Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D0870919	(X3) Date Survey Completed 07/18/2023
Name of Provider or Supplier Riverside Pediatrics, Inc	**Street Address, City, State** 2873 S Ingram Ave, Sedalia, MO	

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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) 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. This STANDARD is not met as evidenced by: Based on review of the Horiba ABX Micro ES 60 operations manual, lack of temperature and humidity logs, and interview with the testing personnel (TP) #1, the laboratory failed to follow manufacturer's instructions for monitoring and documenting room temperature and humidity for 3 of 3 months. Findings: 1. Review of the Horiba ABX Micro ES 60 operations manual states, "Instrument operating temperature: from +16 C (+61 F) to +30 C (+86 F). Relative humidity of 85% maximum, without condensation." 2. Lack of room temperature logs confirmed no documentation of room temperature and humidity in May 2023 to date July 18, 2023 in the Horiba ABX Micro ES 60 room. 3. Interview with the TP #1 on July 18, 2023 at 2:00 PM confirmed the laboratory failed to follow manufacturer's instructions for monitoring and documenting room temperature and humidity.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

	This CONDITION is not met as evidenced by: Based on review of performance specifications, review of proficiency testing, lack of procedures and interviews, the laboratory failed to meet the condition of laboratory director (LD). The LD failed to verify the manufacturer's reference intervals (Refer 6013); failed to ensure the laboratory followed an approved corrective action plan for proficiency testing (Refer 6019); and failed to ensure an approved procedure manual was available to all testing personnel responsible for any aspects of the testing process (Refer 6031).
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on review of performance specifications for the Horiba ABX Micro ES 60 hematology analyzer and interview with the testing personnel (TP) #1, the laboratory director failed to use verification procedures adequate to determine the manufacturer's reference intervals (normal values) as pertinent performance characteristics prior to reporting patient test results for 6 of 6 analytes. Findings: 1. Review of the performance specifications for the Horiba ABX Micro ES 60 hematology analyzer showed the laboratory director failed to use verification procedures adequate to determine the manufacturer's reference intervals (normal ranges) were appropriate for the laboratory's patient population for the analytes: red blood cell (RBC), hemoglobin, hematocrit, platelet, white blood cell (WBC) and differential prior to the beginning of patient testing in May 2023. 2. Interview with the TP#1 on July 18, 2023 at 2:00 PM confirmed the laboratory failed to verify performance specifications prior to reporting patient test results.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of 2022 and 2023 proficiency testing (PT) results, lack of corrective action plan, and interview with testing personnel (TP) #1, the laboratory director failed to ensure the laboratory followed an approved corrective action plan for PT

	results found to be unacceptable or unsatisfactory. Findings: 1. Review of PT results showed no approved corrective action plan for the following: -2022 hematocrit was unsatisfactory at 80% for event 1, 2, and 3. -2022 red blood cell was unsatisfactory at 80% for event 1. -2022 hemoglobin was unsatisfactory at 80% for event 3. -2023 hematocrit was unacceptable at 0% for event 1. 2. Interview with TP # 1 on July 18, 2023 at 2:30 PM confirmed the laboratory director failed to ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on review of laboratory procedures and interview with testing personnel (TP) #1, the laboratory director (LD) failed to ensure an approved procedure manual was available to all testing personnel responsible for any aspect of the testing process. Findings: 1. Review of laboratory procedures showed no laboratory procedures are available for the following: -Validation of new testing equipment -Approved normal ranges for testing -General operating of hematology analyzer 2. Interview with TP #1 on July 18, 2023, at 3:00 PM confirmed the LD failed to ensure an approved procedure manual was available to all testing personnel.