Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0667583	08/27/2019
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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on surveyor's review of the manufacturer's package inserts for McKesson True Track Smart Glucometer and OraQuick Advanced HIV 1/2 , Siemens Multistix 10 SG urine test strips and interview with the laboratory manager/testing person, the laboratory failed to follow the manufacturer's requirements for performing external controls with each new kit for above tests. FINDINGS: 1. The surveyor reviewed the manufacturer's package insert and the quality control (QC) requirements for the test kits at survey. 2. The laboratory manager/testing person confirmed on August 27, 2019 at approximately 10:30 AM, that the laboratory failed to follow the manufacturer's requirements for external controls and perform the required QC for the following test kits and tests: a. McKesson True Track Smart Glucometer and test strips requires low and high controls be tested with each new lot of test strips. The last date the reagent test strips (# MT1727 exp. date 10/13/17) were tested was on 9/16/16 using control lots low 5BC1A04 and high 4BC2A04. b. OraQuick Advanced HIV 1/2 test kit requires positive and negative controls be tested with each new kit. The last date the reagent test strips (6627812 exp. date 3/14) were tested was on 3/17 using control lots negative 6626032 and positive 6626031. c. The laboratory failed to retain copies of the Consult urine controls range sheets, controls that are used to perform quality control on the Siemens Multistix 10 SG urine test strips. The surveyor was unable to determine if the control results were in range. The current urine reagent test strips in use (#612057 exp. date. 6/30/20) were tested with controls negative #098783 and positive #098734 exp. date. 4/19, last date tested 5/24/18.

D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on surveyor's review of Quality Control (QC) records for the Abbott Emerald hematology analyzer and an interview with the laboratory manager/testing person, the laboratory failed to retain copies of the control & calibration assay information sheets from 1/1/2018 through survey date. FINDINGS: The laboratory director/testing person confirmed on August 27, 2019 at approximately 11:30 AM that the laboratory failed to retain the control and calibration assay information sheets Abbott Emerald analyzer from 01/2018 through survey 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 the surveyor review of College of American Pathologists (CAP) Proficiency Testing (PT) records for calendar years 2018 and 2019 and confirmed in an interview with the laboratory manager/testing person, the laboratory failed to retain documentation to include signed attestation forms and a signed PT summary reports for the 1st and 2nd events of 2019 hematology, urine sediment and bacteriology challenges.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a review of competency policies, staff competency records and an interview with the laboratory testing person, the laboratory failed to follow their establish written policies and procedures to assess the competency of the laboratory testing personnel that perform both Bacteriology/throat cultures and Hematology/CBC testing. FINDINGS: The laboratory manager/testing person confirmed on August 27, 2019 at approximately 2:00 PM, that the laboratory did not follow the established competency evaluation policy. The laboratory did not perform annual competency for nine of nineteen staff members in 2018.
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 surveyor's review of College of American Pathologists (CAP) proficiency testing (PT) reports and an interview with the laboratory manager/testing person, the laboratory failed to evaluate, perform and document remedial action for the PT scores of less than 100% for the following analytes: 2019 first event: Platelets = 80% Cell ID = 80% 2019 second event: Cell ID = 80%
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 a surveyor's review of the laboratory's Quality Assurance (QA) policy and confirmed in an interview with the laboratory manager/testing person, the laboratory failed to follow their established written QA policy and perform an annual QA review, as required by the laboratory's QA policy, for the calendar year 2018.
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 surveyor's review of temperature records an and interview with the laboratory manager/testing person, the laboratory failed to follow the manufacturer's temperature requirement for the LifeSign Uricult urine culture paddle system. FINDINGS: The laboratory manager/testing person confirmed on August 27, 2019 at approximately 11:00 AM, that the laboratory failed to record the laboratory room temperature from 1/1/2018 through survey date. The LifeSign Uricult urine culture paddle system requires a storage temperature of 45-77 F.
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 a surveyor's review of hematology calibration records for the Abbott Emerald hematology analyzer and interview with the laboratory manager/testing person, calibration of the hematology analyzer was not performed at the frequencies required by the laboratory's calibration protocol and by the manufacturer of the analyzer. FINDINGS: 1. The laboratory manager/testing person confirmed on August 27, 2019 at approximately 11;00 AM, that the laboratory failed to perform the required calibration for the hematology analyzer in the calendar year 2018. a. The laboratory's calibration policy and the manufacturer of the hematology analyzer require analyzer calibration every six months. 2. The documentation of the Abbott Emerald analyzer calibration available for review was for calibration performed on 2/28/17, 9/2/17 and 8/23/19. The hematology analyzer was therefore out of calibration from 3/3/18 through 8/23/19. 3. Approximately 1000 patient specimens were tested and reported for hematology during the above time period when analyzer was out of calibration.
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 surveyor's findings and an interview with the laboratory manager/testing person, the laboratory director failed to provide overall management of the laboratory. FINDINGS: The laboratory director failed to: 1. ensure that a corrective action plan was followed for CAP PT, D6018; 2. ensure that the QC plan was followed and maintained, D6020; 3. ensure that the QA plan was followed and maintained, D6021; 4. ensure that documentation for annual competency was available, D6054.
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 surveyor's review of CAP PT reports and an interview with the laboratory manager/testing person, the laboratory director failed to sign & date attestation forms and review the scored proficiency testing reports received from CAP to evaluate the laboratory's performance for all three evnts in 2018, first and second events of 2019. Refer to D3037 and D5211.
D6020	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 the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a surveyor's review of quality control records for hematology and bacteriology testing and an interview with the laboratory manager/testing person, the laboratory director failed to ensure that the QC program for hematology and bacteriology was maintained to assure quality laboratory services. Refer to: D1001, D3031, D5413 and D5437.
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 the surveyor's review of the laboratory's QA policy and confirmed during the interview with the laboratory manager/testing person, the laboratory director failed to ensure that the laboratory's quality assessment (QA) policy/procedure was followed. Refer to: D5291
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 surveyor's review of the personnel files and confirmed in an interview

	with the laboratory manager/testing person, the laboratory director, acting as the technical consultant, failed to perform annual competency evaluation for nine of nineteen testing persons in calendar year 2018. Refer to D5209.