

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2016117	(X3) Date Survey Completed 02/27/2018
Name of Provider or Supplier Crescent City Surgical Centre Diagnostics, Llc	Street Address, City, State 3016 Galleria Drive, Metairie, 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 February 27, 2018 at Crescent City Surgical Centre-CLIA ID # 19D2016117. The laboratory was found in compliance with 42 CFR 493 Requirement for Laboratories; however, standard deficiencies were cited.
D6030	<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 maintained for assessing personnel competency, and whenever necessary, identify needs for remedial training or continuing education to improve skills. Refer to D6051.</p>
D6051	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.</p>

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the Technical Consultant failed to ensure all testing personnel were assessed through testing previously analyzed specimens, internal blind samples, or external proficiency samples. Findings: 1. Review of the laboratory's CMS-209 (Laboratory Personnel Report) form revealed the following testing personnel: Personnel 3 Personnel 4 Personnel 5 Personnel 6 Personnel 7 Personnel 8 Personnel 9 Personnel 10 Personnel 11 2. Review of the laboratory's "Personnel Competency" policy revealed "Competency evaluations should be accomplished by fulfilling the following requirements for each test that personnel are approved to perform: Assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing." 3. Review of the laboratory's 2017 and 2018 American Proficiency Institute (API) Proficiency Testing (PT) and personnel competency assessment records revealed the following personnel did not perform previously analyzed specimens, internal blind samples, or external proficiency samples testing: Personnel 4 Personnel 5 Personnel 6 Personnel 7 Personnel 8 Personnel 9 Personnel 10 Personnel 11 4. In interview on February 27, 2018 at 2:30 pm, Personnel 3 stated she performs all testing of PT samples. Personnel 3 confirmed the identified testing personnel were not assessed through testing previously analyzed specimens, internal blind samples, or external proficiency samples.