Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D1000553	(X3) Date Survey Completed 10/18/2018
Name of Provider or Supplier Perimeter North Medical Associates	**Street Address, City, State** 960 Johnson Ferry Road, Suite 300, Atlanta, 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 October 18, 2018. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, 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 general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on proficiency test (PT) document review and staff interview, the laboratory failed to monitor and evaluate the overall quality of the general laboratory systems and correct identified problems for each specialty and subspecialty of testing performed. Findings include: Refer to D 5221
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 proficiency test (PT) document review and staff interview, the laboratory failed to review all unsatisfactory PT scores and ensure corrective action was

	performed. 1. American Proficiency Institute (API) document review revealed all unsatisfactory PT scores were not reviewed and corrective action was not performed for the following PT events: 2017- Chemistry (First Event - Endocrinology); 2018 - Hematology/Coagulation and Chemistry (First Event); 2018 - Chemistry(Second Event). 2. An interview with Staff #3 (CMS 209) in a conference room on 10/18/2018 at approximately 3:00 p.m. confirmed all unsatisfactory PT scores were not reviewed and corrective action was not performed for the aforementioned unacceptable PT results. This is a REPEAT deficiency. .
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. 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 include required policies and procedures. Findings include: 1. SOP review revealed the laboratory failed to establish a policy and procedure for specimen acceptability and rejection. 2. An interview with Staff #3 (CMS 209) on 10/18/2018 in a conference room at approximately 3:00 p.m. confirmed there was not a policy for specimen acceptability and rejection in the laboratory SOP.
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 equipment temperature document review and staff interview, the laboratory failed to protect equipment from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. Findings include: 1. Refrigerator temperature document review revealed the temperature was out of range for the following dates: September, 2016 -- 2 of 30 days; April, 2018 -- 1 of 30 days. 2. Freezer temperature document review revealed the temperature was out of range for the following dates: 2016 -- September (3 out of 30 days); November (10 out of 30 days); 2017 -- February (8 of 28 days), August (8 of 31 days), November (10 of 30 days), December (10 of 31 days); 2018 -- January (9 of 31 days), April (4 of 30 days), July (10 of 31 days), September (11 of 30 days). 3. Refrigerator and Freezer temperature document review also revealed management was notified regarding each occurrence of temperatures being out of range. 4. At interview with Staff #3 (CMS 209) on 10/18/2018 in a conference room at approximately 3:00 p.m. confirmed the aforementioned temperatures out of range. During the same interview Staff #3 (CMS 209) also confirmed management was notified regarding each occurrence of temperatures being out of range.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on testing personnel (TP) competency document review and staff interview, the laboratory director (LD) failed to delegate technical consultant (TC) responsibilities to qualified personnel as required. Findings include: 1. TP document review revealed unqualified TP performed initial competencies for the following: 2017 -- Staff #5, Staff #6, Staff #7, and Staff #8; 2018 -- Staff #4. 2. An interview with Staff ## (CMS 209) on 10/18/2018 in a conference room at approximately 3:00 p.m. confirmed the aforementioned competencies were performed by unqualified TP.
D6005	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(c) 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. (c) The laboratory director must be accessible to the laboratory to provide onsite, telephone or electronic consultation as needed. This STANDARD is not met as evidenced by: Based on testing personnel (TP) document review and staff interview, the laboratory

	director (LD) failed to ensure the employment of competent laboratory TP. Findings include: 1. TP competency document review revealed the LD failed to ensure an initial training competency was performed for the technical consultant (TC), Staff #2 (CMS 209), in 2017. 2. TP competency document review revealed the LD failed to ensure a six-month competency was performed for the TC in 2018. 2. An interview with Staff #3 (CMS 209) on 10/18/2018 in a conference room at approximately 3:00 p. m. confirmed an initial training competency was not performed for the TC (Staff #2--CMS 209) in 2017. During the same interview Staff #3 (CMS 209) confirmed a six-month competency was not performed for the TC (Staff #2 -- CMS 209).
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure manual (SOP) and staff interview, the laboratory director(LD) failed to specify in writing the duties and responsibilities of each person engaged in all phases of laboratory testing. Findings include: 1. SOP review revealed the LD did not establish a duties and responsibilities policy for each person engaged in the performance of preanalytic, analytic, and postanalytic laboratory testing. 2. An interview with Staff #3 (CMS 209) on October 18, 2018, in a conference room at approximately 3:00 p.m. confirmed there was not a duties and responsibilities policy in the laboratory SOP.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on testing personnel (TP) document review and staff interview, the laboratory

	failed to employ qualified TP due to lack of education documentation. Findings include: 1. TP document review revealed the laboratory failed to provide education documentation at the time of survey for Staff #4 (CMS 209). 2. An interview with Staff #3 (CMS 209) in a conference room on 10/18/2018 at approximately 3:00 p.m. confirmed no education documentation was available for the aforementioned TP at the time of survey.