Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2013710	08/16/2018
Name of Provider or Supplier	**Street Address, City, State**	
Community Urgent Care Of Hartselle	1635 Al Hwy 31 Nw Suite C, Hartselle, 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
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on reviews of quality control (QC) records, quality assurance (QA) records, and an interview with Testing Personnel (TP) #2, the surveyor determined the laboratory failed to ensure the corrective actions implemented on multiple days when QC was outside acceptable ranges effectively remediated a systemic problem identified in the analytic system. The findings include: 1. A review of QC records for the Abbott Cell Dyn Emerald (the previous Hematology analyzer) and the Horiba ABx Micros 60 (in use since January 2018) revealed multiple days when QC was outside acceptable ranges, as follows: A) 6/02/2017: Low and High QC out; performed by a previous testing personnel (TP #6 on the 2016 Form CMS-209) B) 5/05/2018: Normal and High QC out; performed by TP #3 and a previous testing personnel C) 5/17/2018: Normal and High QC out; performed by TP #4 D) 5/22/2018: Normal and High QC out; performed by TP #4 E) 6/15/2018: Low and Normal QC out; performed by TP #5 and #8 F) 7/24/2018: Low and Normal QC out; performed by TP #4 [Note: There was no documentation of training on the new Horiba ABx Micros 60 for TP #3, #4 or #5; refer to D6045.] 2. A review of the QA records revealed the only corrective action taken for the above events was to review the outages with each of the above testing personnel, who then signed a statement, "I understand that if 2 out [of] 3 controls do not run within range, I cannot report or run patient samples". In addition, the letter TP #4 signed after the 5/22/2018 incident specified retraining was undertaken since the problem had also occurred four days earlier. The records also included documentation

	of reviews by the Laboratory Director and physician of patient results performed on the above dates. 3. During the exit interview on 8/16/2018 at 2:00 PM, these concerns were discussed with TP #2. The surveyor reviewed the corrective actions taken for days when QC was outside acceptable ranges, and explained an important step in the quality assurance process was to assess whether the problem has been corrected, and would not recur. The surveyor found no evidence the laboratory had implemented additional actions (such as initials indicating a daily review by the Lab Director or qualified supervisor) to ensure patient samples were not run and reported until at least two levels of QC were within acceptable ranges. The surveyor also noted ten other days when one or two levels of QC were outside acceptable range on the first run, and required repeating a second or third time. Thus, the laboratory had also failed to take action to ensure the new Horiba was operating correctly since the necessity to repeat the QC was a common occurrence. .
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; This STANDARD is not met as evidenced by: Based on a review of the installation records for the Horiba ABx Micros 60 Hematology analyzer, personnel records, and an interview with Testing Personnel (TP) #2, the surveyor determined the Technical Consultants failed to ensure training on the new Horiba was performed and documented for five out of ten testing personnel who routinely performed patient CBC (Complete Blood Count) testing. The findings include: 1. A review of the January 2018 installation records for the Horiba ABx Micros 60 revealed TP #1, #2 and a previous testing personnel (who supervised the laboratory) received training by the Horiba Technician on 1/11/2018. Patient testing on the new Horiba began on 1/19/2018. 2. A review of personnel records revealed TP #8, #9 and #10 were new employees with training on the Horiba documented with their initial competency evaluations in March and June 2018. A review of records for TP #3, #4, #5, #6, and #7 revealed no documentation of training on the Horiba. 3. In an interview on 8/16/2018 at 10:30 AM, TP #2 was asked if TP #3 - #7 had received training on the Horiba. TP #2 stated she thought the testing personnel who had previously supervised the laboratory had performed the training. However, the laboratory was unable to provide documentation of the training for the five employees. Thus, the above noted findings were confirmed. SURVEYOR:Laura T. Williams, BS, MT (ASCP) Licensure and Certification Surveyor