Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0264038	(X3) Date Survey Completed 01/08/2020
Name of Provider or Supplier Primary Pediatrics Of Macon	**Street Address, City, State** 5300 Bowman Road, Macon, 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 8, 2020. 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:
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 review of the employee competency assessments, and staff interview, the laboratory failed to provide Initial training documents for the four new employees hired in 2019. Findings: 1. Review of the employee competency assessments, 2019 competencies were performed from 12-17-2019 to 12-30-2019. There were four employees hired in 2019 (HIRE DATES: 4-10-19, 4-25-19, 10-26-19, and 3-7-19) that only had competency assessments performed in December of 2019. There was no documentation of an initial training for these 4 employees. 2. Interview with the Laboratory Manager, on January 8, 2020 at approximately 2:45 pm in the training room, confirmed that the four new hires, with the above listed hire dates, did not have initial training documents.

D6047	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b(8)(i) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. This STANDARD is not met as evidenced by: Based on review of the 2019 Testing personnel Competency evaluations, and staff interview the Laboratory Director (LD), performing the duties of the Technical Consultant (TC), did not perform the competencies for the testing personnel, following the six minimal regulatory requirements for assessment of competency for all personnel performing laboratory testing. There were no 2018 competency assessment documents available. Findings: 1. Review of the competency check off sheets documented for 2019, the sheet consisted of a simple check off sheet. The Six minimal regulatory requirements for assessment of competency was not addressed in the documentation. 2. Interview with the laboratory manager at approximately 2:30 pm, on January 8, 202, in the training room, confirmed that the TC did not evaluate the testing personnel using the Six minimal regulatory requirements of competency as required, and that there were no 2018 competency assessment documents available.
D6070	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(1) Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results. This STANDARD is not met as evidenced by: Based on review of the policy and procedure manual (SOP), observation during the lab tour, and staff interview, the laboratory failed follow the policy for labeling specimens collected. Findings include: 1. Observation during the lab tour at 10:15 AM reveals 8 urine specimens on the lab counter to the right of the sink labeled with the patient first name initial and the patient last name. A second unique identifier was not on the labeled specimens. 2. Review if the SOP reveals the lab policy that specimens are to be labeled with two (2) unique identifying factors such as name, date of birth, or patient ID (identification) number. 3. Interview with the lab manager on 1/8 /2020 in the laboratory at approximately 10:20 AM, confirmed the urine specimens were not labeled with 2 unique identifiers.