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| <b>Statement of Deficiencies</b>                                                                                           | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>11D0976863 | <b>(X3) Date Survey Completed</b><br><br>06/03/2019 |
| <b>Name of Provider or Supplier</b><br><br>Prime Pediatrics Pc                                                             | <b>Street Address, City, State</b><br><br>1610 Broadrick Drive, Dalton, 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                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
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| D0000              | A proficiency testing desk review was completed on June 3, 2019. 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<br/>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:<br/>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 American Proficiency Institute (API) proficiency testing proficiency testing (PT) reports, the laboratory failed to maintain satisfactory performance in two consecutive</p> |

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|              | <p>events (Event 2 of 2018 and Event 1 of 2019), resulting in the first unsuccessful occurrence for red blood cell count (RBC) #0775, hematocrit (HCT) #0785, hemoglobin (HGB) #0795, and Hematology #0760. Findings include: Refer to D2130</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>D2130</b> | <p><b>HEMATOLOGY</b><br/>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:<br/>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 American Proficiency Institute (API) proficiency testing (PT) reports, the laboratory failed to maintain satisfactory performance in two consecutive events (2nd Event of 2018 &amp; Event 1 of 2019), resulting in the first unsuccessful occurrence for Hematology #0760, red blood cell count (RBC) #0775, hematocrit (HCT) #0785, and hemoglobin (HGB) #0795. The findings include: 1. Desk review of Casper Reports 153 and 155 disclosed the laboratory failed Hematology #0760, red blood cell count (RBC) #0775, hematocrit (HCT) #0785, and hemoglobin (HGB) #0795 on Event 2 of 2018 with a score of 0% and Event 1 of 2019 with a score of 0%. 2. The criteria for acceptable performance for the specialty of Hematology is a score of 80%. 2. Desk review of the laboratory's proficiency testing reports from the American Proficiency Institute (API) confirmed the laboratory failed Hematology on Event 2 of 2018 and Event 1 of 2019 resulting in the first unsuccessful performance.</p> |
| <b>D6000</b> | <p><b>MODERATE COMPLEXITY LABORATORY DIRECTOR</b><br/>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:<br/>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 American Proficiency Institute (API) proficiency testing (PT) reports, the laboratory director failed to ensure the laboratory maintained satisfactory performance in two of three consecutive events (2nd Event of 2018 and 1st Event of 2019), resulting in the first unsuccessful occurrence for Hematology #760, red blood cell count (RBC) #0775, hematocrit (HCT) #0785, and hemoglobin (HGB) #0795. The findings include: Refer to D 6016</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>D6016</b> | <p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b><br/>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</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |

required under Subpart H of this part;

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 American Proficiency Institute (API) proficiency testing (PT) reports, the laboratory director failed to ensure the laboratory maintained satisfactory performance in two of three consecutive events (3rd event of 2018 and 1st event of 2019), resulting in the first unsuccessful occurrence for Hematology #760, red blood cell count (RBC) #0775, hematocrit (HCT) #0785, and hemoglobin (HGB) #0795. The findings include: 1. Desk review of Casper Reports 153 and 155 disclosed the laboratory failed Hematology #0760, red blood cell count (RBC) #0775, hematocrit (HCT) #0785, and hemoglobin (HGB) #0795 on Event 2 of 2018 with a score of 0% and Event 1 of 2019 with a score of 0%. 2. Desk review of the laboratory's proficiency testing reports from the American Proficiency Institute (API) confirmed the laboratory failed Hematology on event 2 of 2018 and event 1 of 2019 resulting in the first unsuccessful performance.