| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 11D0726627 | 03/27/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Pediatric First, Pc | 1049 N Houston Rd, Warner Robins, 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 March 27, 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** | 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 proficiency testing desk review using the Centers for Medicare and Medicaid (CMS) Casper Reports 155 and 153 and review of the laboratory's College of American Pathology (CAP) proficiency testing (PT) reports, the laboratory failed to maintain satisfactory performance in two consecutive events (3rd event of 2018 and |

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| | 1st event of 2019), resulting in the first unsuccessful occurrence for platelets (PLT) # 815. Findings include: Refer to D 2127 & D 2130 |
| **D2127** | HEMATOLOGY<br>CFR(s): 493.851(d)<br><br>Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.<br><br>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 College of American Pathology (CAP) proficiency testing (PT) reports, the laboratory failed to submit results to CAP within the time frame specified by the program. Findings include: 1. Desk review of Casper Reports 153 and 155 disclosed the laboratory failed analyte #815 platelets on event 3 of 2018 with a score of 0%. 2. Desk review of the laboratory's proficiency testing reports from CAP confirmed the laboratory failed platelets on event of 3 of 2018 with a score of 0% and revealed the 0% score was because CAP received results from the lab after the due date. |
| **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 proficiency testing desk review using the Centers for Medicare and Medicaid (CMS) Casper Reports 155 and 153 and review of the laboratory's College of American Pathology (CAP) proficiency testing (PT) reports, the laboratory failed to maintain satisfactory performance in two consecutive events (3rd event of 2018 and 1st event of 2019), resulting in the first unsuccessful occurrence for platelets (PLT) # 815. Findings include: 1. Desk review of Casper Reports 153 and 155 disclosed the laboratory failed analyte #815 platelets on event 3 of 2018 with a score of 0% and event 1 of 2019 with a score of 60%. 2. Desk review of the laboratory's proficiency testing reports from CAP confirmed the laboratory failed platelets on event 3 of 2018 and event 1 of 2019 resulting in the first unsuccessful performance. 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 College of American Pathology (CAP) proficiency testing (PT) reports, the laboratory failed to maintain satisfactory performance in two consecutive events (3rd event of 2018 and 1st event of 2019), resulting in the first unsuccessful occurrence for platelets (PLT) # 815. Findings include: |
| **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. |

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| | 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 College of American Pathology (CAP) proficiency testing (PT) reports, the laboratory director failed to ensure the laboratory maintained satisfactory performance in two consecutive events (3rd event of 2018 and 1st event of 2019) and failed to ensure the the laboratory submitted results to CAP within the time frame specified by the program., resulting in the first unsuccessful occurrence for platelets (PLT) # 815. Findings include: Refer to D 6016 |
| **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 proficiency testing desk review using the Centers for Medicare and Medicaid (CMS) Casper Reports 155 and 153 and review of the laboratory's College of American Pathology (CAP) proficiency testing (PT) reports, the laboratory director failed to ensure the laboratory maintained satisfactory performance in two consecutive events (3rd event of 2018 and 1st event of 2019) and failed to ensure the laboratory submitted results to CAP within the time frame specified by the program., resulting in the first unsuccessful occurrence for platelets (PLT) # 815. Findings include: 1. Desk review of Casper Reports 153 and 155 revealed the laboratory failed analyte #815 platelets on event 3 of 2018 with a score of 0% and event 1 of 2019 with a score of 60%. 2. Desk review of the laboratory's proficiency testing reports from CAP confirmed the laboratory failed platelets on event 3 of 2018 and event 1 of 2019 resulting in the first unsuccessful performance. 3. Desk review of the laboratory's proficiency testing reports from CAP also revealed the laboratory failed platelets on event of 3 of 2018 with a score of 0% because CAP received results past the due date. |