazards. This STANDARD is not met as evidenced by: Based on tour of the laboratory, the director failed to ensure the safety of the testing environment. Findings: 1. The laboratory did not have the appropriate and required PPE for the testing personnel. 2. Refer to citation D3011 for more information.
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, the director failed to ensure the PT samples are tested as required. Findings: 1. Review of proficiency testing records demonstrated that PT is not being rotated among all testing personnel. 2. Refer to citation D2007 for more information.
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 the Quality Assessment (QA) plan and interview with testing personnel, the director failed to ensure the establishment and maintenance of the QA program. Findings: 1. The QA policy states that a Systems Assessment Checklist, titled "Form SA-1," will be submitted to the director and reviewed three times per year. Upon review of the QA documents, the SA-1 form was only completed twice in 2018 (January and September). 2. The QA policy states that preanalytic systems shall be reviewed twice per year on the form titled "SA-2." Upon review, no completed SA-2 forms could be found for 2017 or 2018. 3. The QA policy states that the staff will meet twice per year to review all findings and document changes, as needed. No documentation of the biannual meetings could be found. Per interview with TP1 on 5 /30/2019 at approximately 12:49PM, no QA meetings have occurred.
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 personnel records, the director failed to ensure the appropriate education of the testing personnel was documented. Findings: 1. Review of personnel records found no diplomas or transcripts to document the education of 4 of the 5 testing personnel.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, the director failed to ensure an approved procedure manual is available for use by testing personnel. Findings: 1. Refer to citation D5407 for more information.

D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of personnel records, the director failed to assign, in writing, the duties for each testing person. Findings: 1. Review of the personnel records found a Technical Consultant Job Description for each testing person. Each job description was signed and dated by the testing personnel. 2. No job descriptions outlining testing personnel responsbilities could be located for 5 of the 5 current testing personnel.