

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0986272	(X3) Date Survey Completed 06/20/2019
Name of Provider or Supplier Uab Cancer Center At Russell Medical	Street Address, City, State 3446 Highway 280, Alexander City, 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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on a review of the 2017 - 2019 CAP (College of American Pathologists) proficiency testing (PT) records, personnel records, and an interview with Testing Personnel #1, the surveyor determined the laboratory failed to ensure proficiency testing samples were rotated between all personnel who performed moderate complexity Hematology testing on patients. This was noted on seven of seven surveys reviewed. The findings include: 1. A review of CAP attestation statements revealed Testing Personnel (TP) #1 had performed all the testing on the seven surveys performed from 2/6/2017 through 5/10/2019 (the most current survey). None of the PT testing had been performed by TP #2 or #3. 2. A review of the personnel files revealed TP #3 was full time, and had been qualified to perform moderate complexity Hematology testing since the previous survey (on 3/7/2017). TP #2 was trained in the laboratory on 1/21/2019. 3. During an interview on 6/20/2019 at 11:58 AM, TP #1 confirmed she had performed all the Hematology proficiency testing because she was the primary testing personnel. The surveyor then asked about the work schedules for TP #2 and #3; TP #1 stated both were full-time employees in the clinic, however they only performed CBC (Complete Blood Count) testing on patients when TP #1 was off. The surveyor explained the laboratory must schedule all testing personnel included on the CMS-Form 209 (Laboratory Personnel Report) to periodically participate in the performance of proficiency testing. Thus the above noted findings were confirmed. .</p>
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on observations and interviews during the entrance tour, a lack humidity records, and a review of the Sysmex XP-300 Instructions for Use Manual, the surveyor determined the laboratory failed to monitor humidity in the room where Hematology testing was performed since the previous survey on 3/7/2017. The findings include: 1. During the initial laboratory tour on 6/20/2019, the surveyor reviewed the current environmental logs for the room in which CBC's (Complete Blood Counts) are performed on the Sysmex XP-300 Hematology analyzer. The surveyor noticed there was no log documenting room humidity; at 9:25 AM Testing Personnel #1 confirmed she did not monitor or document humidity. 2. A review of the Sysmex XP-300 Instructions for Use Manual on page 2-2 included the following, "Installation ... Use the instrument in places where relative humidity ranges between 30% and 85%." 3. A review of the environmental monitoring records revealed the laboratory only recorded the daily room temperatures for the testing area. There was no documentation of the daily room humidity for 2017, 2018, or 2019. 4. During an interview on 6/20/2019 at 9:50 AM, Technical Consultant #1 confirmed the laboratory has not monitored and recorded the daily room humidity, and stated the Testing Personnel thought she had a choice to monitor either temperature or humidity. TP #1 had not realized she needed to document both parameters. SURVEYOR ID# 32558
Licensure and Certification Surveyor