

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D1061564	(X3) Date Survey Completed 04/25/2023
Name of Provider or Supplier Primary Pediatrics Of McDonough	Street Address, City, State 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 April 25, 2023. 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:
D3011	<p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on the laboratory tour and staff interview, the laboratory failed to ensure the fire extinguisher was inspected, the last inspection date was November 2021. The Findings include: 1. Laboratory tour revealed that the fire extinguisher closest to the laboratory was last inspected in November 2021. It is required to check the fire extinguisher on an annual basis. 2. During an interview with the General Supervisor on April 25, 2023 at 4:45 PM, in the breakroom, confirmed the fire extinguishers were last inspected in November 2021.</p>
D5203	<p>SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232</p> <p>The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.</p>

	<p>This STANDARD is not met as evidenced by: Based on the tour of laboratory and staff interview, the laboratory failed to ensure two identifier's were present on the blood agar plates. Findings include: 1. During the laboratory tour, 9 out of 9 blood agar plates in the incubator was observed with only one identifier, during the survey. 2. During an interview with the Testing Personnel #1 (CMS-209) on April 25, 2023 at 5:25 PM in the laboratory, confirmed the lack of two identifier's on the blood agar plates.</p>
<p>D5209</p>	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on laboratory policy and procedure manual (SOP) review and staff interview, the laboratory failed to perform competency for 3 out of 6 Testing Personnel (TP) for 2021, 2022, and thus far 2023. The Findings include: 1. Competency documents revealed the annual competencies were performed but not reviewed by the Laboratory Director for Testing Personnel #1, 2, and 6(CMS-209) for 2021 and 2022, and thus far 2023(January-April). 2. During an interview with the Testing Personnel #1 (CMS-209) on April 25, 2023 at 2:45 PM, in the back office, confirmed that competencies were performed for the Testing Personnel (TP), but the competencies were not performed for 2021, 2022, and thus 2023 for Testing Personnel #1, 2, and 6 (CMS-209).</p>
<p>D6030</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12)</p> <p>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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;</p> <p>This STANDARD is not met as evidenced by: Based on laboratory policy and procedure manual (SOP) review and staff interview, the Laboratory Director (LD) failed to perform competency for 3 out of 6 Testing Personnel (TP) for 2021, 2022, and thus far 2023. The Findings include: 1. Competency documents revealed the annual competencies were performed but not reviewed by the Laboratory Director for Testing Personnel #1, 2, and 6(CMS-209) for 2021 and 2022, and thus far 2023(January-April). 2. During an interview with the Testing Personnel #1 (CMS-209) on April 25, 2023 at 2:45 PM, in the back office, confirmed that the Laboratory Director (LD) failed to perform competencies on 3 out of 6 Testing Personnel (TP): Testing Personnel #1, 2, and 6 (CMS-209).</p>