

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0688964	(X3) Date Survey Completed 06/12/2018
Name of Provider or Supplier Acadiana Family Practice Lab, Inc	Street Address, City, State 717 Curtis Drive, Rayne, LA	
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
D0000	A Certification Survey was conducted on June 12, 2018 at Acadiana Family Practice Laboratory, Inc - CLIA ID # 19D0688964. The laboratory was found in compliance with 42 CFR 493 Requirement for Laboratories; however, standard deficiencies were cited.
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policy and procedure manual, and interview with personnel, the laboratory failed to establish written policies and procedures to assess employee and, if applicable, consultant competency. Findings: 1. Review of the Laboratory's Policy and Procedure Manual revealed the laboratory did not establish written instructions that include the following six (6) procedures as a minimal requirement for assessing the competency of all personnel involved in any phase of 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. 2. Further review of the policy and procedure manual revealed the laboratory did not establish detailed written instructions for Clinical Consultant and Technical Consultant competency assessment to include the frequency to be performed. 2.</p>

	<p>Interview with Personnel 3 on June 12, 2018 at 12:15 pm confirmed the laboratory did not have detailed written instructions to assess employee and consultant competency.</p>
<p>D5417</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview with personnel, the laboratory failed to ensure supplies have not exceeded their expiration date. Findings: 1. Observation by surveyor during laboratory tour on June 12, 2018 revealed the following expired item: * Drew Scientific Inc Ex-Cal Hematology Calibrator - Lot EX0418-CAL, Exp 05/05/2018 2. In interview on June 12, 2018 at 10:15 am, Personnel 3 stated the calibrators come in the same box as the controls for the Hematology analyzer and that he was unaware that the calibrator was expired.</p>
<p>D6014</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii)</p> <p>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)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.</p> <p>This STANDARD is not met as evidenced by: Based on observation, and interview with personnel, the Laboratory Director failed to ensure laboratory supplies have not exceeded their expiration date. Refer to D5417.</p>
<p>D6030</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12)</p> <p>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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures were established for assessing personnel</p>

competency, and whenever necessary, identify needs for remedial training or continuing education to improve skills. Refer to D5209.