Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2053185	12/11/2018
Name of Provider or Supplier	**Street Address, City, State**	
Perimeter North Medical Associates	1505 Northside Blvd, Suite 4400, Cumming, 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 December 11, 2018. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiency was cited:
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on quality assurance (QA) document review and staff interview, the laboratory failed to document all general laboratory systems QA activities. Findings include: 1. Based on QA document review and staff interview, the laboratory failed to document QA activities for 2017. 2. An interview with Staff #2 (CMS 209) in a conference room on 12/11/18 at approximately 3:45 p.m. confirmed QA checklists for 2017 were not available at the time of survey.
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 proficiency test (PT) document review and staff interview, the laboratory director (LD) failed to provide overall management and direction of the laboratory as required. Findings include: Refer to D6018
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 proficiency test (PT) document review and staff interview, the laboratory director (LD) failed to reviewed PT reports as required. Findings include: 1. American Academy of Family Physicians (AAFP) PT document review revealed the LD failed to review the Hematology PT report for Event 1 of 2017. 2. An interview with Staff #2 (CMS 2090 in a conference room at approximately 3:45 p.m. on 12/11/18 confirmed the LD failed to review the aforementioned PT documents. This is a repeat deficiency.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, This STANDARD is not met as evidenced by: Based on proficiency test (PT) document and staff interview, the laboratory director (LD) failed to ensure that all necessary remedial actions were taken and documented for unsuccessful PT participation as required. Findings include: 1. American Academy of Family Physicians (AAFP) PT document review revealed the LD failed to ensure corrective action was performed for 2017 Hematology Event 1 for scores less than 100 percent. 2. An interiew with Staff #2 (CMS 209) on 12/11/18 in a conference room at approximately 3:45 p.m. confirmed corrective action was not performed for the aforementioned PT event.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. 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 TP receive appropriate training and have demonstrated the ability to provide and report accurate results. Findings include: 1. TP document review revealed an initial training competency was not performed for Staff #4 (CMS 209) in 2018. 2. TP document review revealed a six-month competency was not performed for Staff #4 (CMS 209), who is also the technical consultant, in 2018. 2. An interview with Staff #4 (CMS 209) on 12/11/18 in a conference room at approximately 3:45 p.m. confirmed the lack of an initial training competency or a six-month competency for the aforementioned TP in 2018.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on testing personnel (TP)document review and staff interview, the technical consultant (TC) failed to provide technical oversight over the laboratory as required. Findings include: Refer to D6054
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 testing personnel (TP) document review and staff interview, the technical consultant (TC) failed to perform an annual competency on TP as required. Findings include: 1. TP document review revealed an annual competency was not performed on Staff #2 (CMS 209) in 2017. 2. TP document review revealed an annual competency was not performed on Staff #4 (CMS 209) in 2018. 3. An interview with Staff #2 (CMS 209) on 12/11/8 in a conference room at approximately 3:45 p.m. confirmed the aforementioned competencies were not performed. This is a repeat deficiency.