

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0871507	(X3) Date Survey Completed 05/14/2024
Name of Provider or Supplier Kevin G Kelly Md	Street Address, City, State 13150 Hwy 43 South Suite 10, Russellville, AL	
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
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by: Based on a review of the AAB (American Association of Bioanalysts) proficiency testing (PT) records, corrective action documentation, and an interview with the Technical Consultant (TC), the laboratory failed to ensure PT results were submitted prior to the reporting deadline. This was noted for one of one event reviewed in 2024. The findings include: 1. A review of the AAB PT records revealed the reporting deadline was 2/23/2024 for the 2024 M1 Non-Chemistry for Complete Blood Count (CBC) Hematology survey. The records included documentation of the laboratory's self evaluation submitted to AAB on 3/15/2024. 2. A further review of the corrective action documentation revealed, "Failed to submit results prior to the deadline due to noting the due date incorrectly. Ordered off cycle testing for replacement. Off cycle self evaluation scored 100% ". 3. During an interview on 5/14/2024 at 11:30 AM, the TC confirmed the above findings.</p>
D5437	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p> <p>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)</p>

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 review of the Hematology calibration records, a review of the policy and procedures manual, and an interview with the TC (Technical Consultant), the Laboratory failed to perform calibrations on the AcT Diff 2 Hematology analyzer every six months as per the laboratory policy. This was noted for one of two 2022 calibrations. The findings include: 1. A review of the Hematology calibration records revealed the AcT Diff 2 was calibrated 5/27/2022 and then nine months later on 2/24 /2023. There was no documentation of calibration the second half of 2022. 2. A review of the policy "CBC Machine Preventative Maintenance and Cleaning Schedule" revealed, "S-CAL Auto-calibrator must be performed at least every six months." 3. During an interview on 5/14/2024, at 12:15 PM, the TC confirmed the calibration due in November 2022 was not performed.

D5781

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b) (1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on a review of the refrigerator temperature records, a review of the Hematology QC (Quality Control) package insert, and an interview with the TC (Technical Consultant), the Laboratory failed to implement and document corrective actions when the refrigerator temperature was outside the manufacturer's acceptable ranges for items stored therein. The surveyor noted refrigerator temperatures were below acceptable ranges for 50 days of the 4 months reviewed in 2024. The findings include: 1. A review of the temperature records for the refrigerator where Hematology QC was stored revealed no documentation of corrective action for days when temperatures were below the acceptable ranges specified on the log (2 - 8 Celsius), as follows: a) February 2024: 2 days b) March 2024: 27 days c) April 2024: 19 days d) May 2024: 2 days 2. A review of the Hematology 4C-ES Cell Control QC package insert revealed, "Open Vial Stability ...Closed Vial Stability ... stored at 2 - 8 Celsius (35.6- 46.4 degrees Fahrenheit)." 3. During an interview on 5/14/2024, at 12:15 PM, the TC confirmed the above findings.