

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0641484	(X3) Date Survey Completed 04/17/2019
Name of Provider or Supplier Acculab Inc	Street Address, City, State 401 Arnold Street Ne, Cullman, 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	<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, 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 verification records for Chemistry, a review of the manufacturer's instructions for use of the Audit Micro-controls for calibration verifications, a review of the QA (Quality Assurance) records, and an interview with the testing personnel, the surveyor determined the laboratory failed to ensure calibration verification raw data was evaluated to determine the accuracy of the instrument's (Cobas Integra 400 plus) Analytical Measurable Range (AMR). This affected five of five calibration verifications performed from January 2017 through March of 2019. The findings include: 1. A review of the Chemistry calibration verification records for 2017 - 2018 revealed the raw data for procedures performed on January 12 and July 27 of 2017, and January 11 and July 5 of 2018. There was no documentation of the laboratory's review and evaluation of the raw data to determine the accuracy of the AMR, achieved by the Cobas Integra 400 plus. 2. In an interview on 4/17/2019 at 1:35 - 1:43 PM, the surveyor asked the testing personnel how the raw data was evaluated. The testing personnel stated she reviewed and compared the test run values to the known, expected values on the manufacturer's package inserts. When</p>

asked if the evaluations were documented, the testing personnel replied no evaluations were documented and no graphs had been generated. The surveyor inquired if the testing personnel was able to determine the AMR of each analyte or the linear range simply by looking at the raw data and comparing it to the package inserts. The testing personnel stated she thought she could, however did not explain the results for each of the calibration verifications. The testing personnel further stated she had usually sent the data to Audit to be evaluated, but had failed to do so for the last two years. Upon further questioning, the testing personnel stated the laboratory director visited about every other month to review the laboratory reports. However, the laboratory director had not reviewed the calibration verifications, because the testing personnel failed to provide the data for review. When asked if the calibration verification had been performed since July 5, 2018 (should be performed every six months), the testing personnel stated she had performed the calibration verification in 2019, however she had not printed nor evaluated the results for accuracy of AMR. The 2019 report was not provided for review by the surveyor. 3. A review of the Audit Micro-controls package insert revealed the following: verifying and validating the AMR; Expected values: Each lot of product is manufactured such that a linear relationship exists among levels. The degree of acceptable non-linearity is an individual judgement based on methodology, clinical significance and medical decision levels of test analytes. Also included in the manufacturer's insert was a section on calculation of results, which included the following: Once each vial of the total set is tested, raw data may be entered via Auditor QC (Quality Control) program (online) to determine slope and intercept. 4. The QA records for 2019 (January - March), 2018 and 2017 failed to indicate the laboratory had identified any problems or discrepancies of policies and procedures within the laboratory systems.

D6017

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(ii)

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)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program.

This STANDARD is not met as evidenced by:

Based on a review of the CASPER reports (0096D), a review of API (American Proficiency Institute) proficiency testing records, and an interview with the testing personnel, the surveyor determined the laboratory director failed to ensure the timely submission of the results to API for grading, for Chemistry Event #3, 2018, resulting in a "Failure to Participate" (zero test scores). This affected one of eight testing events reviewed by the surveyor. The findings include: 1. A review of the CASPER report revealed the laboratory scored zero percent (%), a "Failure to Participate," for routine Chemistry, Event #3 of 2018, due to the laboratory's failure to submit the results by the deadline, established by the program provider. 2. A review of the API proficiency testing reports for Event #3, 2018 revealed the laboratory documented on the review form the results were not submitted to API, due to an oversight. The instrument printouts revealed the specimens were tested on 9/06/2018. The laboratory did not provide the instructions with the submission deadline date. 3. In a interview on 4/17

/19 at 12:00 PM, the testing personnel stated the instructions were on-line, including the deadline for submitting the results. The testing personnel stated she failed to submit the results by the submission deadline, which resulted in the zero scores.

D6023

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(6)

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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;

This STANDARD is not met as evidenced by:

Based on a review of calibration verification records for Chemistry, a review of the manufacturer's instructions for use of the Audit Micro-controls for calibration verifications, a review of the QA (Quality Assurance) records, and an interview with the testing personnel, the surveyor determined the laboratory director failed to ensure calibration verification raw data was evaluated to determine the accuracy of the instrument's (Cobas Integra 400 plus) Analytical Measurable Range (AMR). This affected five of five calibration verifications performed from January 2017 through March of 2019. The findings include: 1. A review of the Chemistry calibration verification records for 2017 - 2018 revealed the raw data for procedures performed on January 12 and July 27 of 2017, and January 11 and July 5 of 2018. There was no documentation of the laboratory's review and evaluation of the raw data to determine the accuracy of the AMR, achieved by the Cobas Integra 400 plus. 2. In an interview on 4/17/2019 at 1:35 - 1:43 PM, the surveyor asked the testing personnel how the raw data was evaluated. The testing personnel stated she reviewed and compared the test run values to the known, expected values on the manufacturer's package inserts. When asked if the evaluations were documented, the testing personnel replied no evaluations were documented and no graphs had been generated. The surveyor inquired if the testing personnel was able to determine the AMR of each analyte or the linear range simply by looking at the raw data and comparing it to the package inserts. The testing personnel stated she thought she could, however did not explain the results for each of the calibration verifications. The testing personnel further stated she had usually sent the data to Audit to be evaluated, but had failed to do so for the last two years. Upon further questioning, the testing personnel stated the laboratory director visited about every other month to review the laboratory reports. However, the laboratory director had not reviewed the calibration verifications, because the testing personnel failed to provide the data for review. When asked if the calibration verification had been performed since July 5, 2018 (should be performed every six months), the testing personnel stated she had performed the calibration verification in 2019, however she had not printed nor evaluated the results for accuracy of AMR. The 2019 report was not provided for review by the surveyor. 3. A review of the Audit Micro-controls package insert revealed the following: verifying and validating the AMR; Expected values: Each lot of product is manufactured such that a linear relationship exists among levels. The degree of acceptable non-linearity is an individual judgement based on methodology, clinical significance and medical decision levels of test analytes. Also included in the manufacturer's insert was a section on calculation of results, which included the following: Once each vial of the total set is tested, raw data may be entered via Auditor QC (Quality Control) program (online) to determine slope and

intercept. 4. The QA records for 2019 (January - March), 2018 and 2017 failed to indicate the laboratory had identified any problems or discrepancies of policies and procedures within the laboratory systems.