Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 15D2086917	**(X3) Date Survey Completed** 10/31/2022
Name of Provider or Supplier Kids First Pediatric Specialists Georgetown	**Street Address, City, State** 5300 Sr 64, Ste 105, Georgetown, IN	
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**
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to evaluate the zero scores for four of 14 Hematology analytes (Granulocytes, Lymphocytes, Monocytes, and White Blood Cell Differential) received during event 1 2021. Findings Included: 1.) Review of American Proficiency Institute Proficiency Testing (PT) evaluation documentation for Hematology/Coagulation Event 1 in 2021 revealed the following: White Blood cell differential- 0% Granulocytes- 0% Lymphocytes-0% Monocytes-0% The lab did not have the original instrument printouts for the Proficiency Testing failure documentation, nor documentation of an evaluation of the scores. 2.) During an interview on 10/31/2022 at 2:49 PM, SP#1 (Office Manager) confirmed the laboratory did not retain the original instrument printouts or documentation of evaluation of the zero scores for proficiency testing received during event 1 of 2021 for the above analytes.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the

	overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on observation, record review and interview, the laboratory failed to: a) ensure three of three controls (High, Normal, and Low) were not expired. (Refer to D5417); b) perform six-month calibrations for one of one Hematology analyzer (Cell-Dyn Emerald) for twelve of twelve months (January to December) in 2021. (Refer to D5439); and run two levels of controls (Low or normal) for complete blood Count (CBC) testing on 3/17/2021 (Refer to D5445).
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) 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. This STANDARD is not met as evidenced by: Based on observation, record review and interview, the laboratory failed to ensure three of three controls (High, Normal, and Low) in use for ten of ten patients tested from 10/27/2022 to 10/31/2022 on one of one hematology machine (Cell-Dyn Emerald) were not expired. Findings Included: 1.) During a tour of the lab on 10/31 /2022 at 10:00AM, revealed a refrigerator containing the following controls: a.) High control lot H 2234 was opened on 10/17/2022 b.) Normal control lot N2234 opened on 10/17/2022. c.) Low control lot L2234 opened on 10/17/2022 There were no other open controls in the refrigerator. Cell Dyn controls are used in the Cell-Dyn Emerald system. 2.) Review of "Cell-DYN 18 Plus Control" package insert, not dated, read "Storage and Stability ... Unopened containers are stable until the expiration date indicated. Once opened, containers can be used only for the number of days stated on the assay sheet." 3.) Review of the assay sheet for the Cell-Dyne 18 Plus control, dated August 5, 2018, read "8 consecutive-day Open Tube Stability." 4.) Review of October CBC "Lab Log" revealed ten patients were tested for complete blood count (CBC) from 10/24/2022 to 10/31/2022. This was past the eight consecutive day "open tube stability" date of 10/24/2022. 5.) The annual test volume for Hematology is 285. 6.) During an interview on 10/31/2022 at 4:29 PM, SP#1 (Office Manager) confirmed the laboratory failed to use High, Normal and Low controls that were not expired in for ten out of ten patients tested.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following

	occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on observation, record review and interview, the laboratory failed to perform six-month calibrations for one of one Hematology analyzer (Cell-Dyn Emerald) for twelve of twelve months (January to December) in 2021. Findings included: 1.) During a tour of the lab on 10/31/2022 at 10:00 AM, revealed a Cell-Dyn Emerald used in Hematology testing for complete blood count (CBC). 2.) Review of the "Cell-DYN Emerald Operator's Manual" page 6-1 states, "calibration is a procedure that confirms the accuracy of the Cell-DYN Emerald." 3.) Review of "Services and Maintenance Log" for Cell-Dyn Emerald indicated the frequency for calibration is semi-annually. 4.) Review of 2021 "Service and Maintenance Logs" for Cell-DYN Emerald revealed for January-December in 2021 no calibrations were performed on the Cell-DYN Emerald. 5.) During interview on 10/31/2022 at 4:29 pm, SP#1 (Office Manager) confirmed the laboratory failed to perform six-month calibration as required for the Cell-Dyn Emerald during 2021.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation, record review and interview, the laboratory failed to run two levels of controls (Low or Normal) for PT#4 tested for complete blood count (CBC) testing on 3/17/2021. Findings included: 1.) During a tour of the lab on 10/31/2022 at 10:00 AM revealed a Cell-Dyn Emerald used in Hematology testing for CBC testing. 2.) Review of Cell DYN Emerald Control printouts revealed a high control was run on 3/17/2021 at 9:48 AM. There was no documentation of a normal and low control run for 3/17/2021. 3.) Review of "CELL-DYN 18 Plus Control" manufacturer's instructions read, "Summary and Principle ... It is an established laboratory procedure to use stable quality control material to monitor the performance of diagnostic tests. CELL-DYN 18 Plus Control is composed of stable materials that provide a means of verifying the accuracy and precision of CELL-DYN hematology results. It is handled and run in the same manner as patient specimens, and it is available in three levels

	representing low, normal, and high results." 4.) Review "CELL-DYN Emerald Operator's Manual" on page 11-9 stated, "before running patient specimens, run a minimum of two levels of control." 5.) Review of patient reports revealed that PT#4 was tested for CBC on 3/17/2021. 6.) During interview on 10/31/2022 at 4:29 pm, SP#1 confirmed the laboratory failed to run two levels of control (Low or Normal) for PT#4 tested for CBC on 3/17/2021.