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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 18D0321880 | (X3) Date Survey Completed 01/18/2024 |
| Name of Provider or Supplier Kaplan Barron Pediatrics | Street Address, City, State 4117 Browns Ln, 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 01/18/2024. The facility was found to not be in compliance with the laboratory requirements of 42 CFR Part 493 with standard deficiencies cited. |
| D3039 | <p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(5)</p> <p>Quality system assessment records. Retain all laboratory quality system assessment records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to keep record of quality assurance (QA) documentation for 2023 for two (2) of two (2) consecutive quarters. Findings included: Record review on 01/18/2024 at 3:05 p.m. revealed that QA was not completed for quarter months of September 2023 and December 2023. During an interview on 01/18/2024 at 3:05 p.m., Testing Personnel (TP) #1 confirmed that QA was not documented for September 2023 and December 2023.</p> |
| D5807 | <p>TEST REPORT CFR(s): 493.1291(d)</p> <p>Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to monitor accuracy of patient test reference ranges within the procedure when compared to reference ranges in patient test reports for year 2022 and 2023 for four (4) of four (4) patient test</p> |

reports. Findings included: Record review on 01/18/2024 at 3:30 p.m. revealed reference ranges in a patient test report did not match reference ranges in the laboratory's procedure for Lymphocyte (LYM) %. a.) Patient test report had ranges for LYM% for an individual twelve (12) to eighteen (18 years) as 24% to 54% b.) Laboratory ranges for LYM% for an individual twelve (12) to eighteen (18 years) as 24%-50% During an interview on 01/18/2024 at 3:30 p.m., Testing Personnel (TP) #1 and the Laboratory Director (LD) confirmed that reference ranges on the patient test reports did not match reference ranges in the laboratory's procedure for Lymphocyte (LYM) analyte.