Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D1033284	(X3) Date Survey Completed 08/17/2021
Name of Provider or Supplier Bienville Medical Center	**Street Address, City, State** 1175 Pine Street, Suite 200, Arcadia, 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 Recertification survey was performed on August 17, 2021 at Bienville Medical Center, CLIA ID # 19D1033284. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: I. Based on review of the laboratory's policies and interview with personnel, the laboratory failed to establish written policies and procedures to assess competency assessment policies for testing personnel. Findings: 1. Review of the laboratory's polices revealed the laboratory did not have a written policy for assessing the competency of personnel performing laboratory testing that included frequency of performance and the following six (6) procedures as a minimal requirement: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b) Monitoring the recording and reporting or 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. In interview on August 17, 2021 at 10:39 am, the Laboratory Manager stated the laboratory does have a policy but could not find it in the policy and procedure manual. The Laboratory Manager confirmed the laboratory does not have a competency assessment policy for Testing Personnel. II.

	Based on review of the laboratory's policy and procedure manual, personnel records, and interview with personnel, the laboratory failed to establish written policies and procedures to assess competency and perform an assessment for the Technical Consultant. Findings: 1. Review of the laboratory's CMS-209 form (Laboratory Personnel Report) form revealed that Personnel 2 serves as the Technical Consultant. 2. Review of the laboratory's policies revealed the laboratory did not have procedures for assessing the competency of the Technical Consultant. 3. Review of personnel records for the Technical Consultant revealed the Laboratory Director did not perform a competency assessment for his duties as Technical Consultant. 4. In interview on August 17, 2021 at 10:39 am, the Technical Consultant confirmed the laboratory did not have a competency assessment policy nor perform an assessment for the Technical Consultant
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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; 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 for assessing personnel competency were established and maintained. Findings: 1. The laboratory failed to establish written policies and procedures to assess competency assessment policies for testing personnel. Refer to D5209 I. 2. The laboratory failed to establish written policies and procedures to assess competency and perform an assessment for the Technical Consultant. Refer to D5209 II.