Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0371341	01/23/2018
Name of Provider or Supplier	**Street Address, City, State**	
Northeast Pediatrics Assoc, Pc	75 Barclay Circle Ste 115, Rochester Hills, MI	

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
D3027	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(1) Test requisitions and authorizations. Retain records of test requisitions and test authorizations, including the patient's chart or medical record if used as the test requisition or authorization, for at least 2 years. This STANDARD is not met as evidenced by: . Based on procedure review, record review, and interview, the laboratory failed to retain patient written order requisitions for three (#4, 6, and 17) of 21 patient charts audited in 2016 and 2017. Findings include: 1. On January 23, 2018 at 10:39 a.m., "Technical Policies and Procedures - Testing Ordering" procedure review revealed "Records of test requisitions are saved for at least two years. 2. On January 23, 2018 at 12:36 p.m. record review for three of 21 patient charts audited revealed the laboratory was not able to provide the surveyor the documentation to show the tests requested. 3. On January 23, 2018 at 12:36 p.m. when queried, testing personnel #1 as listed on the CMS-209 was informed by the office staff that "requisitions were discarded starting in 2017". 4. During the interview on January 23, 2018 at 12:36 p. m., testing personnel #1 confirmed the laboratory did not retain patient written order requisitions in 2017.
D5002	BACTERIOLOGY CFR(s): 493.1201 If the laboratory provides services in the subspecialty of Bacteriology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1261, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by:

	. Based on document review and interview, the laboratory failed to meet Bacteriology requirements as specified in 493.1230 through 493.1256. Findings include: 1. The laboratory failed to establish performance specifications for the modified bacteriology FDA approved Quidel QuickVue Dipstick Strep A Test kit. Refer to D5423. 2. The laboratory failed to perform and document media checks for the "BBL TSA II" and the "BBL Group A Select SB (SSA)" media with each new batch, lot, or shipment for the ability to support growth and selectivity/inhibition. Refer to D5477. 3. The laboratory failed to maintain a record system that included the identity of the testing personnel. Refer to D5787.
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 record review and interview, the laboratory failed to ensure written competency policies were implemented for two (#8 and #9) of nine testing personnel performing urinary sediments in 2016 and 2017. Findings include: 1. On January 23, 2018 at 9:41 a.m., record review for the annual competency revealed there was no documentation to show competency was performed for two of nine testing personnel performing the urinary sediment examinations. 2. During the interview on January 23, 2018 at 9:41 a.m., testing personnel #1 as listed on the CMS-209 confirmed the annual competency was not completed as required.
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 document review and interview, the laboratory failed to evaluate and document the corrective action taken for the unsatisfactory hematology proficiency testing scores for four (A and C in 2016 and B and C in 2017) of six events reviewed; urine microscopy for one (event A in 2017) of four events reviewed; and bacteriology for one (event B in 2017) of four events reviewed. Findings include: 1. On January 23, 2018 at 9:57 a.m., document review of the College of American Pathologists (CAP) final graded proficiency testing reports for 2016 and 2017 revealed the laboratory did not document corrective action as following: Hematology a. 2016 - no corrective action for FH2-A red blood cell distribution width (RDW) (40%) b. 2016 - no corrective action for FH2-C hematocrit (80%) c. 2017 - no corrective action for FH2-B RDW and Mean Corpuscular Hemoglobin Concentration (MCHC)with the exception code of [24] d. 2017 - no corrective action for FH2-C MCHC with the exception code of [24] Urine Microscopy e. 2017 - no corrective action for CMA (50%) for urine microscopy Bacteriology f. 2017 - no corrective action for MC4-B (80%) for urine colony count 2. On January 23, 2018 at 9:57 a.m. when queried, testing personnel #1 as listed on the CMS-209 was unable to provide the surveyor

	documentation to show corrective action/self grading was performed. 3. During the interview on January 23, 2018 at 9:57 a.m., testing personnel #1 confirmed corrective action/self grading was not performed and documented.
D5301	TEST REQUEST CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by: . Based on document review and interview, the laboratory failed to have a written request for patient testing from an authorized person for five (#1, 4, 6, 15, and 17) of 21 patient charts audited in 2016 and 2017. Findings include: 1. On January 23, 2018 at 12:36 p.m., document review of five of 21 patient charts audited did not have a written request for the hematology complete blood cell count and the urine cultures by an authorized person. 2. During the interview on January 23, 2018 at 12:36 p.m., testing personnel #1 as listed on the CMS-209 confirmed written requests for laboratory testing was not available.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: . Based on document review, manufacturer's instruction review, and interview, the laboratory failed to establish performance specifications for the modified bacteriology FDA approved Quidel QuickVue Dipstick Strep A Test kit for three (#19, 20, and 21) of 21 patient charts audited by using specimen sources (vaginal and anal/rectum) outside the scope of the manufacturer's instructions in 2016 and 2017. Findings include: 1. On January 23, 2018 at 12:43 p.m., document review for three of 21 patient charts audited revealed on the test request log the test "strep" ordered with the specimen source of vaginal or anal/rectum written on the log. 2. On January 23, 2018 at 12:43 p.m. when queried, testing personnel #1 as listed on the CMS-209 confirmed the specimen sources written on the log were the actual specimen used for the waived Quidel QuickVue Dipstick Strep A testing. 3. On January 23, 2018 at 12:45 p.m., the manufacturer's package instructions state "collect throat swab specimens and culture colonies only" as the source of specimen. 4. On January 23, 2018 at 12:48 p.m. when queried, testing personnel #1 was not able to provide the surveyor documentation to demonstrate the laboratory had established performance specifications for the modification of the strep kit for using specimens outside of manufacturer's

	instructions. 5. During the interview on January 23, 2018 at 1:19 p.m., testing personnel #1 confirmed the laboratory had modified the procedure and did not establish performance specifications.
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 record review and interview, the laboratory failed to perform and document media checks for the "BBL TSA II" and the "BBL Group A Select SB (SSA)" media with each new batch, lot, or shipment for the ability to support growth and selectivity/inhibition for two (2016 and 2017) of two years. Findings include: 1. On January 23, 2018 at 11:53 a.m., record review for two of two years for the BBL TSA II and the BBL Group A Select SB (SSA) media revealed there was no documentation to show the ability to support growth and selectivity/inhibition checks were performed and documented with each new batch, lot or shipment. 2. During the interview on January 23, 2018 at 11:53 a.m., testing personnel #1 as listed on the CMS-209 confirmed the media checks were not performed and documented with each new batch, lot or shipment in 2016 and 2017.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to maintain a record system that included the identity of the testing personnel for three (#9, 15, and 17) of 21 patient charts audited for the bacteriology urine and throat cultures testing in 2016 and 2017. Findings include: 1. On January 23, 2018 at 12:36 p.m., record review for three of 21 patient charts audited revealed the laboratory did not have a record system in place that included the identity of the testing personnel who performed and documented the bacteriology testing in the patients medical records. 2. During the interview on January 23, 2018 at 12:36 p.m., testing personnel #1 as listed on the CMS-209 confirmed the testing personnel identity was not documented.