Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	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
D2007	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	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 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	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	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 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	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	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	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	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.