Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0692396	01/31/2018
Name of Provider or Supplier	**Street Address, City, State**	
North Fulton Pediatrics Pc	1285 Hembree Rd Suite 100, Roswell, GA	

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
D0000	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on January 31, 2018. The laboratory was not in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiency was cited:
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on proficiency testing (PT) document review and staff interview, the laboratory failed to ensure the PT samples were tested with the laboratory's regular patient workload by testing personnel (TP) who routinely perform the testing. Findings include: 1. College of American Pathology (CAP) PT document review revealed Staff #8 (CMS 209) tested the Bacteriology Identification Throat Culture specimens for the second and third PT events for 2016. 2. CAP PT document review revealed Staff #6 and Staff #8 (CMS 209) tested the Bacteriology Identification Throat Culture specimens for all three events for 2017. 3. An interview with Staff #6 (CMS 209) in the main laboratory on 1/31/18 at approximately 1:30 p.m. confirmed TP were not rotated for the aforementioned PT events.
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 quality control (QC) document review and staff interview, the laboratory failed to perform quality control (QC) for bacteriology media as required. Findings include: Refer to D5477
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 policy and procedure manual (SOP) review and staff interview, the laboratory failed to establish and follow written policies and procedures to assess testing personnel (TP) competency. Findings include: 1. SOP review revealed the laboratory failed to establish and follow written policies and procedures, with six required procedures, to assess TP competency. 2. SOP review revealed the laboratory failed to establish and follow written policies and procedures for performing a six-month competency for TP evaluation during their first year of laboratory testing. 2. An interview with Staff #6 (CMS 209) in a medical office on 1/31/18 at approximately 2:00 p.m. confirmed the SOP did not contain a competency policy and procedure. During the same interview, Staff #6 (CMS 209) confirmed there was not a six-month TP competency policy and procedure.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on quality control (QC) document review and staff interview, the laboratory failed to monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. Findings include: Refer to D5477
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

	This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure manual (SOP) and staff interview, the laboratory failed to establish a written procedure for all tests, assays, and examinations performed by the laboratory as required. Findings include: 1. SOP review revealed the laboratory failed to establish a policy for a sterility check for each batch of bacteriology Strep Select media. 2. An interview with Staff #6 (CMS 209) on 1/31/18 in a medical office at approximately 2:00 p.m. confirmed there was not a policy in the laboratory SOP for a sterility check of each batch of Strep Select media.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on observation and staff interview, the laboratory failed to perform and document required equipment maintenance. Findings include: 1. Observation during the main laboratory tour on 1/31/18 at approximately 1:30 p.m. revealed the Labcorp Horizon centrifuge was last calibrated on 7/30/14. 2. Observation during the tour of laboratory #2 and #3 on 1/31/18 at approximately 1:45 p.m. revealed there was no eyewash maintenance log for 2016, 2017, and 2018 thus far. 3. An interview with Staff #6 (CMS 209) on 1/31/18 in the main laboratory at approximately 1:30 p.m. confirmed the Labcorp Horizon centrifuge was last calibrated on 7/30/14. 4. An interview with Staff #6 (CMS 209) on 1/31/18 at approximately 1:45 p.m. in laboratory #3 confirmed the eyewash equipment in laboratory #2 and #3 had not been maintained for 2016, 2017, and 2018 thus far.
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 quality control (QC) document review and staff interview, the laboratory failed to perform quality control (QC) for bacteriology media as required. Findings include: 1. Bacteriology QC document review revealed the laboratory failed to perform a sterility check on each batch of media prior to testing for 2016, 2017, and 2018 thus far. 2. Bacteriology QC document review revealed the laboratory failed to check each batch of media for its ability to support and, as appropriate, select or inhibit specific organisms for 2016, 2017, and 2018 thus far. 3. An interview with

	Staff #6 (CMS 209) on 1/31/18 in a medical office at approximately 2:00 p.m. confirmed no sterility checks or growth/no growth QC of bacteriology media was performed for 2016, 2017, and 2018 thus far. ***** REPEAT DEFICIENCY*****
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 testing personnel (TP) document review and staff interview, the laboratory director/technical consultant (LD/TC) failed to provide overall management as required. Findings include: Refer to D6046
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on testing personnel (TP) document review and staff interview, the Technical Consultant/Laboratory Director (TC/LD) failed to evaluate the competency of all TP as required. Findings include: 1. TP document review revealed the TC/LD failed to perform annual competencies on 7 of 7 TP in 2016 and 7 of 7 TP in 2017. 2, TP document review revealed the TC/LD failed to perform a six-month competency on Staff #9 (CMS 209) in 2017. 3. An interview with Staff #6 (CMS 209) in a medical office on 1/31/18 at approximately 2:00 p.m. confirmed the TC/LD did not perform annual competencies on 7 of 7 TP in 2016 and 7 of 7 TP in 2017. During the same interview, Staff #6 (CMS 209) confirmed the TC/LD did not perform a six-month competency on Staff #9 (CMS 209) in 2017. *****REPEAT DEFICIENCY*****
D6049	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii) The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. This STANDARD is not met as evidenced by: Based on review of quality control (QC) documents, quality assurance (QA) documents, and staff interview, the technical consultant /laboratory director (TC/LD) failed to perform document review as required. Findings include: 1. Review of laboratory temperature logs, QA logsheets, and Bacteriology Taxo A disc QC logs, the TC/LD failed to perform a review of these documents for 2016, 2017, and 2018

	thus far. 2. An interview with Staff #6 (CMS 209) on 1/31/18 in a medical office at approximately 2:00 p.m. confirmed the TC/LD had not confirmed the aforementioned QC an QA documents for 2016, 2017, and 2018 thus far.