| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 26D0870919 | 09/11/2025 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Riverside Pediatrics, Inc | 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 |
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| **D1001** | CERTIFICATE OF WAIVER TESTS<br>CFR(s): 493.15(e)<br><br>493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation of laboratory and interview with the office manager the laboratory failed to ensure tests kits and supplies were not used when they had exceeded their expiration date. Findings: 1. Observation of the laboratory showed the following still in use: -1 container of Dia Trust Extraction buffer COVID-19 AG Rapid test lot #COVGCB1008 expiration 11/19/22 -1 container of Dia Trust Extraction buffer COVID-19 AG Rapid test lot #COVGCA1017 expiration 12/3/22 -1 box celltrion Dia Trust COVID-19 AG negative control swabs lot #COBGCA1002 expiration 10/24/22 and positive swabs lot #COVGCA1002 expiration 10/24/22 -2 bottles of Leadcare 11 lead control lot #2010m expiration 3/17/22 -Leadcare 11 heparinized capillary tubes lot #1710 expiration 6/19/22 -1 box Abbott ID Now influenza A & B2 lot #M113356 expiration 11/5/20 -2 boxes of Binax Now COVID-19 self test lot #189608 expiration 5/19/23 -1 box Status Lifesign COVID-19/Flu A & B test lot #883A11H expiration 3/2018 2. Interview with the office manager on 9/10 /25 at 10:30 AM confirmed the laboratory failed to ensure test kits and supplies were not used when they had exceeded their expiration date. |
| **D5400** | ANALYTIC SYSTEMS<br>CFR(s): 493.1250<br><br>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 |

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| | 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.<br><br>This CONDITION is not met as evidenced by:<br>Based on review of Horiba ABX Micros 60 procedures, hematology patient reports, Horiba ABX Minocal Calibrator and Horiba ABX Minotrol 16 Whole Blood Hematology Control package inserts and hematology patient numbers, lack of temperature logs, observations of laboratory room temperature supplies and laboratory refrigerator and interviews, the laboratory failed to meet the condition of analytic systems. The laboratory failed to provide an accurate written procedure for complete blood count (Refer to D5401); failed to document laboratory refrigerator temperature (Refer to 5413); failed to ensure laboratory hematology calibrators and EDTA (ethylenediaminetetraacetic acid) capillary tubes were not used when they had exceeded their expiration date (Refer to 5417). |
| **D5401** | PROCEDURE MANUAL<br>CFR(s): 493.1251(a)<br><br>(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of Horiba ABX Micros 60 procedure, review of patient reports, and interview with the testing personnel (TP) #1, the laboratory failed to provide an accurate written procedure for complete blood count (CBC). Findings: 1. Review of Horiba ABX Micros 60 procedure showed normal range for white blood cell (WBC), red blood cell (RBC), hemoglobin (HGB), hematocrit (HCT), and platelet (PLT): 2-4 weeks WBC (10^3/MM^3) 5.0-21.0 RBC (10^6/MM^3) 3.90-5.80 HGB (g/dL) 12.5-19.5 HCT (%) 38.0-63.0 PLT (um^3) 150-450 1-2 months WBC (10^3/MM^3) 5.0-19.5 RBC (10^6/MM^3) 3.0-5.4 HGB (g/dL) 32.0-42.0 HCT (%) 10.5-14.0 PLT (um^3) 150-450 2-6 months WBC (10^3/MM^3) 5.5-18.0 RBC (10^6/MM^3) 3.8-5.4 HGB (g/dL) 10.0-16.5 HCT (%) 32.0-48.0 PLT (um^3) 150-450 7 months-6 years WBC (10^3/MM^3) 6.0-15.0 RBC (10^6/MM^3) 4.20-6.30 HGB (g/dL) 10.5-14.0 HCT (%) 33.0-42.0 PLT (um^3) 150-450 2. Review of patient reports showed 1-2 months normal range: HGB (g/dL) 10.5-14.0 HCT (%) 32.0-42.0 3. The laboratory was unable to provide a CBC report for a patient greater than 6 years. 4. Interview with TP #1 on September 10, 2025 at 11:30 AM stated "we see patient's older than 6 years of age". 5. Interview with TP #1 on September 10, 2025 at 11:30 AM confirmed the laboratory failed to provide an accurate written procedure for CBC. |
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>(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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) |

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| | Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.<br><br>This STANDARD is not met as evidenced by:<br>Based on lack of temperature logs, observation of laboratory refrigerator, review of package inserts and interview with the testing personnel (TP) #1, the laboratory failed to document refrigerator temperature from 2023 to date September 10, 2025. Findings: 1. Lack of temperature log showed no documentation of refrigerator temperature. 2. Observation of laboratory refrigerator revealed Horiba ABX Minocal Calibrator and Horiba ABX Minotrol 16 Whole Blood Hematology Control stored within refrigerator on September 10, 2025. 3. Review of Horiba ABX Minocal Calibrator and Horiba ABX Minotrol 16 Whole Blood Hematology Control package inserts showed storage requirements, " Do not freeze. ABX Minocal and Minotrol tubes should be tightly capped and stored at 2 to 8 degrees Celsius". 4. Interview with the TP #1 on September 10, 2025 at 11:00 AM confirmed the laboratory failed to document refrigerator temperature. |
| **D5417** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(d)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation of laboratory refrigerator, observation of room temperature supplies, review of hematology patient numbers, and interview with the office manager, the laboratory failed to ensure laboratory hematology calibrators and EDTA (ethylenediaminetetraacetic acid) capillary tubes were not used when they had exceeded their expiration date. Findings: 1. Observation of laboratory refrigerator showed Horiba Minocal Calibrator lot # CX498 expiration 10/05/2024 still in use. 2. Observation of room temperature showed EDTA capillary tubes lot #22H015 expiration 8/31/24 still in use. 3. The laboratory performs approximately 450 CBC's (complete blood counts) per year. 4. Interview with the office manager on September 10, 2025 at 11:00 AM confirmed the laboratory failed to ensure laboratory hematology calibrators and EDTA capillary tubes were not used when they had exceeded their expiration date. |
| **D6000** | MODERATE COMPLEXITY LABORATORY DIRECTOR<br>CFR(s): 493.1403<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>Based on observations of a laboratory drawer and the hematology area, and interviews, the laboratory failed to meet the condition of laboratory director (LD). The LD failed to provide a safe environment in which employees are protected from |

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| | physical, chemical, and biological hazards (Refer to D6011); the LD failed to ensure testing personnel are performing hematology test methods as required for accurate and reliable results (Refer to D6014). |
| **D6011** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(2)<br><br>(e)(2) provide a safe environment in which employees are protected from physical, chemical, and biological hazards;<br><br>This STANDARD is not met as evidenced by:<br>Based on observation of a drawer in the laboratory and interview with the office manager, the laboratory director (LD) failed to provide a safe environment in which employees are protected from physical, chemical, and biological hazards. Findings: 1. Observation of a drawer in laboratory showed an open package of "sky flakes crackers". 2. Interview with the office manager on September 10, 2025 at 12:00 PM confirmed the LD failed to provide a safe environment in which employees are protected from physical, chemical, and biological hazards. |
| **D6014** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(3)(iii)<br><br>(e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results;<br><br>This STANDARD is not met as evidenced by:<br>Based on observation of hematology area, interview with testing personnel (TP) #1 and office manager, the laboratory director (LD) failed to ensure testing personnel are performing hematology test methods as required for accurate and reliable results. Findings: 1. Observation of hematology area showed EDTA capillary tubes lot #22H015 expiration 8/31/24 still in use. 2. Interview with TP #1 stated they only perform finger stick for CBC's (complete blood count). 3. The laboratory performs approximately 450 CBC's annually. 4. Interview with TP #1 stated she did not know the EDTA capillary tubes had an expiration date. 5. Interview with the office manager on September 10, 2025 at 12:00 PM confirmed the LD failed to ensure testing personnel are performing hematology test methods as required for accurate and reliable results. |
| **D6054** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(9)<br><br>(b)(9) Thereafter, evaluations must be performed at least annually<br><br>This STANDARD is not met as evidenced by:<br>Based on review of testing personnel (TP) competency assessments, and interview with the office manager, the technical consultant (TC) who is also the laboratory director (LD), failed to document annual competency assessment for two of two moderate complexity testing personnel in 2023, 2024 and to date September 10, 2025. Findings: 1. Review of 2023 competency assessments showed no TC signature documented on competency for TP #1 and TP #2. 2. Review of 2024 competency |

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| | assessments showed no TC signature documented on competency for TP #1 and TP #2. 3. Interview with the office manager on September 10, 2025 at 10:15 AM confirmed, the TC failed to document competency assessment for two moderate testing personnel. |