Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0303212	04/11/2018
Name of Provider or Supplier	**Street Address, City, State**	
Huntsville Pediatric Associates	2004 Airport Road, Huntsville, 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
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 reviews of the installation and validation records and the Procedure manual for the new Beckman Coulter AcT diff 2 Hematology Analyzer, and the hand-written procedure for the Bacteriology "Media QC" (Quality Control), and an interview with Testing Personnel (TP) #1, the laboratory failed to ensure the Laboratory Director documented her review and approval of new procedures with her signature and date before use by the testing personnel. The findings include: 1. A review of the validation and installation records and the Procedure Manual for the AcT diff 2 Hematology analyzer revealed the Laboratory Director's had failed to document her signature and date to indicate her review and approval of the new procedures before patient testing began on 8/31/2016. 2. A review of the hand-written procedure entitled "Media QC" (put in use after the previous survey on 3/30/2016) revealed no review and approval by the Laboratory Director (as indicated by her signature and date). This procedure further failed to specify the acceptable or expected results of the Media QC. 3. During an interview on 4/11/2018 at 2:30 PM, TP #1 was asked if the Laboratory Director had reviewed, dated and signed her approval for the new Hematology analyzer. TP #1 stated the Director looked at the validation documentation, but she did not sign her approval. During a second interview at approximately 4:55 PM, TP #1 was asked if the Laboratory Director had approved the new procedures for the media QC. TP #1 stated she had written the procedure herself (with no education or experience in Microbiology other that plating the Bacteriology cultures) after consultation with the culture media manufacturer. Thus confirming the above noted findings. .

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 reviews of the installation and validation records for the Beckman Coulter (B-C) AcT diff 2 Hematology analyzer, patient results, and an interview with Testing Personnel (TP) #1, the surveyor determined the laboratory failed to ensure a complete validation of the manufacturer's performance specifications, including reportable range, accuracy, and normal reference range verification was performed before patient testing began. The findings include: 1. A review of the installation procedures for the B-C AcT diff 2 Hematology analyzer revealed a calibration, precision (reproducibility) study and three levels of quality controls were performed on 7/11/2016 and on 8/22/2016. The laboratory also ran samples from a Coulter LIN-C Linearity Control kit on 8/22/2016, however there was no documentation the data was analyzed and evaluated to determine the reportable ranges of the analyzer. 2. A further review of the documentation revealed the laboratory ran a correlation study on thirty patients, however there was no documentation the data was analyzed and evaluated to demonstrate the accuracy of the analyzer as stated in the manufacturer's performance specifications. There was also no documentation of the reference range verification for the laboratory's patient population. 3. The validation and installation records for the AcT diff 2 also failed to include the Laboratory Director's signature and date indicating her review and approval of the new procedures before patient testing began. 4. In an interview on 4/11/2018 at 12:10 PM, when asked if the Laboratory Director reviewed, approved and dated the new AcT diff 2 procedures, TP #1 stated the Director looked at the validation documentation, but she did not sign her approval. The surveyor then asked if reference ranges were verified, and whether the reportable range and correlation data had been analyzed and evaluated as verification of the manufacturer's performance specifications; TP #1 stated the records on file were all they had been given by the installation technician. When asked when patient testing began on the new instrument, TP #1 referred to her patient testing records and stated 8/31/2016. Thus the above noted findings were confirmed. .
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on reviews of the quality control (QC) logs and patient results for the Reichert

	Bilirubinometer (used for newborn Bilirubin testing), and an interview with Testing Personnel (TP) #1, the laboratory failed to ensure two levels of Bilirubin QC were performed and documented for two days of patient testing in August 2016. The findings include: 1. A review of the poorly organized Reichert Bilirubinometer QC records revealed testing personnel were required to perform two levels of external Pediatric Bilirubin QC each day of patient testing. However on 8/6 and 8/7/2016 only the Level 1 QC was performed. [Note: The QC sheets in use by the laboratory were divided in half with space at the top of both columns for the QC Levels, lot numbers and expected ranges. However, instead of using the sheets as intended, the laboratory chose to record the values for Level 1 QC on one sheet, and values for Level 2 on another sheet in another section of the binder, which made QC review difficult.] 2. During an interview on 4/11/2018 at 2:30 PM, TP #1 reviewed the QC records and was unable to find results for the Level 2 Bilirubin QC for the above dates. After reviewing the patient results, TP #1 stated one Neonatal Bilirubin was performed on each of these dates. Thus the above noted findings were confirmed. .
D5507	BACTERIOLOGY CFR(s): 493.1261(b)(c) (b) For antimicrobial susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antimicrobial agent(s) before, or concurrent with, initial use, using approved control organisms. (b)(1) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure. (b)(2) The laboratory's zone sizes or minimum inhibitory concentration for control organisms must be within established limits before reporting patient results. (c) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on a review of the Bacteriology Quality Control (QC) records and an interview with Testing Personnel (TP) #1, the surveyor determined the laboratory failed to ensure zone sizes or minimum inhibitory concentration (MIC) for control organisms were within established limits for culture media and antimicrobial discs each day of patient testing in 2016-2018, in the absence of an Individualized Quality Control Plan (IQCP). The findings include: 1. A review of the 2016-2018 Bacteriology QC records revealed the laboratory performed antimicrobial susceptibility (zone sizes or MIC) testing on one gram positive (Staphylococcus aureas) and one gram negative (Escherichia coli) and occasionally on Pseudomonas aeruginosa control organisms, once a week, not every day of patient testing in the absence of an IQCP. 2. During the exit summation and review of the records on 4/11/2018 at 5:20 PM, TP #1 confirmed the laboratory did not have an optional IQCP for tests performed in the Bacteriology specialty. The surveyor explained the previous Equivalent Quality Control (EQC) regulation which allowed weekly MIC QC testing was replaced on 1/1/2016, and the laboratory needed to implement an IQCP if they wished to continue decreased frequency of the antimicrobial susceptibility QC testing (QC performance only once a week instead of each day of patient testing). .
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of quality assurance (QA) records and an interview with Testing Personnel #1, the surveyor determined the laboratory failed to implement effective quality assessment reviews to identify and correct problems identified in the analytical systems. The findings include: 1. A review of quality assurance documentation revealed the laboratory routinely performed monthly QA activities, however the reviews were inadequate to discover and correct problems noted in the following areas: A.) Ensure the Laboratory Director documented her review and approval of all new procedures with her signature and date before use by the testing personnel. (Refer to D5407.) B.) Ensure an analysis of the data generated during the Beckman Coulter AcT diff 2 Hematology analyzer installation was performed and documented to prove the accuracy and reportable ranges of the parameters as stated in the manufacturer's performance specifications; and ensure the Laboratory Director documented and dated her review and approval of the initial procedures verifying performance specifications before patient testing began. (Refer to D5421.) C.) Ensure two levels of QC were performed each day of patient testing. (Refer to D5447.) [Note: The laboratory's mechanism for documenting the QC results for Neonatal Bilirubin, and Mycoplasma made review of the QC records difficult.] D) Ensure the implementation of an optional Individualized Quality Control Plan (IQCP) to allow decreased QC frequency of once a week, or ensure zone sizes or minimum inhibitory concentration (MIC) for control organisms were within established limits for culture media and antimicrobial discs each day of patient testing. (Refer to D5507.) 2. During the exit summation on 4 /11/2018 at approximately 5:20 PM, these concerns were reviewed and confirmed with Testing Personnel #1. .
D6055	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 whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on a review of the personnel records and an interview with Testing Personnel (TP) #1, the surveyor determined the Technical Consultant (also the Laboratory Director) failed to ensure training and competency on the new Beckman Coulter AcT diff 2 was documented for five of five testing personnel before they began patient testing. The findings include: 1. A review of the personnel files revealed TP #1 thru #5 were employed when the new Beckman Coulter AcT diff 2 Hematology analyzer was installed in July 2016. Patient testing on the new instrument began 8/31/2016, however there was no documentation of training and competency available for any of the testing personnel during the survey. 2. In an interview on 4/11/2018 at 12:10 PM, TP #1 was asked if there were any records of training and competency for the testing personnel on the AcT diff 2 before they began patient testing. TP #1 reviewed her records and stated the Beckman Coulter technician had instructed the staff in the operation, however he had not left the laboratory a copy of the training. Thus the

	above noted findings were confirmed. SURVEYOR: Laura T. Williams, BS, MT (ASCP) Licensure and Certification Surveyor