| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 25D0861270 | 10/13/2021 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Childrens Medical Group Madison | 7726 Old Canton Road, Madison, MS | |

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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| **D2016** | SUCCESSFUL PARTICIPATION<br>CFR(s): 493.803(a)(b)(c)<br><br>(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.<br><br>This CONDITION is not met as evidenced by:<br>Based on surveyor desk review of the laboratory proficiency testing (PT) records (graded copies from the proficiency testing provider and the Centers for Medicare and Medicaid Services data system) on 10/13/21, the laboratory did not successfully participate in proficiency testing for ERYTHROCYTE COUNT. Findings include: Our records indicate the following proficiency testing scores for your laboratory for ERYTHROCYTE COUNT: PROFICIENCY TESTING PROVIDER: AMERICAN PROFICIENCY INSTITUTE (API) YEAR 2020 1st Event: 40% YEAR 2020 3rd Event: 60% YEAR 2021 2nd Event: 40% Scores less than 80% for this analyte or parameter indicate failure or unsatisfactory performance. A failure of the analyte or |

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| | parameter for two consecutive or two out of three testing events is scored as initial unsuccessful performance. Repeat failures are scored as non-initial unsuccessful performance. |
| **D2130** | HEMATOLOGY<br>CFR(s): 493.851(f)<br><br>Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor desk review of the laboratory proficiency testing (PT) records (graded copies from the proficiency testing provider and the Centers for Medicare and Medicaid Services data system) on 10/13/21, the laboratory did not successfully participate in proficiency testing for ERYTHROCYTE COUNT. Findings include: Our records indicate the following proficiency testing scores for your laboratory for ERYTHROCYTE COUNT: PROFICIENCY TESTING PROVIDER: AMERICAN PROFICIENCY INSTITUTE (API) YEAR 2020 1st Event: 40% YEAR 2020 3rd Event: 60% YEAR 2021 2nd Event: 40% Scores less than 80% for this analyte or parameter indicate failure or unsatisfactory performance. A failure of the analyte or parameter for two consecutive or two out of three testing events is scored as initial unsuccessful performance. Repeat failures are scored as non-initial unsuccessful performance. |
| **D6000** | MODERATE COMPLEXITY LABORATORY DIRECTOR<br>CFR(s): 493.1403<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>Based on surveyor desk review of the laboratory proficiency testing (PT) records (graded copies from the proficiency testing provider and the Centers for Medicare and Medicaid Services data system) on 10/13/2021, the laboratory director has not provided overall management and direction in accordance with 493.1407 of this subpart. |
| **D6016** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(4)(i)<br><br>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;<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor desk review of the laboratory proficiency testing (PT) records |

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| | (graded copies from the proficiency testing provider and the Centers for Medicare and Medicaid Services data system) on 10/13/2021, the laboratory director has failed to ensure the proficiency testing samples were tested as required under subpart H of this part. |