

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  33D0971664	<b>(X3) Date Survey Completed</b>  06/29/2018
<b>Name of Provider or Supplier</b>  Ronald C Fagan Md Pc	<b>Street Address, City, State</b>  4900 Hempstead Turnpike, Farmingdale, NY	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5211</b>	<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: Based on the surveyor's review of American Proficiency Institute (API) Proficiency Testing (PT) reports and an interview with the testing person, the laboratory failed to evaluate, perform and document remedial action for the PT scores of less than 100% for the following analytes: 2017 first event: Hematocrit = 80% Hemoglobin = 80%</p>
<b>D5417</b>	<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 a surveyor's review of the hematology quality Control (QC) records and an interview with the testing person, the laboratory failed to discontinue the use of the expired quality control materials. FINDINGS: 1. On June 29, 2018 at approximately 3: 30 PM the testing person confirmed surveyor's findings that the laboratory used 3 levels of expired QC for hematology analytes testing from 10/24/17 through 10/30/17. Low QC lot # 067500, normal QC lot 077500, high QC lot # 087500 expiration date 10/23/17. 2. Approximately 30 patients were tested for hematology using the expired quality control materials during the above time frame.</p>

**D5437**

**CALIBRATION AND CALIBRATION VERIFICATION**

CFR(s): 493.1255(a)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:

Based on a surveyor's review of hematology calibration records and interview with the testing person, calibration of the hematology analyzer was not performed at the frequencies required by the laboratory's calibration protocol and by the manufacturer of the analyzer. FINDINGS: 1. The laboratory is using the Coulter AcT Diff analyzer. The laboratory's calibration policy and the manufacturer of the hematology analyzer require analyzer calibration every six months. 2. On June 29, 2018 at approximately 3:30 PM the testing person confirmed that the documentation of the AcT Diff analyzer calibration available for review was for calibration performed on 7/16/16, 9/20/17 and 1/6/18. The hematology analyzer was therefore out of calibration from 1/17/2017 through 9/19/2017. 3. The records of calibration performed on 7/8/2017 indicated that calibration failed for multiple analytes. 4. Approximately 100 patient specimens were tested and reported for hematology during the above time period when analyzer was out of calibration.

**D5469**

**CONTROL PROCEDURES**

CFR(s): 493.1256(d)(10)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on surveyor's review of Quality Control (QC) records and interview with the testing person, the laboratory failed to program the manufacturer expected ranges, as defined on the QC assay sheets, into the Beckman Coulter AcT Diff analyzer. FINDINGS: 1. On June 29, 2018 at approximately 3:30 PM the testing person confirmed the surveyor's review of QC records finding that the laboratory failed to

program the established QC ranges into the Beckman Coulter AcT Diff analyzer for hematology tests performed in calendar year 2017 and up to survey date. 2. Approximately 500 patients' specimens were tested and reported for hematology during this time period.