

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0210275	(X3) Date Survey Completed 04/24/2019
Name of Provider or Supplier Riverdale Park Pediatrics Pc	Street Address, City, State 6103 Baltimore Ave T-1, Riverdale, MD	
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
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on quality control (QC) record review, observation, and interview with the technical consultant (TC), the laboratory failed to ensure that hematology QC was not used after it exceeded its expiration date. Findings: 1. The laboratory uses the "Minotrol-16 Hematology Reference Control" to run QC on their Horiba ABX Micros 60 hematology analyzer. During a tour of the laboratory at 9:15 AM, it was observed that the in-use hematology QC, lot # MX416, expiration date 5/5/19 was not labeled with the date the control was opened. 2. During an interview, the TC and testing person #1 stated that the opened QC was "good until the expiration date on the box"; and 3. A review of the package insert that came with the QC showed that under "stability and storage," "opened tubes are stable for 16 days provided they are handled properly." 4. During an interview on 4/24/19 at 12:00 PM, the TC confirmed that hematology QC was run using controls which had expired.</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</p>

the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on hematology analyzer validation record review and interview with the technical consultant (TC), the laboratory did not ensure that the comparison study between the old and new hematology analyzer was evaluated for acceptability before using the new instrument. Findings: 1. The laboratory began using a Horiba ABX Micros 60 hematology analyzer in May, 2018. A comparison study was performed on 5/1/18 by running 30 specimens on the old and new hematology analyzer. 2. A review of the comparison study showed that the results were not evaluated for acceptability by the laboratory director before the analyzer was put in to use. 3. During an interview on 4/24/19 at 12:00 PM, the TC confirmed that the comparison study between the old and new hematology analyzer was incomplete at the time of the survey.