| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 01D0688523 | 08/21/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Montgomery Pediatric Associates | 420 Cotton Gin Road, Montgomery, AL | |

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 |
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| **D5217** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(c)(1)<br><br>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the test menu, a review of the policy and procedure manual (package insert), a lack of documentation of proficiency checks for Streptozyme testing, and interviews with the Laboratory Manager [also Testing Personnel (TP) #1], the surveyor determined the laboratory failed to verify the accuracy of the Streptozyme (qualitative) testing, at least twice annually. This affected the survey review period for 2018 - day of survey (August 21, 2019). The findings include: 1. During the initial tour of the laboratory on August 21, 2019 at 9:30 AM, the laboratory manager stated the laboratory performed a qualitative Streptozyme testing, which she believed to be waived testing. The surveyor stated this would be verified by further review by the surveyor. 2. A review of the package insert at 10:43 AM on August 21, 2019 for the Wampole ColorCard Streptozyme, revealed the test is a moderate complexity test. 3. During an interview on August 21, 2019 at 10:19 AM, the surveyor reviewed the package insert with the laboratory manager. At this time, the surveyor inquired how the laboratory performed proficiency or accuracy of interpretation for the testing. The laboratory manager stated the laboratory was not enrolled in organized proficiency testing for the Streptozyme; and although the laboratory had one time performed split sampling, it does not perform enough Streptozyme testing to do split-sampling proficiency testing, particularly for 2018. The laboratory manager confirmed the test was only reported as positive or negative. 4. A review of the Split-Sample Record revealed a date of 9/16/18 with the laboratory's recording of a positive Streptozyme test. However there were no results |

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| | of a comparison study to confirm the laboratory had the interpretation verified by another laboratory or staff member. There was no documentation of any split-sample testing at least twice for 2018, nor for 2019, to date of the survey. |
| **D5449** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(3)(ii)(g)<br><br>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the test menu, a review of the policy and procedure manual (package insert), a lack of documentation of quality control testing for Streptozyme testing, and interviews with the Laboratory Manager [also Testing Personnel (TP) #1], the surveyor determined the laboratory failed to perform quality control testing of at least a positive and negative control with each day of patient testing. The laboratory had not established any IQCP (Individualized Quality Control Plan) to reduce the frequency of quality control to less than the CLIA standard of each day of patient testing for Streptozyme analyses. The findings include: 1. During the initial tour of the laboratory on August 21, 2019 at 9:30 AM, the laboratory manager stated the laboratory performed a qualitative Streptozyme testing, which she believed to be waived testing. At 9:35 AM, the laboratory manager stated only a few, maybe one to three, Streptozyme tests were performed in a year's time. 2. A review of the package insert at 10:43 AM on August 21, 2019 for the Wampole ColorCard Streptozyme, revealed the test is a moderate complexity test. According to the package insert, the manufacturer provided a positive and negative control sera, and recommended each control serum be tested for each new test kit and as often as the laboratory dictated. NOTE: Effective January 1, 2016, CLIA requires for qualitative tests, at least a positive and negative control be tested with each day of procedure, unless the laboratory develops an IQCP, which could allow frequency of testing quality control to be reduced. [See regulatory language at 493.1256 for control practices, utilizing an IQCP.] 3. A review of the records for Streptozyme revealed the laboratory performed a patient test on 9/16/18, but did not document results for a positive and negative quality control. 4. At 12:23 PM on August 21, 2019, the surveyor discussed with the laboratory manager the requirement of quality control testing for the Streptozyme tests. |
| **D5471** | CONTROL PROCEDURES<br>CFR(s): 493.1256(e)(1)(g)<br><br>(e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. |

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| | This STANDARD is not met as evidenced by:<br>Based on a review of the test menu, a review of the Microbiology Quality Control (QC) records and an interview with the laboratory manager, who is also Testing Personnel (TP) #1, the surveyor determined the laboratory failed to perform and document positive and negative reactivity for each batch, lot number or shipment of Bacitracin disks. The laboratory used the Bacitracin disks with TSA (Tryptic Soy Agar) with five percent ( 5 %) sheep blood for the interpretation of throat cultures. This affected the survey review period, September 2017 - day of the survey (August 21, 2019). The findings include: 1. During the tour of the laboratory at 9:30 AM on August 21, the laboratory manager stated throat cultures for positive or negative growth were performed using TSA plates with the Bacitracin disks. 2. A review of the media quality control revealed the laboratory verified the ability of the TSA plates to support growth, by inoculating the plates with Ecoli (Escherichia). However, the laboratory did not perform and document any quality control verifications of the the Bacitracin disks. 3. During an interview on August 21, 2019 at 12:20 PM, the surveyor asked the laboratory manager if the laboratory performed any quality control of the A-disks (Bacitracin). The laboratory manager (TP #1) reviewed the media quality control records (as described in paragraph #1) and stated this was the only media QC performed, as she believed this was all that was necessary based on previous instructions. The surveyor discussed the need for the laboratory to perform quality control on the Bacitracin disks in a manner to ensure the disks responded appropriately to the pathogens expected on the TSA plates. The growth of the Ecoli on the plates shows the ability of the media to support growth, but is not related to the reactivity of the Bacitracin disks. 4. Please note the attached reference for performing quality control for bacitracin disks. This is only a reference, provided by the surveyor as a quide for the laboratory to establish a policy and procedure for quality control testing of the media and bacitracin disks. |