Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	01D2154250	02/14/2019
Name of Provider or Supplier	**Street Address, City, State**	
Liberty Mountain Pediatrics	4600 Hwy 280 S, Suite 103, Birmingham, AL	

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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of the policies and procedures and an interview with Testing Personnel #1, the surveyor determined the Laboratory Director failed to sign her review and approval of the Horiba ABX Micros 60 Hematology Analyzer Daily Guide in use by the testing personnel for the performance of CBC's (Complete Blood Counts) before patient testing began on 11/1/2018. The findings include: 1. A review of the laboratory policy and procedure manual in "Section 2-CBC" revealed the statement, "See Horiba Hematology Analyzer Daily Guide". 2. A review of the Horiba ABX Micros 60 Hematology Daily Guide revealed no evidence (as indicated by a signature and date) of the Laboratory Director's review and approval of the procedures used by the testing personnel. A review of Hematology records revealed patient CBC testing began on 11/1/2018. 3. During an interview on 2/14/2019 at 11: 10 AM, Testing Personnel #1 reviewed the manuals with the surveyor, and confirmed the above noted findings. .
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 a review of the policies and procedures and an interview with Testing Personnel #1, the surveyor determined the laboratory failed to ensure the Policy and Procedure Manual included a protocol to follow when patients' CBC (Complete Blood Count) results yielded imminent life threatening results or panic values. The laboratory further failed to include requirements for specimen collection, labeling, storage, and criteria for specimen acceptability in their procedures. The findings include: 1. A review of the laboratory policy and procedure manual revealed there was also no protocol to follow when testing personnel obtained imminent life threatening results or panic values. There were also no specimen collection and labeling procedures, nor was the criteria for specimen acceptability specified. 2. During an interview on 2/14/2019 at 11:10 AM, Testing Personnel #1 reviewed the manuals with the surveyor, and confirmed the above noted findings. .
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 reviews of the "Daily Checklist" logs, a review of the Horiba ABX Micros 60 Hematology Daily Guide, and an interview with Testing Personnel (TP) #1, the surveyor determined the laboratory failed to specify acceptable ranges for environmental parameters for the room in which the Hematology analyzer was operated for four months. The findings include: 1. A review the "Daily Checklist" logs (November 2018 thru February 2019) revealed testing personnel documented completion of general laboratory duties along with recording the daily room temperature and humidity, however there were no acceptable ranges specified for these parameters. 2. A review of the Horiba ABX Micros 60 Hematology Daily Guide revealed under, "9. Environmental Precautions", room temperature requirements of 18-32 degrees Centigrade, and humidity requirements of less the 85 percent. 3. During an

	interview on 2/14/2019 at 12:35 PM, the surveyor asked TP #1, what were the acceptable ranges for room temperature and humidity in the Hematology area; TP #1 answered she was not sure. The surveyor then reviewed information in the Horiba ABX Micros 60 Daily Guide, and explained the CLIA requirement to define the acceptable ranges; otherwise there was the potential of environmental parameters exceeding the manufacturer's requirements without corrective actions by the testing personnel. .
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 a review of the installation and validation documentation for the Horiba ABX Micros 60 Hematology analyzer and an interview with the Testing Personnel #1, the surveyor determined the Laboratory Director failed to document (as indicated by signature and date) her review and approval of the initial validation procedures for precision and reportable ranges, as verifying the manufacturer's performance specifications for the analyzer, before patient testing began. The findings include: 1. A review of the installation and validation records for the Horiba ABX Micros 60 Hematology analyzer revealed no documentation of review and approval by the Laboratory Director (as indicated by a signature and date) on the initial verification procedures for precision and reportable ranges performed on 10/17/2018. 2. A review of Hematology records revealed patient CBC (Complete Blood Count) testing on the analyzer began on 11/1/2018. 3. During an interview and review of these records on 2 /14/2019 at 11:10 AM, Testing Personnel #1 confirmed the above noted findings. SURVEYOR ID#32558 Licensure and Certification Surveyor