| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 44D0685723 | 06/08/2021 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Children's Clinic Of Nashville Plc The | 4322 Harding Road Suite #313, Nashville, 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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| **D2007** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(1)<br><br>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<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the American Proficiency Institute Proficiency Testing (PT) attestation statement's for all 3 event's in 2020, 1st event 2021and interview with the primary testing person, determined that the PT samples were not tested with three out of four testing personnel listed on the Laboratory Personnel Report Form 209. The findings include: 1. A review of the attestation PT records revealed lack of testing personnel signatures on the PT attestation statements for all 3 events in 2020 and 1st event 2021. 2. Interview with primary testing person on 10:00 am on June 8, 2021, confirmed that the PT samples was not performed by three out of four testing personnel as listed on the Laboratory Personnel Report Form 209. |
| **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 the American Proficiency Institute (API) Proficiency Testing (PT) attestation statement's for all 3 events of 2020, 1st event 2021 and interview with the primary testing person, determined the attestation statements were not signed by the |

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| | Laboratory Director and the testing personnel. Findings include: 1. Review of API attestation sheets for all 3 events of 2020 and 1st event 2021 revealed the Laboratory Director and testing personnel did not sign the API PT attestation statements. 2. Interview with primary testing person on June 8, 2021 at 10:00 am confirmed that the Laboratory Director and testing personnel did not sign the API PT attestation statements. |
| **D2015** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(5)(6)<br><br>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the Proficiency Testing (PT) records and interview with the Practice Manager it was determined the laboratory failed to maintain all copies of the instrument printouts, attestation sheets and performance summaries for the PT 1st, 2nd and 3rd events of 2019. The findings include: 1. There were no 2019 PT records available for review to include the instrument printouts, attestation sheets and performance summaries sheets. 2. An interview with the Practice Manager on June 8, 2021 at 10:00 am confirmed the laboratory failed to maintain all copies of instrument printouts, attestation sheets and the performance summaries for the PT 1st, 2nd and 3rd events of 2019. |
| **D3000** | FACILITY ADMINISTRATION<br>CFR(s): 493.1100<br><br>Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.<br><br>This CONDITION is not met as evidenced by:<br>Intakes: TN00054407 Based on lack of SARS CoV2 reporting documentation and interview with the Practice Manager, the laboratory failed to report all SARS CoV2 performed to the Public Health Department between Jan 6, 2021 through June 8, 2021. Findings include: 1. Lack of documentation available for review determined the laboratory failed to report 280 SARS CoV2 test results between Jan.6, 2021 through |

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| | June 8, 2021. 2. Interview with the Practice Manager confirmed the laboratory failed to report 280 SARS CoV2 test results performed between Jan.6, 2021 through June 8, 2021 to the Public Health Department. |
| **D5291** | GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1239(a)<br><br>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory Quality Assurance Plan (QA) and interview with Practice Manager, the laboratory failed to follow the laboratory's written QA plan for 2019, 2020 and January through May 2021. Findings include: 1. Review of the laboratory's QA Plan state's the laboratory will perform quarterly evaluations of the laboratorys set of systems to include: Patient test management Quality control and instrumentation Proficiency testing Comparison of test results Personnel assessment Communications Laboratory errors Complaints 2. Interview June 8, 2021 at 11:00 am with the Practice Manager confirmed that the laboratory failed to perform quarterly evaluations of the laboratory set of services for 2019, 2020 and January through May 2021. |
| **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 lack of laboratory room temperature and humidity logs and interview with the Practice Manager, the laboratory failed to define and monitor the laboratory room temperature and humidity for 2019 and 2020. Findings: 1. There were no room temperature or humidity logs available for review for 2019 and 2020. 2. Interview with Practice Manager on June 8, 2021 at 08:30 am confirmed the laboratory failed to to define and monitor the laboratory room temperature and humidity for 2019 and 2020. |
| **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 |

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| | 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 the laboratory's Proficiency Testing (PT) records, personnel records and lack of quality assessment (QA) records and interview with the practice manager, the Laboratory Director failed to oversee the overall operations of the laboratory for 2019, 2020 and January through May 2021. The findings include: 1. Review of the PT records revealed the laboratory director failed to sign the attestation statements attesting to the routine integration of PT the samples among all testing personnel for 2019, 2020 and January through May 2021. 2. Review of the personnel records revealed the laboratory director failed to ensure the testing personnel competency assessments included the six criteria for competency assessment required by Centers for Medicare and Medicaid (CMS) in 2019 and 2020. 3. Lack of quality assessment records available for review revealed the laboratory director failed to ensure the laboratory follow the written QA plan for 2019 and 2020 and January through May 2021. 4. Interview with the practice manager on June 8, 2021 at 12:30 pm confirmed the laboratory director failed to oversee the overall operations of the laboratory for 2019, 2020 and January through May 2021. |
| **D6046** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(8)<br><br>(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of employee personnel records for 2019 and 2020 and interview with the practice manager, the laboratory's Technical Consultant failed to observe and document the six required criteria for assessing personnel competencies of 4 of the 4 testing personnel. The findings include: 1) Review of employee personnel records for 2019 and 2020 revealed the six required criteria of competencies was not documented to include: direct observation of routine patient test performance; monitoring the recording and reporting of test results; review of intermediate test results or worksheets, quality control records, proficiency testing results and preventative maintenance records; direct observation of performance of instrument maintenance and function checks; assessment of test performance through previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and, assessment of problem solving skills. 2) An interview with the practice manager on June 8, 2021 at 10:00 am, confirmed 4 of 4 testing personnel were not evaluated by the Technical Consultant using the six criteria for competency assessment required by Centers for Medicare and Medicaid (CMS) in 2019 and 2020. |