Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0670561	10/08/2025
Name of Provider or Supplier	**Street Address, City, State**	
Children's Home Of Pittsburgh, The	5324 Penn Avenue, Pittsburgh, PA	

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
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 review of the laboratory's Proficiency Testing (PT) Procedure, College of American Pathologists (CAP) PT records, lack of documentation, and interview with Technical Consultant (TC) #5, the laboratory failed to document the evaluation and verification activities performed for 1 of 2 CAP PT chemistry testing events in 2025. Findings include: 1. The laboratory's PT procedure states, "All results outside of the acceptable range will be investigated and documented on proficiency testing investigation and unacceptable result form." 2. On the day of the survey, 10/08/2025 at 10:55 am, review of the laboratory's CAP PT records revealed the laboratory failed to document the corrective action taken when the laboratory received a score of less than 100% for the following 1 of 2 CAP PT chemistry testing events performed in 2025: - CAP AQIS-A-2025 Critical Care Blood Gas: (PCO2) 60% 3. TC #5 (CMS 209 personnel #26, dated 09/30/2025) confirmed the above findings on 10/8/2025 at 11:28 am.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's verification of performance specifications records, lack of documentation, and interview with Technical Consultant (TC) #5, the laboratory failed to verify the required performance specifications for Chemistry and Hematology testing performed on 1 of 3 i-STAT system analyzers before reporting patient test results from 01/09/2024 to the day of survey. Findings Include: 1. On the day of survey, 10/8/2025 at 10:30 am, review of the laboratory's verification of performance specification records for 1 of 3 i-STAT system analyzers (s/n 21340355) performed on 01/09/2024 revealed the laboratory failed to perform a reference range /normal value study appropriate for the laboratory's patient population for the following analytes from 01/09/2024 to 10/08/2025: - pH - Carbon Dioxide Partial Pressure (PCO2) - Oxygen Partial Pressure (PO2) - Chloride (Cl) - Sodium (Na) - Ionized calcium (iCa) - Potassium (K) - Glucose (Glu) - Urea Nitrogen (BUN) - Hematocrit (HcT) 2. The laboratory could not provide a policy that included the laboratory's criteria to ensure a reference range/normal value study was appropriate for the laboratory's patient population. 3. The laboratory performed 2850 chemistry tests and 570 hematology tests in 2024 (CMS 116, estimated annual volume, dated 09 /30/2025). 4. TC #5 (CMS 209 personnel #26, dated 09/30/2025) confirmed the above findings on 10/8/2025 at 11:28 am.