

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D0963688	(X3) Date Survey Completed 01/02/2020
Name of Provider or Supplier Palmetto Adult Medicine	Street Address, City, State 1295 Wilson Hall Road, Sumter, SC	
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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: During an onsite recertification survey on 1/2/2020, based on lack of documentation and testing personnel interview, the laboratory failed to retain hematology quality control (QC) and calibration records for at least two years. Findings include: 1. Hematology QC records from January 2019 through September 2019 and hematology calibration records from 2018 were not available for review on the day of the survey. 2. Testing personnel confirmed during an interview at 3:30 pm that the records were not available.</p>
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: During an onsite recertification survey on 1/2/2020, based on proficiency testing record review and testing personnel interview, the laboratory failed to review and evaluate proficiency testing results for five of five proficiency testing events reviewed from 2018 through 2019 (2018, Events 1, 2, and 3; 2019, Events 1 and 2), and failed to evaluate failures on two of five proficiency events reviewed (2018, Event 1 and 2019, Event 2). Findings include: 1. Review of graded proficiency testing reports</p>

from American Proficiency Institute (API) revealed the following reports that were not reviewed: 2018, Events 1, 2, and 3; 2019, Events 1 and 2. 2. Review of graded proficiency testing reports from API revealed the following scores: a. 2018, Event 1: 60% monocytes b. 2019, Event 2: 60% creatine kinase There was no documentation of evaluation or corrective action for the failures. 3. Testing personnel confirmed during the exit interview at 4:30 pm that the laboratory had failed to evaluate the unacceptable proficiency testing results.