

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D0871507	<b>(X3) Date Survey Completed</b>  12/18/2019
<b>Name of Provider or Supplier</b>  Kevin G Kelly Md	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<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 review of the 2019 Hematology quality control (QC) records, a review of the manufacturer's package insert for QC material, a review of the patient test logs for CBCs (Complete Blood Counts), and an interview with Testing Personnel (TP) #1 (newly qualified Technical Consultant), the surveyor determined the laboratory staff used expired quality control (three levels) beyond the expiration date. This affected one month (May) in 2019. The findings include: 1. A review of the Hematology QC records (the instrument printouts) for May 2019 revealed the QC material with lot numbers, #069100 (low), expired on 5/3/2019; #079100 (normal), and #089100 (high) expired on 5/6/2019. The laboratory staff continued to use the QC material from 5/6/2019 - 6/2/2019. 2. A review of the manufacturer's package inserts for the above mentioned QC confirmed the expiration date of 5/6/2019 for all three levels (The expiration date for the low level was input incorrectly). 3. A review of the patient test logs for CBCs revealed no testing occurred on 5/24/2019 - 6/2/2019. However patient testing occurred on 5/7/2019 - 5/10 (a total of 73 patient CBCs); and 5/13/2019 - 5/16 (a total of 51 patient CBCs). Patient testing also occurred on 5/17, 5/18, 5/20 - 5/23. The QC material used with these patient test runs had expired. 4. In an interview on 12/19/2019 at 4:03 - 4:30 PM, TP #1 confirmed the manual containing the daily patient test logs were lists of CBCs performed in-house. TP #1 reviewed the QC records and confirmed the use of expired quality control in May of 2019. TP #1 further stated she did not realize the instrument (Act Diff 2) would allow expired QC material to be used. .</p>

**D5481**

**CONTROL PROCEDURES**

CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on a review of the 2018 Hematology quality control (QC) records, a review of the policy and procedure, "CBC MACHINE PREVENTATIVE MAINTENANCE AND CLEANING SCHEDULE," a review of the CBC (Complete Blood Count) patient test logs, the testing personnel's review of the medical records, and an interview with Testing Personnel (TP) #1, the surveyor determined the laboratory proceeded with patient testing when quality controls were not acceptable. This affected two days in June of 2018. The findings include: 1. A review of the 2018 Hematology QC records revealed the laboratory staff failed to ensure at least two levels of quality control were acceptable on 6/17/18, prior to testing patients and reporting the results of the CBCs. On 6/30/18, the background count for Hemoglobin (Hgb) failed; however the staff proceeded with patient testing. 2. A review of the policy and procedure, "CBC MACHINE PREVENTATIVE MAINTENANCE AND CLEANING SCHEDULE," revealed the following: "PURPOSE To ensure quality control standards are met to assure patient sample testing accuracy and precision by ensuring the machine remains in good working order. Startup must be performed each morning and every time the machine is turned off or put through shutdown procedures. ...All startup criteria must "PASS" to proceed EVERY time..." 3. A review of the CBC patient test logs revealed five CBC patient specimens were run on June 17, 2018 and five on June 30. 4. During an interview on 12/19/2019 at 4:03 - 4:30 PM, TP #1 (also the office manager and newly qualified Technical Consultant) reviewed the medical records for the above mentioned dates and confirmed that all except one patient CBC specimen were tested on June 17 and June 30, when QC was not acceptable.