Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0262499	03/26/2019
Name of Provider or Supplier	**Street Address, City, State**	
Childrens Doctor Pc	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 Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on March 26, 2019. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiency was cited:
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on proficiency test (PT) document review and staff interview, the laboratory failed to test the PT samples with the laboratory's patient workload by personnel who routinely perform the laboratory testing as required. Findings include: 1. College of American Pathologists (CAP) PT document review revealed the laboratory failed to perform testing on the 2018 Bacteriology Third Event PT samples. 2. An interview with Staff #2 (CMS 209) on 3/26/2019 in exam room #5 at approximately 1:00 p.m. confirmed the laboratory did not perform testing on the aforementioned PT samples in 2018.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (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. 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 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 nd Unsuccessful PT performace The facility th
D2021	BACTERIOLOGY CFR(s): 493.823(b) 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. 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.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented.

	This STANDARD is not met as evidenced by: Based on proficiency test (PT) document review and staff interview, the laboratory failed to document corrective action for all unsatisfactory PT scores as required. 1. College of American Pathology (CAP) PT report review and staff interview revealed corrective action was not documented for the 2019 Hematology first event with results less than 100 percent. 2. An interview with Staff #2 (CMS 209) in exam room #5 on 3 /26/2019 at approximately 3:00 p.m. confirmed the lack of corrective action for the aforementioned PT event score of less than 100 percent.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure manual (SOP), the laboratory failed to establish and implement a policy and procedure for performing required incubated bacteriology media sterility checks. Findings include: 1. SOP review revealed the laboratory failed to establish and implement an incubated bacteriology media sterility check policy and procedure. 2. An interview with Staff #2 (CMS 209) in exam room #5 on 3/26/2019 at approximately 3:00 p.m. confirmed there was not a policy and procedure in the SOP for performing incubated sterility checks for bacteriology media.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of the policy and procedure (SOP) manual and staff interview, the laboratory failed to comply with manufacturer's recommendations and requirements for testing. Findings include: 1 SOP review revealed the laboratory had not establisheda policy and procedure for monitoring humidity which is required for the AcT Diff hematology analyzer. 2. An interview with Staff #2 (CMS 209) in exam room #5 on 3/26/2019 at approximately 3:00 p.m. confirmed there was not a humidity policy and procedure in the laboratory SOP.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's

	instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of environmental log sheets and staff interview, the laboratory failed to monitor and document required room temperature (RT) readings as required. Findings include: 1. Temperature log review revealed the laboratory failed to monitor and document RT for the following months: 2017 - July (11 of 25 days), November (8 of 25 days); 2018 - January (10 of 26 days), April (11 of 24 days), December - No RT log was available at the time of survey; 2019 - January and February (No RT logs were available at the time of survey). 2. There were no humidity logs available at the time of survey for 2017, 2018, and 2019 thus far. 3. An interview with Staff #2 (CMS 209) in exam room #5 on 3/26/2019 at approximately 3:00 p.m. confirmed the aforementioned lack of RT and humidity readings for 2017, 2018, and 2019 thus far.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of bacteriology quality control (QC), the laboratory failed to check each batch of media for sterility as required. Findings include: 1. Bacteriology QC review revealed the laboratory failed to perform an incubated sterility check of Strep Select media for 2017, 2018, and 2019 thus far. 2. An interview with Staff #2 (CMS 209) in exam room #5 on 3/26/2019 at approximately 3:00 p.m. confirmed sterility checks were not performed for Strep Select media for the aforementioned dates.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 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. 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, 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: Refer to D 6019
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on testing personnel (TP) document review and staff interview, the laboratory director/technical consultant (LD/TC) failed to delegate competency performance responsibility to qualified TP. Findings include 1. TP document review revealed the LD/TC delegated the performance of initial, six-month, and annual TP competencies to unqualified TP in 2017 and 2018. 2. An interview with Staff #2 (CMS 209) in exam room #5 (CMS 209) at approximately 3:00 p.m. on 3/26/2019 confirmed the LD/TC delegated the aforementioned competency performance to unqualified TP.
D6005	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(c) 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. (c) The laboratory director must be accessible to the laboratory to provide onsite, telephone or electronic consultation as needed. This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure manual (SOP), testing personnel (TP) competency document review, review of laboratory temperature documents, and proficiency test (PT) document review, the laboratory director (LD) failed to provide required oversight over the laboratory. Findings include: 1. Review of the laboratory policy and procedure manual (SOP), testing personnel (TP) competency document review, laboratory temperature document review, and proficiency test (PT) document review revealed the laboratory director (LD) failed to provide required oversight over the laboratory. 2. An interview with Staff #2 (CMS 209) in exam room #5 at approximately 3:00 p.m. on 3/26/2019 confirmed the LD failed to provide oversight over the laboratory upon review of the aforementioned documents.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv)

	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 form revealed event 3 2018 PT specimens were mailed to the laboratory on 12/3/2018. 5. Review of the AOC for initial PT failure in bacteriology revealed the laboratory director signed the AOC on 11/21/2018 which is before specimens for the 3rd event were shipped to the lab.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on testing personnel (TP) document review and staff interview, the technical consultant/laboratory director (TC/LD) failed to perform a required six-month competency on TP. Findings include: 1. TP document review revealed the TC/LD failed to perform a six-month competency for Staff #3 (CMS 209) in 2018. 2. An interview with Staff #2 (CMS 209) in exam room #5 on 3/26/2019 at approximately 3: 00 p.m. confirmed the aforementioned TP did not have a six-month competency performed in 2018.