Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0700618	09/06/2023
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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on information received during the laboratory tour, a lack of documentation for throat cultures, and interviews with Testing Personnel #1 and the Laboratory Director, the laboratory failed to perform proficiency testing or implement another mechanism for accuracy verification on throat cultures, a moderate complexity test. This was noted from the previous survey (7/26/2022) to current survey (9/6/2023). The findings include: 1) During the entrance interview on September 6th, 2023, at 9:10 AM, the Laboratory Director stated the laboratory began performing throat cultures on all patients with a negative Strep A rapid test shortly after the last CLIA survey. However, when the surveyor requested proficiency testing for throat cultures, the Laboratory Director stated the Gadsden laboratory was performing proficiency testing since all the Strep A agar plates were received from the Gadsden laboratory. The surveyor explained the throat cultures were read at this laboratory, so proficiency testing was required for this laboratory. 2) During an interview on September 6th, 2023, at 11:30 AM, the Laboratory Director confirmed the laboratory was not performing any proficiency testing because they did not know it was required.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE

	CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) Proficiency Testing (PT) records and an interview with Testing Personnel #1 and the Laboratory Director, the laboratory failed to document reviews of returned PT results for three of seven 2022-2023 events. The findings include: 1. A review of the API PT records revealed no documentation of a review from the Laboratory Director, or designee, for the following surveys: a) 2022 Hematology 3rd Event. b) 2023 Hematology 1st Event. c) 2023 Hematology 2nd Event. 2. During an interview on September 6, 2023, at 10:11 AM, Testing Personnel #1 and the Laboratory Director confirmed the above 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 a review of the refrigerator temperature records, a lack of documentation of incubator temperatures, the manufacturer's package insert, and an interview with Testing Personnel #1, the Laboratory failed to ensure temperatures were documented for: 1) The refrigerator in which Hematology QC and Microbiology Taxo A discs were stored for 11 of 22 days in November 2022; and 2) The incubator for throat culture agar plates from the previous survey (7/26/2022) to the current survey (9/6 /2023). The findings include: 1. A review of the temperature records revealed the laboratory failed to document temperatures for the refrigerator in which the Cell Dyn+ Hematology Controls and the Microbiology BD Taxo A Discs were stored for the first half (1st-15th) of November 2022. 2. A review of the Cell Dyn 18+ Control package insert reveals, "Cell Dyn 18+ controls should be tightly capped and stored at 2-10 degrees Celsius." 3. A further review of the BD Taxo A Discs package insert reveals, "...store vial or cartridge to protect product integrity at 2 to 8 degrees Celsius." 4. A review of the Ivyx Scientific Incubator records revealed the laboratory failed to document any incubator temperatures from 7/26/2022 to 9/6/2023. 5. During an interview on September 6th, 2023, at 11:06 AM, Testing Personnel #1 confirmed the above findings.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in

	493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on information received during the laboratory tour, a lack of documentation for throat cultures, and interviews with Testing Personnel #1 and the Laboratory Director, the laboratory failed to perform Quality Control (QC) on Becton Dickinson BBL Taxo A Bacitracin discs for throat cultures. This was noted from the previous survey (7/26 /2022) to the current survey (9/6/2023). The findings include: 1) During the entrance interview on September 6th, 2023, at 9:10 AM, the Laboratory Director stated the laboratory began performing throat cultures on all patients with a negative Strep A rapid test shortly after the last CLIA survey. However, when the surveyor requested QC for the BD BBL Taxo A Bacitracin discs for throat cultures, the Laboratory Director stated the Gadsden laboratory performed the QC since all discs were received from the Gadsden laboratory. The surveyor explained the throat culture testing was performed at this laboratory, thus QC on the Bacitracin discs was required to be performed at this laboratory. 2) During an interview on September 6th, 2023, at 11:30 AM, the Laboratory Director confirmed the laboratory was not performing any QC on the Bacitracin discs since the QC was performed at the Gadsden laboratory. The Laboratory Director stated he did not realize on-site QC must also be performed at this laboratory.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on information received during the laboratory tour, a lack of documentation for throat cultures, and interviews with Testing Personnel #1 and the Laboratory Director, the laboratory failed to perform Quality Control on Hardy Diagnostics Agar plates for throat cultures. This was noted from the previous survey (7/26/2022) to current survey (9/6/2023). The findings include: 1) During the entrance interview on September 6th, 2023, at 9:10 AM, the Laboratory Director stated the laboratory began performing throat cultures on all patients with a negative Strep A rapid test shortly after the previous survey. However, when the surveyor requested QC on the Hardy agar plates for throat cultures, the Laboratory Director stated the Gadsden laboratory was performing QC since all the Strep A agar plates were received from the Gadsden laboratory. The surveyor explained the throat culture testing was performed at this laboratory, so the laboratory was required to document an inspection of the media, and implement a mechanism to check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms. 2) During an interview on September 6th, 2023, at 11:30 AM, the Laboratory Director confirmed

	the laboratory was not performing any QC on the agar plates since QC was performed at the Gadsden laboratory.
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 Laboratory Director, the Laboratory Director failed to ensure Testing Personnel #2 provided appropriate educational documentation prior to performing patient testing. This was noted for one of two testing personnel. The findings include: 1. A review of the personnel records revealed no educational documentation for Testing Personnel #2. 2. During an interview on September 6, 2023, at 9:43 AM, the above noted findings were reviewed and confirmed with the Laboratory Director.
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 American Proficiency Institute (API) proficiency testing (PT) records, temperature records, a lack of throat culture quality control documentation, and an interview with the Laboratory Director, the Technical Consultant failed to provide adequate technical and scientific oversight of the laboratory. These failures were noted to occur from previous survey on 7/26/2022 to the current survey. The findings include: 1. A review of the laboratory records revealed the Technical Consultant failed to provide adequate technical and scientific oversight to ensure the following: (A) PT results for three of seven 2022-2023 events had documentation of review. (Refer to D5211) (B) Temperatures were documented for the refrigerator in which Hematology QC and Microbiology Taxo A discs were stored for 11 of 22 days in November 2022; and the temperatures were monitored and recorded for the throat culture incubator from the previous survey (7/26/2022) to the current survey.(Refer to D5413). (C) Proficiency testing was performed, or another mechanism for accuracy verification was implemented for throat cultures, a moderate complexity test. (Refer to D2000). (D) Quality Control (QC) on Becton Dickinson BBL Taxo A Bacitracin discs for throat cultures was performed. (Refer to D5471). (E) Quality Control on Hardy Diagnostics Agar plates for throat cultures was performed. (Refer to D5477). 2. During the exit interview and summation on September 6, 2023, at 12:45 PM, the above noted findings were reviewed and confirmed with the Laboratory Director.