Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0868677	06/14/2018
Name of Provider or Supplier	**Street Address, City, State**	
Uab Student Health And Wellness Laboratory	1714 9th Avenue South 3rd Floor Lrc, Birmingham, 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
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on a review of the 2016 - 2017 CAP (College of American Pathologists) Proficiency Testing (PT) records and interviews with Testing Personnel #2, the laboratory failed to perform and document corrective action for three of six surveys with results less than 100% (percent). The findings include: 1. A review of the CAP Proficiency Testing survey results revealed no documentation of investigation or corrective action for three surveys with results less than 100%, as follows: A) 2016 CM-B Microscopy: Wet Prep with a score of 0% B) 2017 FH2-B Hematology: Hematocrit with a score of 80%, resulting in an overall score of 97% for the Hematology survey C) 2017 CM-B Microscopy: Urine Sediment with a score of 75% 2. In an interview on 6/14/2018 at 2:30 PM, Testing Personnel #2 was asked for missing PT records and other documentation. As the interview continued at approximately 3:15 PM, Testing Personnel #2 confirmed the laboratory had not performed and documented corrective actions for the above surveys with scores less than 100%.
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 reviews of the Horiba Micros 60 calibration guide, calibration and quality control records, patient result logs, and an interview with Testing Personnel (TP) #2, the surveyor determined the laboratory failed to follow the manufacturer's instructions to verify calibrations by running quality controls (QC) before patient CBC (Complete Blood Count) testing resumed, for two out of four calibrations of the Hematology analyzer performed in 2016 - 2018. The findings include: 1. A review of calibration records for the Horiba Micros 60 revealed the instrument was calibrated on the following dates with patient testing resuming afterwards, as follows: A.) 11/17/2016 at 4:47 PM; four patient CBC's were then run between 5:09 and 5:26 PM B.) 4/27 /2018 at 11:30 AM; 3 patient CBC's were then run between 11:30 AM & 5:59 PM However, there was no documentation QC was run after the calibrations, and before the patient testing resumed. 2. An on-site review of the November 2016 and April 2018 monthly cumulative QC records revealed QC was only run in the early morning on the above dates. 3. During an interview on 6/14/2018 at approximately 3:00 PM, the surveyor asked TP #2 about the manufacturer's instruction for performing a calibration on the Hematology analyzer. A review of the directions on the publication "M60 Calibration Guide when using Lite DM" revealed as the final steps under the calibration section, "...15. Run QC as normal. ...". TP #2 stated she would check her file to verify whether she had run QC after the 4/27/2018 calibration. 4. As the interview continued at 3:25 PM, TP #2 confirmed she had missed running QC after the 4/27/2018 calibration, and she was unaware of whether the previous personnel had performed QC after the 11/17/2016 calibration. [TP #2 e-mailed additional 11/17 /2016 QC records to CLIA on 6/15/2018, however the QC was performed between 4: 24-4:27 PM, before the 4:47 PM Calibration.] Thus the above noted findings were confirmed. SURVEYOR:Laura T. Williams, BS, MT (ASCP) Licensure and Certification Surveyor