

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0978199	(X3) Date Survey Completed 02/12/2021
Name of Provider or Supplier Middle Georgia Pediatrics Llc	Street Address, City, State 1508 B Hardeman Avenue, Attn Michelle Kelly, Macon, GA	
<p>For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.</p>		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	<p>A Clinical Laboratory Improvement Amendments (CLIA) Recertification survey was completed on February 12, 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:</p>
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Proficiency Testing(PT) documents from American Proficiency Institute (API), the laboratory failed to complete an attestation statement for 2019 Hematology/Coagulation 3rd event, and 2019 Microbiology 1st event. A signed attestation statement certifies that as closely as possible, these proficiency testing samples were tested in the same manner as patient specimens. Findings: 1. Review of the 2019 PT documents from API, the Hematology /Coagulation 3rd event had not be signed by the LD or TP. The 2019 Microbiology 1st event showed that the LD did not sign the required attestation statement to confirm that the PT samples were tested in the same manner of patient specimens. 2. An interview with staff #1 (CMS form 209) on February 12, 2021, in the facility breakroom, confirmed that the attestation statements were not completed.</p>
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing</p>

performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:

Based on review of the Proficiency Testing (TP) documents from the American Proficiency Institute (API), the Laboratory Director (LD) failed to sign the Performance Evaluation after reviewing the PT results. The 2019 Microbiology 1st event, Hematology / Coagulation and Microbiology 3rd event, and 2020 Microbiology 1st event were not signed by the LD as being reviewed. Findings: 1. A review of the API PT Performance Review for 2019 confirmed that the LD failed to sign the Performance Review as being reviewed for Microbiology 2nd Event, Hematology 3rd event, and Microbiology 3rd event. In 2020, the LD failed to sign the Performance Review for Microbiology 1st event. 2. An interview with staff #1 (CMS 209 form), on February 12, 2021, at approximately 4:15 pm, confirmed that the above mentioned Performance Review documents were not signed by the LD.

D6024

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(7)

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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified,

This STANDARD is not met as evidenced by:

Based on review of the Daily Temperature Logs(Temp Logs), the laboratory failed to provide corrective action when the room temperature(RT) fell outside of the established Room Temperature Range. In 2019, 2020, and January 2021. The acceptable RT range on the Temp Logs was listed as 64 to 90 degrees Farenheit. Findings: 1. Review of the Temp Logs for RT, showed that the laboratory failed to provide Corrective Action on the day the RT fell outside of the established range of 64 to 90 degrees Farenheit. 2019: 31 days out of 332 days the RT temperature was documented as being outside the established range of 64 to 90 degrees Farenheit without corrective action documented. 2020: 33 days out of 304 days, the RT temperature was documented as being outside the established range of 64 to 90 degrees Farenheit without corrective action documented. 2021 5 days out of 27 days (January 2021), the RT temperature was documented as being outside the established range of 64 to 90 degrees Farenheit without corrective action documented. 2. An Interview with staff #1 (CMS 209 form), on February 12, 2021, at approximately 4pm in the facility lounge confirmed that there was not corrective action documented for the above number of days in 2019, 2020, and January 2021.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on review of the Employee Competency documents, the Laboratory Director (LD) whom also perform duties of the Laboratory Technical Consultant (TC), as noted on the CMS 209 Laboratory Personnel Report, failed to perform competencies on all Testing Personnel (TP). Findings: 1. A review of the Employee Competency documents revealed that the LD performed 1 out of 9 competency for the year 2019, and 1 out of 10 for the year 2020. There have been no competencies performed in 2021 up to the date of the survey. (2-12-2021) The competency performed in 2019 and 2020 were initial training documents for new hires. 2. An Interview with staff #1 (CMS 209 form), on February 12, 2021, at approximately 4:30 pm in the facility breakroom, confirmed that there was one initial training documented in 2019, and one initial training documented in 2020, There had not been any competencies performed in 2021.