| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 44D0311945 | 02/21/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Children's Clinic Pllc | 221 W Tyrone Rd, Oak Ridge, TN | |

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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| **D2009** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(1)<br><br>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.<br><br>This STANDARD is not met as evidenced by:<br>========== Based on review of Proficiency Testing attestation sheets for 2017 and 2018 and interview with the primary testing person, determined the primary testing person signed in the director's signature space, resulting in immediate jeopardy. The findings include: 1. Review of Proficiency Testing attestation sheets for 2017 and 2018 revealed primary testing person's signature in the director's signature space. 2. An interview with the primary testing person at approximately 3:00 p.m. February 21, 2019 confirmed he signed in the director's signature space on the 2017 and 2018 PT attestation sheets.<br>========== |
| **D3031** | RETENTION REQUIREMENTS<br>CFR(s): 493.1105(a)(3)<br><br>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.<br><br>This STANDARD is not met as evidenced by:<br>========== Based on review of quality control printouts and assay sheets for CBC testing from September 28, 2017 to February 20, 2019, review of patient CBC orders during those dates and upon interview with the |

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| | primary testing person, determined the laboratory failed to retain 268 days of CBC quality control printouts and no assay sheets for 2017 and 2018 when patient testing was performed, resulting in immediate jeopardy. The findings include: 1. Review of quality control printouts revealed 268 days of quality control not available for review and no control assay sheets for review for 2017 and 2018. 2. Review of patient CBC orders during the 268 days of missing quality control revealed 537 patients were tested. 3. An interview with the primary testing person confirmed he failed to retain CBC quality control printouts and assay sheets for the two year period between September 2017 and February 2019. ========== |
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>========== Based on observation of the laboratory's reagent refrigerator temperature charts, lack of defined reference range for storage of CBC controls, taxo discs, urine and throat culture media plates and upon interview with the primary testing person, determined the laboratory failed to define the proper storage temperature from 2017 to current date, resulting in immediate jeopardy. The findings include: 1. Observed reagent refrigerator's temperature charts which lacked defined reference range for storage of CBC controls, taxo discs, urine and throat culture media plates stored in refrigerator. 2. An interview with the primary testing person at approximately 3:00 p.m. February 21, 2019 confirmed the temperature charts did not contain a defined storage reference range since 2017. ========== |
| **D5415** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(c)<br><br>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.<br><br>This STANDARD is not met as evidenced by:<br>========== Based on observation of in use Complete Blood Count (CBC) controls with no open date expiration date on controls, manufacturer's assay sheet information and upon interview with the primary testing person, determined the laboratory failed to document the 14 day open vial expiration date per manufacturer's assay sheet information on the CBC controls in use, resulting in immediate jeopardy. The findings include: 1. Observation at approximately 9:00 a. m. February 21, 2019 of in use CBC controls with no open date expiration date |

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| | documented. 2. Manufacturer's assay sheet stated the open vial expiration date is 14 days. 3. Interview with the primary testing person at approximately 3:00 p.m. February 21, 2019 confirmed he did not know there was an open vial expiration date for the CBC controls, so none had been documented. ========== |
| **D5417** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(d)<br><br>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.<br><br>This STANDARD is not met as evidenced by:<br>========== Based on review of CBC quality control printouts for 2018 and 2019 which included lot numbers and expiration dates and interview with the primary testing person, determined the controls were used when they had exceeded their expiration date, resulting in immediate jeopardy. The findings include: 1. Review of CBC quality control printouts to include lot number and expiration dates for 2018 and 2019 revealed controls were used after their expiration on the following dates: -3/20/18, 3/27/18, 3/29/18, 4/4/18, 4/6/18, 4/19/18, 5 /4/18, 5/7/18: control lot number-73400712; expiration date=3/14/18. -11/7/18, 12/18 /18, 1/23/19, 1/24/19: control lot number-81420712; expiration date=8/29/18. -2/18 /19, 2/19/19: control lot number-83100712; expiration date=2/13/19. 2. Interview with the primary testing person at approximately 3:00 p.m. February 21, 2019 confirmed the CBC quality control printouts showed controls had exceeded their expiration dates. ========== |
| **D5421** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(1)<br><br>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i) (B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.<br><br>This STANDARD is not met as evidenced by:<br>========== Based on review of new CBC instrument installation validation material 9/27/17, lack of accuracy documentation and lack of verification of normal values for the patient population and an interview with the primary testing person, determined the laboratory failed to perform accuracy and normal patient range verification prior to reporting patient test results, resulting in immediate jeopardy. The findings include: 1. Review of the new CBC installation validation material for 9/27/17 lacked documentation for accuracy and verification of normal values for the patient population. 2. An interview with the primary testing person at approximately 3:00 p.m. February 21, 2019 confirmed that accuracy and verification of patient normal ranges had not been performed for the new CBC instrument. ========== |

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| **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.<br><br>This CONDITION is not met as evidenced by:<br>========== Based on documentation of laboratory deficiencies, determined the laboratory director has not fulfilled his duty to provide overall management and direction for the laboratory in accordance with $493.1407; failed to hire staff with competent experience (Refer to D6004); failed to ensure overall administration of the lab (Refer to D6014); failed to endure proficiency testing reports were reviewed by appropriate staff (Refer to D6018); failed to ensure quality control plan was maintained (Refer to D6020); failed to ensure testing personnel have appropriate education and experience (Refer to D6029) resulting in immediate jeopardy. ========== |
| **D6004** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(a)(b)<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. (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.<br><br>This STANDARD is not met as evidenced by:<br>========== Based on review of primary testing person's documented competencies and work performance since hire date of 11/17 /2016 and upon interview with the primary testing person, determined the laboratory director failed to hire someone with competent experience to perform CBC's (Complete Blood Counts), Urine and Throat Cultures and Urine Sediment Analysis since November of 2016, resulting in immediate jeopardy. The findings include: 1. Review of primary testing person's initial competency upon hire, documented 1/02 /2017, failed to include Urine Sediment Analysis; no documentation of semi-annual competency and review of 2018 annual competency revealed primary testing person documented his own competency. 2. Review of primary testing person's work performance since hire date revealed CBC Quality Controls (QC) not saved for 268 days of patient testing, no background counts and maintenance documented for CBC testing since hire date, expired CBC quality controls documented with patient testing, no quality control performance for Taxo Discs, urine and throat culture media. 3. Interview with the primary testing person at approximately 3:00 p.m. February 21, 2019 confirmed he had never worked in a clinical laboratory prior to hire date and did not know he was supposed to save QC, background counts, document maintenance and perform QC for Taxo Disc, Urine and Throat Culture medias.<br>========== |

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| **D6014** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(3)(iii)<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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.<br><br>This STANDARD is not met as evidenced by:<br>========== Based on review of CBC quality control reports, review of proficiency testing (PT) attestation and result forms, lack of quality controls for taxo discs, urine and throat culture media and interview with laboratory director, determined the laboratory director failed to ensure overall administration of the laboratory ensuring competent personnel since November 2016, resulting in immediate jeopardy. The findings include: 1. Review of CBC quality control (QC) reports revealed no review by director and QC not saved each day of patient testing for 268 days. 2. Review of proficiency testing attestation sheets for 2017 and 2018 revealed primary testing person signed as director and there was no director review for PT results. 3. Lack of quality controls for taxo discs, urine and throat culture media since 2017. 4. Interview with laboratory director at approximately 3:30 p.m. February 21, 2019 confirmed he failed to ensure overall administration of the laboratory to ensure competency of testing personnel since November 2016. ========== |
| **D6018** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(4)(iii)<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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;<br><br>This STANDARD is not met as evidenced by:<br>========== Based on review of 2017 and 2018 Proficiency Testing result forms and upon interview with primary testing person, determined the laboratory director had not ensured review of all proficiency testing results for the two year period, resulting in immediate jeopardy. The findings include: 1. Review of proficiency testing result forms for 2017 and 2018 failed to show review by laboratory director to ensure acceptable performance and to identify problems for the two year period. 2. Interview with the primary testing person at approximately 3: 00 p.m. February 21, 2019 confirmed that all proficiency testing result forms for 2017 and 2018 had not been reviewed by director.<br>========== |
| **D6020** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(5) |

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| | 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.<br><br>This STANDARD is not met as evidenced by:<br>========== Based on review of the quality controls for 2017 through current date 2019 for CBC's, taxo disc, urine and throat culture media, quality control plan and an interview with the laboratory director, determined the laboratory director failed to ensure the quality control plan was maintained since 2017, resulting in immediate jeopardy. The findings include: 1. Review of quality controls for CBC's for 2017 to current date revealed 268 days where quality controls had not been retained. 2. Review of taxo disc, urine and throat culture media for 2017 to current date revealed no quality controls performed. 3. Review of quality control plan revealed that CBC QC was to be performed each day of patient testing and saved for two years. 4. Review of quality control plan for taxo disc revealed that QC was to be performed weekly. 5. Review of quality control plan for urine and throat culture media was to be performed with each new shipment and/or lot number. 6. Interview with the laboratory director at approximately 3:30 p.m. February 21, 2019 confirmed he had failed to review quality controls since 2017 to ensure the quality control plan was maintained.<br>========== |
| **D6029** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(11)<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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.<br><br>This STANDARD is not met as evidenced by:<br>========== Based on review of primary testing person's initial and annual competency since hire date in November of 2016, education and experience and interview with the primary testing person, determined the director failed to ensure testing person's experience, training and competency prior to testing patient specimens, resulting in immediate jeopardy. The findings include: 1. Review of primary testing person's initial competency failed to contain competency review for urine microscopic testing. 2. The primary testing person's annual competency documentation for 2018 was documented by the primary testing person. 3. No proof of education and/or experience performing non-waived testing prior to hire date was available for the primary testing person. 4. Interview with the primary |

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| | testing person at approximately 3:00 p.m. February 21, 2019 confirmed he did not have the education and/or experience working in a non-waived testing laboratory prior to hire date in November 2016. ========== |
| **D6072** | TESTING PERSONNEL RESPONSIBILITIES<br>CFR(s): 493.1425(b)(3)<br><br>Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.<br><br>This STANDARD is not met as evidenced by:<br>========== Based on review of laboratory's quality control (QC) plan for CBC's, taxo disc QC, urine and throat culture media QC, lack of quality controls and maintenance and upon interview with the primary testing person, determined the primary testing person failed to follow laboratory's quality control plan since hire date of November 2016, resulting in immediate jeopardy. The findings include: 1. Review of the laboratory's QC plan for CBC's, taxo disc, urine and throat culture media states to perform and document CBC QC and maintenance daily, taxo disc QC weekly and culture media QC with each new shipment and/or lot number. 2. Lack of CBC quality control and maintenance documentation each day of patient testing, lack of weekly QC documentation for taxo disc and lack of media QC documentation with each shipment and/or lot number. 3. Interview with primary testing person at approximately 3:00 p.m. February 21, 2019 confirmed he failed to follow laboratory's QC policies since hire date. |