

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D1061564	(X3) Date Survey Completed 03/09/2022
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	The laboratory failed to maintain satisfactory proficiency testing (PT) performance for automated white blood cell (WBC) differential analyte # 765 in 2020 events one and two resulting in the 1st unsuccessful occurrence and in 2021 event one resulting in the second unsuccessful occurrence for WBC differential.
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: The laboratory failed to maintain satisfactory proficiency testing (PT) performance for automated white blood cell (WBC) differential analyte # 765 in 2020 events 1 and 2</p>

	<p>resulting in the 1st unsuccessful occurrence and in 2021 event 1 resulting in the second unsuccessful occurrence for WBC differential. Findings include: Refer to D 2130</p>
<p>D2130</p>	<p>HEMATOLOGY CFR(s): 493.851(f)</p> <p>Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.</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 review of the laboratory's 2020 and 2021 proficiency testing (PT) evaluation reports from the American Proficiency Institute (API) , the laboratory failed to maintain satisfactory performance in three proficiency testing events for the automated white blood cell (WBC) differential #765, resulting in the second unsuccessful PT occurrence for WBC differential. The findings include: 1. Review of the CMS 155 revealed the following unsatisfactory automated WBC differential scores: - 2020 event 1 0% / 2020 event two 73% (1st unacceptable occurrence) - 2021 event 1 0% (2nd unacceptable occurrence) 2. Review of the API 2021 event 1 evaluation report revealed unacceptable scores for Granulocytes % for sample number Hem-3 score of 0%; Lymphocytes for the sample number Hem-3 score of 0% resulting in the 2nd unsuccessful PT occurrence.</p>
<p>D6000</p>	<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: 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 director failed to ensure the laboratory maintained satisfactory performance in PT event 1 of 2021 resulting in the second unsuccessful occurrence for WBC Diff , analyte # 765. Findings include: Refer to D 6016</p>
<p>D6016</p>	<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:</p>

Based on a desk review of the Centers for Medicare and Medicaid Casper Report 155 (CMS 155) and review of the laboratory's 2020 and 2021 proficiency testing (PT) evaluation reports from the American Proficiency Institute (API) , the laboratory director failed to ensure the laboratory maintained satisfactory performance in 2021 event 1 proficiency testing for the automated white blood cell (WBC) differential #765 resulting in the second unsuccessful PT occurrence for WBC differential. The findings include: 1. Review of the CMS 155 revealed the following unsatisfactory automated WBC differential scores: -2020 event 1 0%, 2020 event two 73% (1st unacceptable occurrence) - 2021 event 1 0% (2nd unacceptable occurrence) 2. Review of the API 2021 event 1 evaluation report revealed unacceptable scores for Granulocytes % for sample number Hem-3 score of 0%; Lymphocytes for the sample number Hem-3 score of 0% resulting in the 2nd unsuccessful PT occurrence.