

| | | |
|--|--|---|
| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 11D0978199 | (X3) Date Survey Completed 05/19/2022 |
| Name of Provider or Supplier Middle Georgia Pediatrics Llc | Street Address, City, State 1508 B Hardeman Avenue, Attn Michelle Kelly, 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 proficiency testing desk review was completed on May 19, 2022. 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 | <p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(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.</p> <p>This CONDITION is not met as evidenced by: Based on proficiency testing desk review using the Centers for Medicare and Medicaid (CMS) Casper Reports 155 and 153 and review of the laboratory's proficiency testing (PT) reports, the laboratory failed to maintain satisfactory</p> |

| | |
|--------------|---|
| | <p>performance in four (4) consecutive events (Events 1, 2, 3 of 2021 and 1st event of 2022), resulting in the third unsuccessful occurrence for Bacteriology #05. Findings include: Refer to D 2028</p> |
| D2028 | <p>BACTERIOLOGY CFR(s): 493.823(e)</p> <p>Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on proficiency testing desk review using the Centers for Medicare and Medicaid (CMS) Casper Reports 155 and 153 and review of the laboratory's proficiency testing (PT) reports, the laboratory failed to maintain satisfactory performance in 4 consecutive events (1st, 2nd, & 3rd events of 2021 and 2022 event 1), resulting in the third unsuccessful performance for Bacteriology #05 (throat culture). Findings include: 1. Desk review of Casper Reports 153 and 155 disclosed the laboratory failed analyte # 05 on: - event 1 of 2021 with a score of 67% - event 2 of 2021 with a score of 60% - event 3 of 2021 with a score of 60% - event 1 of 2022 with a score of 60% 2. Desk review of the laboratory's proficiency testing reports from American Proficiency Institute (API) confirmed the laboratory failed Bacteriology #05 on the aforementioned events of 2021 and 2022 resulting in the 3rd unsuccessful performance.</p> |
| D6000 | <p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: The laboratory director failed to maintain compliance with successful bacteriology #05 proficiency testing (PT) for 4 consecutive events resulting in the 3rd unsuccessful PT occurrence for Bacteriology (throat culture). Refer to D6016</p> |
| D6016 | <p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i)</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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;</p> <p>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 the laboratory's 2021, 2022 proficiency testing (PT) evaluation</p> |

reports, the laboratory director failed to ensure the laboratory maintained satisfactory performance for 4 consecutive proficiency testing events for bacteriology resulting in the third unsuccessful PT occurrence for Bacteriology (throat culture). The findings include: 1. Desk review of Casper Reports 153 and 155 disclosed the laboratory failed analyte Bacteriology #05 (throat culture) on: -event 1 of 2021 with a score of 67% - event 2 of 2021 with a score of 60 - event 3 of 2021 with a score of 60% - event 1 of 2022 with a score of 60% 2. Desk review of the laboratory's proficiency testing reports from American Proficiency Institute (API) confirmed the laboratory failed Bacteriology #05 on Events 1, 2, and 3 of 2021 and 2022 event 1, resulting in the 3rd unsuccessful performance.