Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0667583	05/05/2022
Name of Provider or Supplier	**Street Address, City, State**	
Northeast Pediatrics And Adolescent Medicine, Llp	10 Graham Rd West, Ithaca, NY	

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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) Proficiency Testing (PT) Hematology and sub-speciality Bacteriology records for the 2019, 2020 and 2021 test events and an interview with the testing person, the laboratory director and testing personnel failed to sign the attestation forms attesting that the PT samples were tested in the same routine manner as patient specimens. FINDINGS: 1. Review of the printed instrument Hematology reports and the bacteriology log sheets for the 2019, 2020 and 2021 samples, the laboratory failed to test the hematology and bacteriology specimens in the same routine manner as patient specimens by the testing personnel. a. Twenty-three routine testing personnel perform the moderate complexity testing, automated Complete Blood Count (CBC) and Group B Strep testing. 2. The testing person confirmed on May 5, 2022 at approximately 10:30 AM, that the attestation forms for 2019, 2020 and 2021 were not signed by the laboratory director and the routine testing personnel, therefore, it could not be determine if the PT samples were tested in the same manner as patient specimens by the testing personnel.
D2020	BACTERIOLOGY CFR(s): 493.823(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

	This STANDARD is not met as evidenced by: Based on surveyor's review of the 1st event of 2020 and 1st event of 2022 API PT summary reports and confirmed in an interview with the testing person, at the time of survey, the laboratory failed to obtain an overall score for the sub-specialty Bacteriology/Group B Strep. The following score was assigned: 2020 first event = 60% 2022 first event = 60%
D2122	HEMATOLOGY CFR(s): 493.851(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on review of the 3rd event of 2021 API PT summary reports and an interview with the testing person, the laboratory failed to participate successfully in proficiency testing for the speciality Hematology. The following scores were assigned: 2021 third event = 0%
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 review 3rd event of 2021 API PT summary reports, lack of plan of correction documentation from the PT desk review in 12/23/21 and an interview with the testing person, the laboratory failed to participate successfully in proficiency testing for the speciality Hematology and the test analyte's White Blood Cell Count (WBC); Red Blood Cell Count (RBC); Hemoglobin (HgB), Hematocrit (Hct) and Platelet Count. The following scores were assigned: 2021 third event = 0% (failure to participate) THIS IS A REPEATED DEFICIENCY FROM THE PT DESK REVIEW SURVEY FROM DECEMBER 23, 2021.
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of the 3rd event of 2020, 1st & 3rd 2021 API PT summary reports,

	lack of the plan of correction documentation from the PT Desk review on 5/7/21 & 12 /23/21, and an interview with the testing person, the laboratory failed to participate successfully in proficiency testing program, for the test analyte (Cell I.D./WBC Diff) The following scores were assigned: 2020 third event= 60% 2021 first event = 67% 2021 third event = 0% THIS IS A REPEATED DEFICIENCY FROM THE PT DESK REVIEW SURVEY FROM May 7, 2021 and DECEMBER 23, 2021
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 the review of 2019, 2020 and 2021 API PT records, lack of the plan of correction documentation and an interview with the testing person, the laboratory failed to retain documentation to include signed attestation forms, instrument printouts, API test result forms and signed PT summary reports, corrective action documentation for the 2020 and 2021 events for hematology and sub-speciality bacteriology challenges. Refer to D2009, D2020, D2122, D2123, D2130, D6021 THIS IS A REPEATED DEFICIENCY FROM THE SURVEY CONDUCTED ON AUGUST 27, 2019
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 the review of 2019, 2020 and 2021 API PT summary reports and an interview with the testing person, at the time of survey, the laboratory failed to review and evaluate the API PT summary reports for the Hematology/CBC and sub-Specialty Bacteriology/Group B Strep challenges for all three events in 2019, 2020 and 2021. THIS IS A REPEATED DEFICIENCY FROM THE SURVEY CONDUCTED ON AUGUST 27, 2019
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of the laboratory's Quality Assessment (QA) policy, lack of annual QA review records in 2019, 2020 , 2021 and an interview with the testing person, the laboratory failed to follow their established QA policy and correct problems identified and monitor the remedial actions to ensure the problems do not recur. FINDINGS: 1. The API PT summary reports did not include evidence of review and evaluation of the

	PT results for all three events in 2019, 2020 and 2021. 2. The laboratory failed to rotate the API PT samples among the twenty-three testing personnel who routinely perform hematology and bacteriology testing 3. The testing person confirmed on May 5, 2022, at approximately 11:00 AM, that the laboratory failed to perform an annual QA review as required by their established QA procedure. Refer to D2009 and D5211 THIS IS A REPEATED DEFICIENCY FROM THE SURVEY CONDUCTED ON AUGUST 27, 2019
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of laboratory procedures, laboratory records and an interview with the testing person, the laboratory director failed to provide overall management of the laboratory. FINDINGS: The laboratory director failed to implement and maintain the plan of correction from the survey conducted on August 27, 2019. The laboratory director failed to ensure that the laboratory: 1. Reviewed and evaluated the proficiency testing reports, Refer to D6018; 2. Maintained their written QA policy for all phases of laboratory testing, Refer to D6021. THIS IS A REPEATED DEFICIENCY FROM THE SURVEY CONDUCTED ON AUGUST 27, 2019
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 the review of API PT summary reports for 2019, 2020, 2021 and an interview with the testing person, the laboratory director failed to review the scored proficiency testing reports received from API to evaluate the laboratory's performance for all three events in 2019, 2020 and 2021. Refer to D5211. THIS IS A REPEATED DEFICIENCY FROM THE SURVEY CONDUCTED ON AUGUST 27, 2019
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and

	maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's QA policy, lack of QA documentation and an interview the testing person, the laboratory director failed to follow the establish QA procedure for having an ongoing mechanism to monitor, assess, and when indicated correct problems identified in the general laboratory system. Refer to D5291 THIS IS A REPEATED DEFICIENCY FROM THE SURVEY CONDUCTED ON AUGUST 27, 2019