Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 18D0984842	**(X3) Date Survey Completed** 08/24/2023
Name of Provider or Supplier All-Star Pediatrics	**Street Address, City, State** 6425 Bardstown Rd, Louisville, KY	
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 Recertification Survey was conducted on 08/24/2023. The facility was found not to be in compliance with the laboratory requirements of 42 CFR Part 493 with deficiencies cited.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) 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. This STANDARD is not met as evidenced by: Based on observation, manual review, and confirmed in interview with Laboratory Director (LD) and Testing Personnel 1 (TP1), the laboratory failed to perform two of the four required verification of performance specifications for an unmodified, FDA-cleared or approved system. Findings include: 1. Observed on 08/24/2023 at 9:15 AM, a Sysmex XP-300 Hematology analyzer was in use for testing. 2. Review of the manual titled "Resource & Validation Manual, Sysmex XP-300 Hematology Analyzer" in Section 3 "Validation Protocols" and "Table of Contents", stated, " It is the customer's responsibility to perform additional studies, following the requirements of their accrediting agencies. The following protocols are provided: "Correlation studies and Reference Range verification." 3. Review of the manual titled "Resource & Validation Manual, Sysmex XP-300 Hematology Analyzer" revealed failure to include verification studies for the following: a. accuracy b. reference intervals. 4. In an interview on 8/24/2023 at 11:25 AM, the LD and TP1 were asked if accuracy and reference interval verification studies had been performed on the XP-300 Hematology

	analyzer. The LD and TP1 stated the accuracy and reference interval verification studies were not performed on the analyzer. This confirmed the findings.