Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D1061564	05/06/2021
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 Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on May 6, 2021. 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:
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 personnel records and interview with the Laboratory Manager, determined that the laboratory failed to establish a written policy that assess the six criteria's for employee competency that include hematology and microbiology testing. The findings include: 1. The laboratory failed to have a written policy and procedure for competency that included the six criteria's for the testing personnel for 2019, 2020, and 2021. 2. An annual competency assessment was not performed for any of the staff for 2019, 2020, and 2021 for hematology and microbiology testing. 3. During an interview with the Laboratory Manager on May 6, 2021, at approximately 12:30 PM, confirmed that the laboratory did not have a policy that assess the six criteria's for the testing personnel in the laboratory.
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 laboratory record review and interview with the Laboratory Manager, the laboratory failed to record and document temperatures for the incubator used for Microbiology testing. The Findings include: 1. Laboratory record review revealed that the testing personnel(TP) did not record and document temperatures for the incubator for 2019, 2020, and 2021 for the use of Microbiology testing. 2. During an interview with the Laboratory Manager on May 6, 2021 at approximately 12:40 PM, in an office confirmed that the laboratory did not record and document incubator temperatures for Microbiology testing for 2019, 2020, and 2021.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on Hematology calibrations document review and interviews with the laboratory manager, the laboratory failed to perform instrument calibrations every six months as required in 2019 and 2020 for the Cell dyn Emerald Hematology Analyzer. Findings include: 1. The Cell Dyn Emerald hematology analyzer calibrations document review revealed the laboratory performed instrument calibrations as follows: None in 2019 and one in 2020 (06-10-2020). 2. An interview with the the laboratory manager in the review room at approximately 12:45 p.m. confirmed hematology analyzer calibrations were not performed during the aforementioned periods in 2019 and 2020.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on Quality Control (QC) data review and laboratory manager's interview, the laboratory director (LD) failed to review QC data for the Celldyn Emerald Hematology analyzer on a monthly basis as specified in the Quality Assurance (QA) manual. 1.) Quality Control data review revealed daily QC data and Levey Jennings graphs were not reviewed and signed by the lab director who is also the Technical Consultant(TC) from January 2019 to April 2021 on a monthly basis. 2.) An interview

	with the laboratory manager on 05/06/2021 at approximately 12:35 pm in the review room confirmed the LD has not been reviewing QC data from this clinic from January 2019 to April 2021.