

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D0321880	(X3) Date Survey Completed 08/24/2021
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
D2128	<p>HEMATOLOGY CFR(s): 493.851(e)</p> <p>(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.</p> <p>This STANDARD is not met as evidenced by: Based on staff interview and record review on 08/24/2021, the laboratory director failed to write a corrective action for the third event of 2020. Findings include: 1. Record review revealed the laboratory scored eighty-six percent (86%) for the third Hematology event in 2020. Further review revealed the laboratory did not document a corrective action for the event. 2. The laboratory staff acknowledged on 08/24/2021 at 10:59 AM that the laboratory did not have a process to ensure all proficiency samples with a score of less than 100% were investigated and reviewed by the medical director.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p>

This STANDARD is not met as evidenced by:

Based on staff interview and procedure review on 08/24/2021, the laboratory director failed to ensure the laboratory's procedure used for labeling samples was followed from 09/18/2019 through 08/24/2021. Findings include: 1. A laboratory tour revealed that the Complete Blood Count (CBC) tube for patient # 1 was labeled with the first name only. 2. The procedure review on 8/24/2021 at 11:05 AM revealed that the laboratories' CBC policy required all samples labeled with name, date of birth, tech initials, and time. 3. The staff acknowledged at 11:05 AM on 08/24/2021 that the facility did not have a mechanism to ensure that the policy for labeling samples was followed from 09/18/2021 through 08/24/2021.