

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0262499	(X3) Date Survey Completed 03/27/2019
Name of Provider or Supplier Childrens Doctor Pc	Street Address, City, State 2366 Battlefield Parkway, Fort Oglethorpe, 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	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: A proficiency testing desk review was completed on January 14, 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 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: Based on proficiency testing desk review using the Centers for Medicare and</p>

	<p>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 three consecutive events (1st, 2nd and 3rd events of 2018), resulting in subsequent unsuccessful occurrence for Bacteriology. Findings include: Refer to D 2021</p>
<p>D2021</p>	<p>BACTERIOLOGY CFR(s): 493.823(b)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.</p> <p>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 College of American Pathology (CAP) proficiency testing (PT) report, the laboratory failed to participate in three consecutive PT events (events 1, 2 and 3 of 2018) which resulted in subsequent unsuccessful occurrence for Bacteriology. Findings include: 1. Desk review of Casper Reports 153 and 155 disclosed the laboratory failed the subspecialty of Bacteriology # 0005 on events 1, 2 and 3 of 2018 with scores of 0% on all three events. 2. Desk review of the laboratory's proficiency testing reports from CAP confirmed the laboratory failed Bacteriology on Events 1, 2 and 3 of 2018 and revealed the 0% scores were for failure to participate. This resulted in subsequent unsuccessful performance.</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 College of American Pathology (CAP) proficiency testing (PT) reports, the laboratory director failed to ensure the laboratory maintained satisfactory performance in three consecutive events (1st, 2nd and 3rd events of 2018) and failed to ensure the laboratory followed the approved allegation of compliance (AOC) for bacteriology, resulting in subsequent unsuccessful occurrence for bacteriology. Findings include: Refer to D 6019</p>
<p>D6019</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv)</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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

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, review of the laboratory's 2018 College of American Pathology (CAP) proficiency testing (PT) reports, and review of the laboratory's November 21, 2018 approved allegation of compliance (AOC), the laboratory director failed to ensure the laboratory maintained satisfactory performance in three consecutive events (1st, 2nd and 3rd events of 2018) and failed to ensure the laboratory followed the approved AOC for bacteriology, resulting in subsequent unsuccessful occurrence for bacteriology. Findings include: 1. Desk review of Casper Reports 153 and 155 disclosed the laboratory failed the subspecialty of Bacteriology # 0005 on events 1, 2 and 3 of 2018 with scores of 0% on all three events. 2. Desk review of the laboratory's proficiency testing reports from CAP confirmed the laboratory failed Bacteriology on Events 1, 2 and 3 of 2018 and revealed the 0% scores were for failure to participate. 3. Review of the laboratory's November 21, 2018 AOC for initial unsuccessful participation in bacteriology PT revealed the following statements, " 3. The Laboratory Director will ensure that the Proficiency Testing Samples are tested as required." and "4. The Laboratory Director will be in direct communication with the Clinical Coordinator/Asst.Coordinator to ensure Proficiency Testing Materials have been received, performed & submitted timely as required. 11/20/18". 4. Review of the laboratory's 2018 event 3 CAP evaluation report revealed the PT samples were mailed to the laboratory on 12/3/2018. 5. Review of the AOC revealed it was signed by the laboratory director on 11/21/2018, which is before the 2018 event 3 samples were mailed to the laboratory.