Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0700618	06/27/2019
Name of Provider or Supplier	**Street Address, City, State**	
Northeast Al Pediatrics	104 West Alabama Avenue Suite B, Albertville, 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
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 a review of the 2017 - 2019 API (American Proficiency Institute) proficiency testing (PT) records, personnel records, and an interview with the Laboratory Director, the surveyor determined the laboratory failed to ensure proficiency testing samples were rotated between all personnel who routinely performed moderate complexity Hematology testing on patients. This was noted on seven of seven surveys reviewed. The findings include: 1. A review of API attestation statements revealed the following: A) 2017-Events #1 and #2: performed by a previous testing personnel who resigned in 2017 B) 2017-Event #3 was performed by TP #3 C) 2018-Events #1, #2, and #3; 2019 Event #1 performed by TP #1 None of the surveys were performed by TP #2. 2. A review of the personnel files revealed TP #1 and #2 were full time employees in the clinic (hired 11/7/2017 and 8/14/2017 respectively) and had been qualified to perform moderate complexity Hematology testing since 5/17/2018 (the date of their initial competency evaluations.) 3. During an interview on 6/27/2019 at 12:30 PM, the Laboratory Director confirmed the laboratory had failed to rotate the Hematology proficiency testing among all personnel who routinely performed patient CBC (Complete Blood Count) testing. The surveyor explained the laboratory must ensure all testing personnel included on the CMS-Form 209 (Laboratory Personnel Report) must periodically participate in the performance of proficiency testing. Thus the above noted findings were confirmed. 4. This is a repeat deficiency. .
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 Abbott Cell Dyn Emerald Hematology analyzer, patient records and an interview with the Laboratory Director, 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 Abbott Cell Dyn Emerald Hematology analyzer revealed a calibration, precision (reproducibility) study and three levels of quality controls (QC) were performed on 1/22/2019. The records also included three levels of QC run five times each, and instrument printouts of the "Linearity" also run on 1/22/2019. However, there was no documentation the data was analyzed and evaluated to determine the accuracy and reportable ranges 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. 2. The validation and installation records for the Cell Dyn Emerald also failed to include the Laboratory Director's (or the Technical Consultant's) signature and date indicating review and approval of the new procedures before patient testing began on 1/23/2019. 3. In an interview on 6/27/2019 at 12:30 PM, the Laboratory Director confirmed the above noted findings. .
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 Abbott Cell Dyn Emerald Hematology analyzer and an interview with the Laboratory Director, the Laboratory Director failed to ensure the initial validation procedures were reviewed, approved and signed/dated (by the Laboratory Director and/or the Technical Consultant) as verifying the manufacturer's performance specifications for the analyzer, before patient testing began. The findings include: 1. A review of the Abbott Cell Dyn Emerald's installation documentation revealed no review and approval (as indicated by a signature and date) by the Laboratory Director (or the previous Technical Consultant) of the initial verification procedures performed on 1/22/2019.

	Records revealed patient CBC (Complete Blood Count) testing on this analyzer began on 1/23/2019. 2. In an interview on 6/27/2019 at 12:30 PM, the Laboratory Director confirmed the above noted findings. .
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on a review of personnel listed on Form CMS-209, a review of laboratory processes and procedures, and an interview with the Laboratory Director, the surveyor determined the laboratory failed to fill the position of the Technical Consultant (TC) after the previous TC had left in April 2019. The findings include: 1. During a review of personnel listed on the Form CMS-209 (Laboratory Personnel Report), the surveyor noted the name of the same Technical Consultant included on the CMS-209 for the previous survey on 5/16/2017. 2. During an interview with the Laboratory Director on 6/27/2019 at 12:35 PM, the surveyor reviewed the deficiencies noted so far in the survey process (refer to D5421 and D6066) , and asked who was performing the responsibilities as the TC, and when was their last on-site visit. The Laboratory Director explained the laboratory had not had a TC since "April or May" 2019, and it had been "a while" since the TC had been on site. (He was unsure of the exact dates.) The surveyor then crossed off the TC listed on the form, and explained CLIA regulations required this position to be filled, however the Form CMS-209 should reflect their current staffing, not the previous personnel. The surveyor further stated the laboratory was required to employ a qualified individual with experience to perform the Technical Consultant's oversight responsibilities or a mandatory Condition deficiency had to be cited. .
D6034	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section. This STANDARD is not met as evidenced by: Based on a review of personnel listed on Form CMS-209, a review of laboratory processes and procedures, and an interview with the Laboratory Director, the surveyor determined the laboratory failed to fill the position of the Technical Consultant (TC) after the previous TC had left in April 2019. The findings include: 1. Refer to D6033. .
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii)

	Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. This STANDARD is not met as evidenced by: Based on a review of personnel listed on Form CMS-209 (Laboratory Personnel Report), a review of the personnel files, and an interview with the Testing Personnel (TP) #1 and #2, the surveyor determined the laboratory failed to ensure two of two new testing personnel had documentation of training for moderate complexity testing completed before performing patient testing. The findings include: 1. A review of Form CMS-209 revealed two of the three testing personnel listed had been hired since the previous survey on 5/16/2017. A review of the test menu for this laboratory revealed moderate-complexity testing personnel performed CBC's (Complete Blood Counts) and waived testing. 2. A review of the personnel files revealed TP #1 was hired on 11/7/2017, and TP #2 was hired 8/14/2017. Three generic competency evaluations were included in each of the testing personnel files, however there was no documentation of training in the files for TP #1 or #2, or indication of the scope of their responsibilities in the laboratory. 3. During an interview on 6/27/2019 at 12:20 PM, the surveyor asked TP #1 and #2 about documentation of their initial training in the operation of the Medonic Hematology analyzer (in use in 2017, 2018 and early 2019 until 1/4/2019.) TP #1 stated the generic competency evaluations dated 5/17 /2018 in their files was documentation of their training. The surveyor explained the Laboratory Director or Technical Consultant should document the tests they were trained to perform, and specify the scope of the training (including proficiency in the performance of quality control, proficiency testing, calibrations, maintenance, and trouble-shooting) along with the pre-analytical and post-analytical procedures associated with the testing. TP #1 confirmed the laboratory had not done this. SURVEYOR ID#32558 Licensure and Certification Surveyor