Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0928124	11/20/2018
Name of Provider or Supplier	**Street Address, City, State**	
Mobile Adult Care Llc	100 Memorial Hospital Drive Suite 3a, Mobile, 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
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 a review of the Beckman Coulter AcT diff 2 Hematology analyzer calibration and quality control records, patient results in the Midlynx Laboratory Information System (LIS) and interviews with Testing Personnel (TP) #1, the surveyor determined the laboratory failed to follow the manufacturer's instructions to verify calibrations by running quality controls (QC) for one of two calibrations of the Hematology analyzer performed in 2017. The findings include: 1. A review of calibration records for the Beckman Coulter AcT diff 2 revealed the instrument was calibrated on 6/29/2017 at 11:40 AM. However, a review of the QC records revealed QC was only run in the morning (7:44-7:50 AM) on 6/29/2017. 2. A review of the Coulter Operator's Guide under the "CALIBRATION" section revealed, "...17. Verify calibration by running 4C PLUS Cell Control. ..." 3. During the exit interview on 11/20/2018 at 5:00 PM, TP #1 was asked if she had any documentation of additional QC performed after the 6/29/2017 calibration. TP #1 looked at the records and confirmed the testing personnel had performed QC only in the morning. When asked if any patient CBC's (Complete Blood Counts) had been performed after the calibration, TP

	#1 reviewed the patient results in the Midlynx LIS for 6/29/2017, and stated one CBC had been run. Thus the above noted findings were confirmed. .
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on a review of the calibration and calibration verification (CV) records for the Beckman Coulter AU480 Chemistry analyzer, and an interview with Testing Personnel (TP) #1, the surveyor determined the laboratory failed to perform calibration verifications every six months as required by the laboratory policy. The laboratory missed performing a second CV in late 2016, resulting in a nine and a half month gap between calibration verification procedures. The findings include: 1. A review of the calibration records for the Beckman Coulter (B/C) AU480 Chemistry analyzer revealed all tests (with the exception of Hemoglobin A1c, Microalbumin and Rheumatoid Factor) are calibrated using one or two calibrators. Tests using less than three calibrators require a CV every six months. 2. A review of the 2016-2017 records for the B/C AU480 revealed a CV was performed on 5/5/2016 and then on 2/21/2017 (nine and a half months after the previous CV). 3. During an interview on 11/20/2018 at approximately 3:30 PM, when asked how often a CV should be performed, the TP #1 confirmed the six month frequency requirement. TP #1 reviewed the records and stated there was only one CV in 2016; the next CV was not performed until February 2017. Thus the above noted findings were confirmed. 4. This is a repeat deficiency. .
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel

	have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on a lack of documentation in the personnel file for Testing Personnel #2 and an interview with TP #1, the Laboratory Director failed to ensure training for TP #2 was performed and documented before patient testing began. This was noted on the records for one of two testing personnel. The finding include: 1. A review of the documentation provided for TP #2 revealed no evidence of training in the laboratory policies and procedures. 2. During an interview on 10/20/2018 at 10:15 AM, the surveyor asked TP #1 about the scope of responsibilities for TP #2. TP #1 stated TP #2 only performed CBC (Complete Blood Count) testing on the Beckman Coulter AcT diff 2 automated Hematology analyzer, and began patient testing in December 2017. When asked if TP #2 received training to perform this procedure, TP #1 stated she had trained TP #2, however she had not realized documenting the training was a requirement. Thus the above noted findings were confirmed. .
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 lack of documentation in the personnel file for Testing Personnel #2 and interviews with the Practice Manager and TP #1, the surveyor determined the Technical Consultant (also the Laboratory Director) failed to ensure the semi-annual competency evaluation was performed and documented within the first year of hire for one of two testing personnel (TP) who perform moderate-complexity patient testing. The findings include: 1. A review of the personnel files revealed TP #2 (who routinely performed moderate complexity testing on patient specimens) had no documentation of a semi-annual competency evaluation in 2018. 2. In an interview on 10/20/2018 at 9:50 AM, the Practice Manager stated she had performed evaluations on the laboratory staff in October 2018 when she realized they were due. A review of the competency evaluation for TP #2 dated 10/10/2018 revealed an assessment of her blood drawing and processing skills, along with her professionalism and other general office tasks. The surveyor then asked the Practice Manager if she had evaluated TP #2 on her competency in performing the laboratory testing; the Manager stated she did not know about the laboratory, and it was not part of her assessment. 3. During an interview on 10/20/2018 at 10:15 AM, the surveyor asked TP #1 about the scope of responsibilities for TP #2. TP #1 stated TP #2 only performed CBC (Complete Blood Count) testing on the Beckman Coulter AcT diff 2 automated Hematology analyzer, and began patient testing in December 2017. The surveyor then asked if anyone had performed a semi-annual competency evaluation for TP #2 in 2018; TP #1 stated an evaluation may have been performed by the Practice Manager. The surveyor then explained the Practice Manager stated she did not actually know about the laboratory, and has not assessed the competency of the testing personnel's performance of the moderate-complexity testing. Thus the above noted findings were confirmed. .

D6054	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 annually, after the first year. This STANDARD is not met as evidenced by: Based on a lack of documentation in the personnel file for Testing Personnel #1 and an interview with the Practice Manager, the surveyor determined the Technical Consultant (also the Laboratory Director) failed to ensure the 2017 and 2018 annual competency evaluation were performed and documented for one of two testing personnel (TP) who perform moderate-complexity patient testing. The findings include: 1. A review of the Form CMS-209 Laboratory Personnel Report revealed one testing personnel (TP #1) performing moderate complexity patient testing employed by the facility since the previous survey. 2. A review of the personnel file for TP #1 revealed no documentation of annual competency evaluation in 2017 or 2018. 3. In an interview on 10/20/2018 at 9:50 AM, the Practice Manager stated she had performed evaluations on the laboratory staff in October 2018 when she realized they were due. A review of the competency evaluation for TP #1 dated 10/10/2018 revealed an assessment of her blood drawing and processing skills, safety awareness, along with her professionalism and knowing the locations of laboratory manuals and logs. The surveyor then asked the Practice Manager if she had evaluated TP #1 on her competency in performing the moderate-complexity laboratory testing; the Manager stated she did not know about the laboratory, and it was not part of her assessment. The Manager further stated additional evaluations for 2017 and 2018 may have been performed by the previous laboratory supervisor and the previous Practice Manager, however they had been unable to locate the documents. Thus the above noted findings were confirmed. SURVEYOR: Laura T. Williams, BS, MT (ASCP) Licensure and Certification Surveyor