

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  19D0461162	<b>(X3) Date Survey Completed</b>  07/05/2018
<b>Name of Provider or Supplier</b>  Acadia Laboratory Llc	<b>Street Address, City, State</b>  715 North Eastern Avenue, Crowley, LA	
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>D0000</b>	A CERTIFICATION SURVEY was performed at Acadia Laboratory LLC - CLIA # 19D0461162 on July 5, 2018. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
<b>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to have a complete policy and procedure manual. Findings: 1. Review of the laboratory policy and procedure manual revealed the laboratory did not have detailed instructions for: Proficiency Testing (PT): a) Ordering and ensuring that you are enrolled for Proficiency Testing. b) What to do when you receive samples from the PT Provider. c) How to handle the samples; who will test, when to test, how do you assure no inter and intra laboratory communication takes place d) How to record results to send into the PT Provider to be scored. e) What records to maintain. f) How to evaluate when you receive your scores from the PT Provider. g) What steps to take if corrective action is needed. h) What steps are required when the laboratory has their first and second two (2) out of three (3) failures. Performance specifications to include: a) Detailed policies and procedures for testing personnel that instructed testing personnel what to do for studies for accuracy, precision (day-to-day, run-to-run, and within-run variation, as well as operator variance), reportable and reference ranges and analytical sensitivity and specificity. a) Acceptability criteria for each of the studies for accuracy, precision, reportable and reference ranges and analytical sensitivity and specificity. a) Policies and procedures for when data from the studies for precision,</p>

accuracy, reportable range, reference range, analytical sensitivity and analytical specificity fail to meet acceptability criteria. Personnel Competency to include written policies and procedures that include the following six (6) procedures as a minimal requirement for assessing the competency of all personnel performing laboratory testing: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b) Monitoring the recording and reporting of test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. f) Assessment of problem solving skills: and that assessments are to be performed semi annually the first year and annually thereafter. Communication Policies and Procedures 2. Interview with the Laboratory Director on July 5, 2018 confirmed the policy and procedure manual was incomplete

**D5421**

**ESTABLISHMENT AND VERIFICATION OF PERFORMANCE**  
CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:  
I. Based on observation, record review, and interview with personnel, the laboratory failed to have complete performance specification verification studies for Vitamin D performed on the Dimension EXL 200 Chemistry Analyzer. Findings: 1. Observation by surveyor during the laboratory tour on July 5, 2018 revealed the laboratory utilizes the Dimension EXL 200 Chemistry Analyzer for patient testing. 2. Review of Task 1 and 3 Form submitted to the surveyor on July 5, 2018 revealed the laboratory performed Vitamin D testing. Interview with the Laboratory Director revealed that the laboratory began testing Vitamin D in September 2017. 3. Review of the laboratory's verification of performance specification revealed: A. EP Evaluator Reports stating prepared by the Technical Application Specialist for the Dimension: a) simple precision b) linearity for reportable range c) Performed 20 patient samples. NOTE: The studies were signed off by the Laboratory Director on September 10, 2017. The laboratory failed to maintain any documentation that laboratory personnel participated in the studies. B. The laboratory failed to include the following: a) Accuracy. b) Complete Precision: day-to-day, run-to-run, and within-run variation, as well as operator variance. c) Reference range: data to support reference ranges in use 4. Interview with the Laboratory Director on July 5, 2018 revealed laboratory personnel did participate; however the Laboratory Director did confirm there was no documentation that laboratory personnel participated. The Laboratory Director also confirmed the laboratory failed to have a complete performance verification study performed prior to patient testing. II. Based on observation, record review, and interview with personnel, the laboratory failed to have complete performance specification verification studies for the Sysmex CA-600 Coagulation Analyzer. Findings: 1. Observation by surveyor during the laboratory tour on July 5, 2018

revealed the laboratory utilizes the Sysmex CA-600 Coagulation Analyzer for patient Prothrombin Time (PT)/ International Normalized Ratio (INR) and Partial Thromboplastin Time (PTT) testing. 2. Interview with the Laboratory Director revealed that the laboratory installed the Sysmex CA-600 Coagulation Analyzer in November 2017. 3. Review of the laboratory's verification of performance specification revealed: A. EP Evaluator Reports stating prepared by the Technical Application Specialist for the Sysmex CA-600 Coagulation Analyzer: a) Correlation Study of one hundred forty three (143) patients performed on both the CA-500 (old instrument) and the CA-600 (new instrument). b) Reference Range Study: utilized one hundred twenty six (126) patients, all performed between November 7, 2017 through November 20, 2017. c) Simple Precision/Accuracy: performed ten (10) runs of CI-TROL Levels 1 and 3 on November 7, 2017. d) Precision: day-to-day, and run-to-run performed by Personnel 4 on March 14, 2018 through March 20, 2018. NOTE: The studies were signed off by the Laboratory Director on November 20, 2017. B. The laboratory failed to include the following: a) Reportable Range. 4. Interview with the Laboratory Director on July 5, 2018 confirmed the laboratory failed to have a complete performance verification study performed prior to patient testing. III. Based on observation, record review, and interview with personnel, the laboratory failed to have complete performance specification verification studies for the BIO-RAD D-10 Hemoglobin A1C (HgbA1C) Analyzer. Findings: 1. Observation by surveyor during the laboratory tour on July 5, 2018 revealed the laboratory utilizes the BIO-RAD D-10 HgbA1C Analyzer for patient testing. 2. Interview with the Laboratory Director revealed the laboratory installed a new BIO-RAD D-10 HgbA1C Analyzer in April 2017. 3. Review of the laboratory's verification of performance specification revealed: A. EP Evaluator Reports stating the analyst was Personnel 1 for the BIO-RAD D-10 HgbA1C Analyzer: a) Simple Precision: QC levels 1 and 2 ran ten (10) times on April 11, 2017. b) linearity for reportable range performed on April 12, 2017. c) Carryover Study performed on April 12, 2017. d) Method Comparison performed on April 12, 2017 through April 13, 2017 between the old and new instrument (same make and model). B. The laboratory failed to include the following: a) Complete Precision: day-to-day, run-to-run, and within-run variation, as well as operator variance. b) Reference range: data to support reference ranges in use 4. Interview with the Laboratory Director on July 5, 2018 confirmed the laboratory failed to have a complete performance verification study performed prior to patient testing.

**D6013**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(3)(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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

This STANDARD is not met as evidenced by:

Based on observations, record review and interview with laboratory personnel, the Laboratory Director failed to ensure that verification procedures are performed to determine accuracy, precision, reportable and reference ranges for two (2) of two (2) new analyzers. Findings: 1. The laboratory failed to have complete performance specification verification studies for Vitamin D performed on the Dimension EXL 200

Chemistry Analyzer. Refer to D5421 I. 2. The laboratory failed to have complete performance specification verification studies for the Sysmex CA-600 Coagulation Analyzer. Refer to D5421 II. 3. The laboratory failed to have complete performance specification verification studies for the BIO-RAD D-10 Hemoglobin A1C (HgbA1C) Analyzer. Refer to D5421 III.

**D6031**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(13)

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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

This STANDARD is not met as evidenced by:

Based on record review and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Findings: 1. Review of the laboratory policy and procedure manual revealed the laboratory did not have detailed instructions for: Proficiency Testing (PT): a) Ordering and ensuring that you are enrolled for Proficiency Testing. b) What to do when you receive samples from the PT Provider. c) How to handle the samples; who will test, when to test, how do you assure no inter and intra laboratory communication takes place d) How to record results to send into the PT Provider to be scored. e) What records to maintain. f) How to evaluate when you receive your scores from the PT Provider. g) What steps to take if corrective action is needed. h) What steps are required when the laboratory has their first and second two (2) out of three (3) failures. Performance specifications to include: a) Detailed policies and procedures for testing personnel that instructed testing personnel what to do for studies for accuracy, precision (day-to-day, run-to-run, and within-run variation, as well as operator variance), reportable and reference ranges and analytical sensitivity and specificity. a) Acceptability criteria for each of the studies for accuracy, precision, reportable and reference ranges and analytical sensitivity and specificity. a) Policies and procedures for when data from the studies for precision, accuracy, reportable range, reference range, analytical sensitivity and analytical specificity fail to meet acceptability criteria. Personnel Competency to include written policies and procedures that include the following six (6) procedures as a minimal requirement for assessing the competency of all personnel performing laboratory testing: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b) Monitoring the recording and reporting of test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. f) Assessment of problem solving skills: and that assessments are to be performed semi annually the first year and annually thereafter. Communication Policies and Procedures 2. Interview with the Laboratory Director on July 5, 2018 confirmed the policy and procedure manual was incomplete