Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0953865	10/16/2018
Name of Provider or Supplier	**Street Address, City, State**	
North Jefferson Pediatrics	934 Grubbs Ave, Gardendale, 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
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on a review of API (American Proficiency Institute) proficiency testing (PT) records for 2016 - 2018, and an interview with Testing Personnel (TP) #1, the surveyor determined the laboratory failed to ensure corrective actions were implemented and documented for proficiency testing scores of less than one hundred percent (%). This affected one of six PT events reviewed by the surveyor. This is a repeat deficiency for the laboratory. The findings included. 1. A review of API proficiency testing records for 2016 (Event #3) - 2018 (Event #2), revealed the laboratory scored 27 % for the White Blood Cell (WBC) Differential, which included zero percent scores for Lymphocytes and Monocytes and an eighty percent score for the Granulocytes. The laboratory scored 80 % for the MCV (Mean Corpuscular Volume) and RDW (Red Cell Distribution Width). 2. The zero percent scores were due to clerical errors by the laboratory staff, upon result submission. The 80 % scores for Granulocytes, RDW and MCV were not evaluated by the laboratory; thus no corrective actions were implemented and documented. 3. In an interview at 1:40 PM on 10/16/18, the surveyor discussed with TP #1 the lack of corrective actions for scores of less than one hundred percent. The surveyor also discussed repeat deficiencies with the testing personnel. When the testing personnel asked the surveyor how to implement and document corrective actions, the surveyor referred the TP to her Technical Consultant and Laboratory Director.
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 a review of the installation records for the Abbott Emerald Cell-Dyn, and interviews with Testing Personnel (TP) #1 and the Laboratory Director (also serves as the Technical Consultant), the surveyor determined the laboratory failed to ensure verification procedures (accuracy, precision, reportable range, and a normal-range study) were performed and approved to ensure the instrument performed according to the manufacturer's specifications. The findings include: 1. A review of the installation records revealed the Abbott Emerald Cell-Dyn was installed in February of 2017. The records included documentation of the calibration, carryover, and simple precision, all of which were signed by the Abbott representative, installation technician. The Laboratory Director had not signed the installation records to indicate his approval of the verification studies. 2. Included in the manual were forms with instructions for "Linearity Study" and "Correlation Study." There was no documentation accuracy and reportable ranges had been performed, evaluated and approved. Nor was there documentation of verification of the manufacturer's reference intervals, which should be appropriate of the laboratory's patient population. 3. On 10/16/18 at 1:40 PM, the surveyor discussed with the Laboratory Director his responsibility to ensure the above mentioned verifications were performed, documented and approved for instrument use in the laboratory. TP #1 was included in the interview.
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 records for the Abbott Emerald Cell-Dyn, and interviews with Testing Personnel (TP) #1 and the Laboratory Director (also serves as the Technical Consultant), the surveyor determined the Laboratory Director failed to ensure verification procedures (accuracy, precision, reportable range, and a normal-range study) were performed and approved to ensure the instrument performed according to the manufacturer's specifications. The findings include: 1. A review of the installation records revealed the Abbott Emerald Cell-Dyn was installed in February of 2017. The records included documentation of the calibration, carryover, and simple precision, all of which were signed by the Abbott representative, installation technician. The Laboratory Director had not signed the installation records to indicate his approval of the verification studies. 2. Included in the manual were forms with instructions for "Linearity Study" and "Correlation Study." There was no

	documentation accuracy and reportable ranges had been performed, evaluated and approved. Nor was there documentation of verification of the manufacturer's reference intervals, which should be appropriate of the laboratory's patient population. 3. On 10 /16/18 at 1:40 PM, the surveyor discussed with the Laboratory Director his responsibility to ensure the above mentioned verifications were performed, documented and approved for instrument use in the laboratory. TP #1 was included in the interview.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on a review of API (American Proficiency Institute) proficiency testing (PT) records for 2018 (Events #1 and #2), and an interview with Testing Personnel (TP) #1, the surveyor determined the Laboratory Director failed to ensure Hematology proficiency testing results for Event #2, 2018 were reviewed and evaluated (self-evaluated) by technical staff to ensure any problems were identified and corrective actions were implemented and documented, if necessary. This affected one of two testing events in 2018, reviewed by the surveyor. The findings include: 1. The laboratory did not submit results for Hematology testing Event #2, 2018 by the submission deadline (7/27/2018), due to instrument (Cell-Dyn Emerald) problems. The laboratory was graded a zero percent by API, due to the laboratory's "Failure to Participate." 2. A review of the PT records for Event #2, 2018 revealed the instrument was serviced by Abbott on 7/30/18, and the proficiency testing was performed on 7/31 /18. The laboratory's documentation included a handwritten note that Abbott was contacted and the results for the event were 100 % (percent), according to the Abbott representative. The note also included instructions for the laboratory to print the data summary for records. The laboratory failed to provide the data summary or result sheets for the surveyor's review. 3. In an interview on 10/16/18 at 1:40 PM, TP #1 recalled the Abbott representative instructing her to print the data summary from on-line. TP #1 confirmed she did not print the data summary for result evaluation, but understood the representative told her the laboratory scored one hundred percent. The surveyor asked TP #1 how did she know the results were within expected ranges. TP #1 only replied because the representative said the results were ok. TP #1 never confirmed the laboratory's results with the expected ranges by API.
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 a review of manuals, provided by the laboratory, and interviews with Testing Personnel (TP) #1 and the Laboratory Director, the surveyor determined the Laboratory Director failed to ensure an approved policy and procedure manual was available to the laboratory staff, to encompass all systems; pre-analytic, analytic and post-analytic. The findings include: 1. For the review of the policies and procedures for the laboratory, TP #1 provided a manual labeled, Procedure Manual, which included instructions of blood collection via fingerstick and venipuncture, a specimen rejection plan, outside lab forms (drop box), PKU procedure, and procedure for improper results; a quality assurance plan; MSDS (Material Safety Data Sheets) manual; Medical Review Policies with ICD 9 codes, manual; OSHA (Occupational Safety Health Administration) manual; and a CLIA manual, which included old correspondences and news letters, a glossary of terms, and another copy of the quality assurance plan. This CLIA manual was not signed (approved) by the Laboratory Director. 2. Also Refer to D5401 (493.1251) from previous survey, dated 11/01/2016. 3. At 11:40 AM on 10/16/18, the surveyor discussed with TP #1 the laboratory being affected by the same concerns as discussed on the previous survey, regarding policies and procedures. The laboratory must have available to all laboratory staff all procedures and policies for the pre-analytic, analytic and post-analytic processes. The laboratory director can delegate to the technical consultant the responsibility of making the procedure manual available, but cannot delegate the responsibility for signing new and revised procedures. The Laboratory Director at this facility also serves as the Technical Consultant. 4. At 1:40 PM on 10/16/18, the surveyor discussed the above noted concerns with the Laboratory Director.
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; This STANDARD is not met as evidenced by: Based on a review of personnel training records, a lack of documentation, the installation manual for the Abbott Cell-Dyn Emerald, and interviews with Testing Personnel (TP) #1 and the Laboratory Director (also the Technical Consultant), the surveyor determined the Technical Consultant failed to ensure TP #1 received training on the Emerald, when it was installed in February of 2017. This affected one of two laboratory testing personnel. The findings include: 1. The installation records for the Emerald indicated the new instrument was installed on February 24, 2017. Of the two testing personnel responsible for using the instrument, TP #1 did not have documented training on the instrument. 2. At 1:40 PM on 10/16/18, the surveyor discussed with the Laboratory Director his responsibility as the Technical Consultant /Laboratory Director to ensure all personnel receive the appropriate and necessary training. 3. At 1:56 PM, TP #1 reviewed the Emerald manual for documentation of training. TP #1 stated she had not noticed the lack of documentation, prior to today, but confirmed there was no documentation of her Emerald instrument training.

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 a review of personnel records and competency assessments, a lack of documentation, a review of a hand-written note regarding frequency of competency assessments, and interviews with Testing Personnel (TP) #1 and the Laboratory Director (also the Technical Consultant), the surveyor determined the Technical Consultant failed to assess the competency of TP #1 at least annually, since the testing personnel's first year of employment. This affected one of two testing personnel of moderate complexity testing. This is a repeat deficiency, and the laboratory's Plan of Correction to update the assessments for TP #1 and any other personnel, if necessary, was not implemented. The findings include: 1. A review of the personnel records revealed annual competency assessments for TP #1, dated for 2010 and 2011. TP # 1 was also listed on the previous survey's personnel report (CMS form #209) from 11/01 /2016. 2. At 11:40 AM on 10/16/18, the surveyor inquired of TP #1 about her annual competency assessments. TP #1 stated she guessed she needed to do competency evaluations for herself. The surveyor and TP #1 reviewed the manual for competency assessments, and TP #1 confirmed the last documented assessment for her was in 2011. The surveyor discussed with TP #1 the reoccurrence of the same issues as the previous survey, and no corrective actions had been implemented. Patricia Watson, BS, MT (ASCP) Licensure and Certification Supervisor