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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 18D0931536 | (X3) Date Survey Completed 01/18/2024 |
| Name of Provider or Supplier Pediatric And Neonatal Specialists | Street Address, City, State 6500 Preston Hwy, 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 |
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| D0000 | A Recertification Survey was initiated on 01/18/2024 and concluded on 01/18/2024. The facility was found not to be in compliance with the laboratory requirements of 42 CFR Part 493 with deficiencies cited. |
| D2009 | <p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on document review of facility proficiency test (PT) records and interview, the laboratory failed to ensure the Laboratory Director (LD) and Testing Personnel (TP) signed a proficiency testing attestation statement for two (2) of three (3) proficiency test events reviewed (Events 1 and 2 of 2023). The LD and TP failed to attest the routine incorporation of the American Proficiency Institute (API) proficiency test samples into the patient workload using the facility's routine methods. Findings included: Review of facility documentation revealed the laboratory had no record of signed attestation statements from the LD and TP for Events 1 and 2 of 2023 for hematology. The attestation statement forms for Events 1 and 2 of 2023 were not available for review. During an interview on 01/18/2024 at 11:03 AM, TP #1 stated the laboratory did not have record of signed attestation statements for Events 1 and 2 of 2023 for hematology.</p> |
| D2127 | <p>HEMATOLOGY CFR(s): 493.851(d)</p> <p>Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a</p> |

score of 0 for the testing event.

This STANDARD is not met as evidenced by:

Based on document review and interview, the laboratory failed to return PT results for hematology within the time frame specified by the program, resulting in unsatisfactory performance and a score of 0 for the testing event. Findings included: Review of the laboratory's records for the hematology PT event 2 of 2023 revealed that the results for one or more testing events were not submitted to the American Proficiency Institute (API) within the required time frame. The laboratory's Proficiency Testing Evaluation reports from the API for the relevant period indicated scores of 0% for the affected testing events (Event 2 of 2023), consistent with the program's policy of assigning a score of 0 for late submissions. During an interview on 01/18/2024 at 11:45AM, Testing Personnel (TP) #1 confirmed that there were delays in submitting the PT results for the specified events due to a change in Technical Consultant (TC) at the end of 2022.