Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0700618	07/26/2022
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
D2123	HEMATOLOGY CFR(s): 493.851(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) proficiency testing records and an interview with the off-site Laboratory Supervisor, the laboratory failed to submit results within the timeframe specified by the proficiency testing provider. This was noted for one out of nine 2019 to 2022 API events. The findings include: 1. A review of the API records revealed the 2021 API Hematology event #1 survey received a score of zero percent due to "Failure to Participate". 2. A review of the API records revealed the laboratory performed the 2021 API Hematology event #1 survey on March 17, 2021. However, the laboratory failed to submit the results by the due date of March 31, 2021, the cutoff date specified by API. 3. During an interview on July 26, 2022, at 11:49 AM, the off-site Laboratory Supervisor confirmed the laboratory failed to submit results by the due date. .
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years.

	This STANDARD is not met as evidenced by: Based on a review of the API (American Proficiency Institute) proficiency testing (PT) records and an interview with the off-site Laboratory Supervisor, the laboratory failed to retain PT records for one of nine 2019 - 2022 API surveys. The findings include: 1. A review of the API PT records revealed the laboratory failed to retain the PT records for API 2019 Event #2. The scores for this survey were pending during the previous CLIA survey review on 6/27/2019. 2. During the exit interview and summation on July 26, 2022, at 3:15 PM, the above noted findings were reviewed and confirmed with the off-site Laboratory Supervisor who stated the records were at the Gadsden laboratory. The surveyor agreed the laboratory could submit the documentation by July 29, 2022, however no additional records were received by the CLIA office. .
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 the American Proficiency Institute (API) Hematology proficiency testing (PT) records and an interview with the off-site Laboratory Supervisor, the laboratory failed to perform an internal evaluation of Hematology results not submitted within the required timeframes specified by API. This was noted for one of nine 2019 to 2022 surveys. The findings include: 1. A review of the API records revealed no API evaluation for the 2021 Hematology event #1 survey. 2. A review of the API records revealed the laboratory performed the 2021 API Hematology event #1 survey on March 17, 2021. However, the laboratory failed to submit the results by March 31, 2021, the cutoff date specified by API. (Refer to D2123.) 3. A further review of the PT records revealed no documentation of an internal evaluation of the laboratory's results when compared to API results (available on the website) to ensure no corrective action was needed for scores less than 100 percent. 4. During an interview on July 26, 2022, at 11:49 AM, the off-site Laboratory Supervisor confirmed the above findings. .
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by:

	Based on reviews of the Abbott Cell Dyn Emerald Hematology analyzer records, the Quick Reference Guide in the Laboratory Procedure Manual, and an interview with the off-site Laboratory Supervisor, the surveyor determined the laboratory failed to perform four of four calibrations as per manufacturer's instructions in 2019 - 2021. The findings include: 1. A review of Abbott Cell Dyn Emerald calibration records revealed the following: A) 11/1/2019: Documentation of an acceptable calibration, however a precision check was not performed. (This is Step # 7 on the Pre-calibration Procedure Checklist; see #2 below) B) 5/14/2020: Documentation of an acceptable calibration, however a precision check was not performed; in addition the "calibration verification" using the second calibrator tube was run only once in the Precision file. (See #3 below) C) 11/19/2020: Documentation of an acceptable calibration, however a precision check was not performed; in addition the "calibration verification" using the second calibrator tube was run only once in the Precision file. D) 7/27/2021: Documentation of the calibrator assay sheet and three levels of quality control (QC) labeled, "Calibration before", and three levels of QC labeled, "Calibration after". There was no documentation of the Calibration Report, the Precalibration Precision or "calibration verification" precision run. E) 4/27/2022: Documentation of a valid calibration with all required records 2. A review of the Cell Dyn Emerald "Pre-Calibration Procedure Checklist revealed, "... 7. Verify instrument precision by running a whole blood specimen 10 times into the PRECISION FILE. ...". 3. A review of the "Calibration Guidelines", on page 6/10 (the last page in the laboratory's procedure manual) in the "Calibration Verification Procedure", revealed, "...3. Run the calibrator two times in the precision file. 4. Using the Calibration Verification worksheet ... enter the assay values ...make a copy for your records.". 4. A review of instructions in the Abbott Cell Dyn Emerald Quick Reference Guide revealed, "... When to Calibrate ... At least every six months ...". 5. During an interview on 7/26 /2022 at 12:45 PM, the surveyor reviewed the calibration records, and the manufacturer's calibrations instructions with the off-site Laboratory Supervisor, and confirmed: A) There was no documentation of the Precalibration precision for the four 2019-2021 calibrations. B) The "calibration verification" using the second calibrator tube run twice in the Precision file was performed incorrectly or not performed in the three 2020-2021 calibrations. C) There was no documentation of the Calibration Report for the 7/27/2021 calibration; the laboratory failed to document a valid calibration between 11/19/2020 until 4/27/2022 (a seventeen month period). D) The laboratory failed to document the calibration activities and calculations on the Calibration Procedure Checklist and the Calibration Verification worksheet, as per the manufacturer's instructions for the four 2019-2021 calibrations. 6. As the interview continued on 4/26/2022 at approximately 12:55 PM, the off-site Laboratory Supervisor stated they had discovered the previous testing personnel was not doing laboratory procedures correctly, and she was no longer working for the clinic as of early 2022. .
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on reviews of the Abbott Cell Dyn Hematology Quality Control (QC) records, patient logs, and an interview with the off-site Laboratory Supervisor, the laboratory

	failed to: (1) ensure QC was documented 14 of 20 days in February 2022; and (2) ensure QC was performed and documented three of 36 days reviewed in April and July 2022. The findings include: 1. A review of the Abbott Cell Dyn Hematology CBC QC records revealed no documentation of QC for 14 of 20 days in February 2022. [The surveyor noted the Hematology printer was inoperable, however, the laboratory failed to implement any other mechanism to document the daily QC results.] A review of patient logs revealed 137 patients were affected. 2. A review of the April and July QC records revealed CBC QC was not performed on 4/5/2022, 7/11 /2022, and 7/12/2022. A review of patient logs revealed 13 patients were affected. 3. During an interview on July 26, 2022, at 1:41 PM, the off-site Office Supervisor confirmed the above findings. .
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 the Quality Assurance (QA) records, policy and procedure manual, and an interview with the Off site Laboratory Manager, the laboratory failed to implement an effective QA program to assess and correct problems identified in the analytical systems. This was noted to occur from July 2019 to the current survey. The findings include: 1. A review of the laboratory's QA records revealed the testing personnel performed monthly QA reviews, however, the reviews failed to discover and correct problems identified during the survey as follows: (A) The Abbott Cell Dyn Hematology Complete Blood Count (CBC) analyzer calibrations were not performed as per the manufacturer's instructions. (Refer to D5437.) (B) Hematology Quality Control (QC) was not documented or performed each day of patient testing. (Refer to D5481.) 2. During the exit interview and summation on July 26, 2022, at 3: 15 PM, the off-site Laboratory Supervisor confirmed the above findings. .
D6017	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(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)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program. This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) proficiency testing records and an interview with the off-site Laboratory Supervisor, the Laboratory Director failed to ensure the laboratory submitted results within the timeframe specified by the proficiency testing provider. This was noted for one out of nine 2019 to 2022 API events. The findings include: 1. A review of the API records revealed the 2021 API Hematology event #1 survey received a score of zero percent due to

	"Failure to Participate". 2. A review of the API records revealed the laboratory performed the 2021 API Hematology event #1 survey on March 17, 2021. However, the laboratory failed to submit the results by March 31, 2021, the cutoff date specified by API. 3. During an interview on July 26, 2022, at 11:49 AM, the off-site Laboratory Supervisor confirmed the laboratory failed to submit results by the due date. .
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 a review of the personnel records and an interview with the off-site Laboratory Supervisor, the Laboratory Director failed to ensure Testing Personnel #2 provided education documentation. This was noted for one of three testing personnel. The findings include: 1. A review of the personnel records revealed no education documentation for Testing Personnel #2. 2. During the exit interview and summation on July 26, 2022, at 3:15 PM, the above noted findings were reviewed and confirmed with the off-site Laboratory Supervisor. The surveyor agreed the laboratory could submit the documentation by July 29, 2022, however no additional records were received by the CLIA office. .
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 reviews of the Abbott Cell Dyn Emerald Hematology calibration and Quality Control (QC) records, and an interview with the off-site Laboratory Supervisor, the Technical Consultant failed to provide adequate technical and scientific oversight of the laboratory. These failures were noted to occur from November 2020 (date of hire) to the current survey. The findings include: 1. Refer to D6036. .
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory.

	This STANDARD is not met as evidenced by: Based on reviews of the Abbott Cell Dyn Emerald Hematology calibration and Quality Control (QC) records, and an interview with the off-site Laboratory Supervisor, the Technical Consultant failed to provide adequate technical and scientific oversight of the laboratory. These failures were noted to occur from November 2020 (date of hire) to the current survey. The findings include: 1. A review of the Hematology records revealed the Technical Consultant failed to ensure: (A) The Abbott Cell Dyn Hematology analyzer calibrations were performed as per the manufacturer's instructions. (Refer to D5437.) (B) Hematology Quality Control (QC) was documented and performed each day of patient testing. (Refer to D5481.) 2. A further review of laboratory records revealed dates of the Technical Consultants visit, however, the laboratory was unable to provide documentation of what records were reviewed or what corrections were recommended. 3. During the exit interview and summation on July 26, 2022, at 3:15 PM, the above noted findings were reviewed and confirmed with the off-site Laboratory Supervisor. SURVEYOR ID #32558 and #46291 Licensure & Certification Surveyors