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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 31D0104132 | (X3) Date Survey Completed 06/17/2021 |
| Name of Provider or Supplier Tenafly Pediatrics | Street Address, City, State 301 Bridge Plaza North, Fort Lee, NJ | |
| 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 |
|---------------------------|---|
| D5411 | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Operators Manual (OM), Procedure Manual (PM), and interview with the Laboratory Director (LD), the laboratory failed to follow the OM for "Preparation for Calibration" from 5/15/19 to the date of survey. The findings include: 1. The OM stated to "perform a repeatability/precision study by running one normal patient sample tens times" , "Calculate the Coefficient of Variation (CV) for each of the 5 parameters to ensure repeatability is acceptable ." 2. There was no CV calculated for Calibration performed on 5/15/19, 10/3/19 and 11/6/20. 3. The LD confirmed on 6/17/21 at 10:45 AM that the laboratory did not follow the OM.</p> |
| D5421 | <p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> |

This STANDARD is not met as evidenced by:

Based on surveyor review of the Performance Specification (PS) records and interview with the Laboratory Director (LD), the laboratory failed to ensure that all PS procedures were performed for Hematology testing on the Horiba ABX Advia from October 2020 to the date of survey. The finding includes: 1. The laboratory did not verify Patient Normal Range. 2. The LD confirmed on 6/17/21 at 11:15 am that not all PS were performed.