Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D1061564	10/03/2018
Name of Provider or Supplier	**Street Address, City, State**	
Primary Pediatrics Of Mcdonough	110 A Regency Park Drive, Mcdonough, 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 proficiency testing desk review was completed on October 3, 2018. At the time of the review, the laboratory was not in compliance with the Clinical Laboratory Improvement Amendments of 1988, 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: The laboratory failed to maintain satisfactory proficiency testing (PT) performance for automated white blood cell (WBC) differential analyte in 2016 events two and three and in 2018 events one and two resulting in the second unsuccessful occurrence for WBC differential. (Refer to D 2130).

D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on a desk review of the Centers for Medicare and Medicaid Casper Report 155 (CMS 155) and review of the laboratory's 2016, 2017 and 2018 proficiency testing (PT) evaluation reports from the American Proficiency Institute (API) , the laboratory failed to maintain satisfactory performance in four of seven consecutive proficiency testing events for the automated white blood cell (WBC) differential resulting in the second unsuccessful PT occurrence for WBC differential. The findings include: 1. Review of the CMS 155 revealed the following unsatisfactory automated WBC differential scores: 2016 event two 67%, 2016 event three 53%, 2018 event one 73% and 2018 event two 73%. 2. Review of the API 2016 event two evaluation report revealed unacceptable scores for Granulocytes % for sample numbers HEM-06, HEM 07 and HEM 10, Lymphocytes % for sample number HEM-06 and Monocyte/Mid% for sample number HEM-10. 3. Review of the API 2016 event three evaluation report revealed unacceptable scores for Granulocytes % for sample numbers HEM-12, HEM 13 and HEM 15, Lymphocytes % for sample numbers HEM-11 and HEM 12 and Monocyte/Mid% for sample numbers HEM-12 and HEM-15. 4. Review of the API 2018 event one evaluation report revealed unacceptable scores for Granulocytes % for sample numbers HEM-03 and HEM 05 and Lymphocytes % for sample numbers HEM-03 and HEM 05. 5. Review of the API 2018 event two evaluation report revealed unacceptable scores for Granulocytes % for sample numbers HEM-06 and HEM 07 and Lymphocytes % for sample numbers HEM-06 and HEM 07.
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: The laboratory director failed to maintain compliance with successful white blood cell (WBC) differential proficiency testing (PT) for four of seven consecutive events , resulting in the second unsuccessful PT occurrence for WBC differential. (Refer to D6016)
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

	This STANDARD is not met as evidenced by: Based on a desk review of the Centers for Medicare and Medicaid Casper Report 155 (CMS 155) and review of the laboratory's 2016, 2017 and 2018 proficiency testing (PT) evaluation reports from the American Proficiency Institute (API) , the laboratory director failed to ensure the laboratory maintained satisfactory performance in four of seven consecutive proficiency testing events for the automated white blood cell (WBC) differential resulting in the second unsuccessful PT occurrence for WBC differential. The findings include: 1. Review of the CMS 155 revealed the following unsatisfactory automated WBC differential scores: 2016 event two 67%, 2016 event three 53%, 2018 event one 73% and 2018 event two 73%. 2. Review of the API 2016 event two evaluation report revealed unacceptable scores for Granulocytes % for sample numbers HEM-06, HEM 07 and HEM 10, Lymphocytes % for sample number HEM-06 and Monocyte/Mid% for sample number HEM-10. 3. Review of the API 2016 event three evaluation report revealed unacceptable scores for Granulocytes % for sample numbers HEM-12, HEM 13 and HEM 15, Lymphocytes % for sample numbers HEM-11 and HEM 12 and Monocyte/Mid% for sample numbers HEM-12 and HEM-15. 4. Review of the API 2018 event one evaluation report revealed unacceptable scores for Granulocytes % for sample numbers HEM-03 and HEM 05 and Lymphocytes % for sample numbers HEM-03 and HEM 05. 5. Review of the API 2018 event two evaluation report revealed unacceptable scores for Granulocytes % for sample numbers HEM-06 and HEM 07 and Lymphocytes % for sample numbers HEM-06 and HEM 07.