

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D1064250	<b>(X3) Date Survey Completed</b>  07/16/2019
<b>Name of Provider or Supplier</b>  After Hours Clinic Sumiton	<b>Street Address, City, State</b>  292 Bryan Road, Sumiton, 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>D5437</b>	<p><b>CALIBRATION AND CALIBRATION VERIFICATION</b> 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, 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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of calibration records for the Medonic Hematology analyzer, a lack of documentation of calibrations since December of 2017, a review of the manufacturer's recommendations, and an interview with the Laboratory Manager [also Testing Personnel (TP) #1], the surveyor determined the laboratory failed to perform and document instrument calibrations, at least every six months as required by the policy. This affected instrument calibrations in 2018 -2019 July. The findings include: 1. A review of the calibration records for the Medonic, since the last survey in March of 2017, revealed the instrument was calibrated on 8/07/2017 by the manufacturer representative during service and again on 12/21/2017. The laboratory failed to provide any documentation the instrument was calibrated since 12/21/2017. 2. A review of the Medonic M-series User's Manual, signed by the Laboratory Director, 4 /13/2017, revealed in Section 7: Calibration: It is recommended to calibrated the instrument every six months. 3. In an interview on 7/16/2019 at 12:10 PM, TP #1 (Laboratory Manager) stated the laboratory's policy was to calibrate the instrument at least every six months. TP #1 reviewed the manuals (2017 - 2019) and boxes for the</p>

missing calibration reports. None were found beyond the calibration performed in December of 2017.

**D6053**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on a review of the personnel records, a lack of documentation, and an interview with the Laboratory Manager [also Testing Personnel (TP) #1], the surveyor determined the Technical Consultant failed to assess the competency of TP #4, semiannually during the first year of employment as testing personnel of moderate complexity testing. This affected one of four testing personnel. The findings include:

1. A review of the personnel records on 7/16/2019, revealed TP #4 was initially trained on 9/21/2016. TP #1 was not listed on the personnel report from the previous survey, dated 3/24/2017. Although the file included competency assessments, dated 7/11/18 and 9/05/17 (annual assessments), there was no documentation the employee's competency had been assessed semiannually the first year of employment (between 9/2016 - 9/2017).
2. During an interview on 7/16/2019 at 11:05 AM, the surveyor inquired of the Laboratory Manager if a semiannual competency assessment had been performed on TP #4. The Laboratory Manager stated the assessment may be at another location, since the personnel also worked at a sister location. The surveyor requested the assessment be faxed to the office of the State Agency by Friday, July 19 at noon.
3. A "Laboratory Personnel Training Checklist" and a "Laboratory Personnel Evaluation" was faxed to the State Agency and received on 7/29/2019. The checklist and evaluation were dated 1/10/2019. No semiannual competency assessment for TP #4 was provided.