

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0300416	(X3) Date Survey Completed 03/27/2018
Name of Provider or Supplier Bbh Primary Care Network	Street Address, City, State 803 North Street, Talladega, 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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on the laboratory test menu listed during the initial laboratory tour, a review of the proficiency testing records and an interview with the Technical Consultant, the surveyor determined the laboratory failed to ensure accuracy verification of urine sediment microscopy was performed at least twice annually in 2016 and 2017. The findings include: 1. During the initial tour of the laboratory on 3/27/2018 at approximately 9:45 AM, the Technical Consultant listed urine sediment microscopy on the on-site test menu. 2. A review of the API (American Proficiency Institute) proficiency testing (PT) records revealed the laboratory enrolled in surveys that included proficiency for urine sediment microscopy in 2015, however the test was discontinued on the 2016-2017 surveys. 3. During an interview on 3/27/2018 at 11:00 AM, when asked if they had verified the accuracy of urine sediment microscopy by another method, the Technical Consultant confirmed they had not. Thus the above noted findings were confirmed. .</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) 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,</p>

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 Abbott Cell Dyn Emerald Hematology analyzer "Quick Reference Guide", calibration, and quality control (QC) records, and interviews with the Technical Consultant and testing personnel, the surveyor determined the laboratory failed to follow the manufacturer's instructions in the performance frequency of calibrations, and failed to verify two out of three calibrations performed in 2016-2017. The findings include: 1. A review of the Abbott Cell Dyn Emerald Hematology analyzer "Quick Reference Guide" revealed, on page 51 the following instructions, "When to Calibrate...At least every six months...". The final step of the procedure included instructions for the user to verify the calibration ("calibration verification") using the second calibrator tube. [Laboratories also have the option of running at least two levels of QC to verify their calibration data.] 2. A review of the Hematology records revealed the following: A) 04/28/2016 at 10:38 AM: Documentation of a calibration, however there was no evidence of "calibration verification" or QC afterwards; a review of the records revealed QC was only performed earlier in the morning on this date. B) 05/04/2017 at 1:36 PM: Data from a calibration and three levels of QC performed approximately one year after the previous calibration. C) 10/31/2017 at 11:18 AM: Documentation of a calibration, however there was no evidence of "calibration verification" or QC afterwards; a review of the records revealed QC was only performed earlier in the morning on this date. 3. During an interview on 3/27/2018 at 11:30 AM, the Technical Consultant was asked if the laboratory had any records of Hematology calibrations performed between April 2016 and May 2017. The Consultant said they had been unable to locate the records for the second calibration performed in 2016. When asked how often the Hematology analyzer should be calibrated, the Technical Consultant stated, "Every six months", and further confirmed the testing personnel knew they should perform QC after all calibrations. 4. During a later interview on 3/27/2018 at 1:24 PM, the testing personnel was asked to provide evidence of QC performed after the 4/28/2016 and 10/31/2017 calibrations. The testing personnel was only able to find QC performed in the mornings on the above dates, thus confirming the above noted findings. SURVEYOR: Laura T. Williams, BS, MT (ASCP) Licensure and Certification Surveyor