

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D1033284	(X3) Date Survey Completed 03/26/2025
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 conducted March 26, 2025 at Bienville Medical Center - CLIA ID # 19D1033284. 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:</p> <p>I. Based on review of the laboratory's policies and procedures, and interview with personnel, the laboratory failed to establish complete procedures to assess competency for testing personnel. Findings: 1. Review of the laboratory's "Laboratory Personnel" policy revealed the policy did not include how the laboratory will evaluate the following six (6) procedures minimally required for the assessment of competency for testing personnel: 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 laboratory's "Laboratory Personnel" policy revealed the policy did not include the frequency at which competency assessment for testing personnel is performed. 3. In interview on March 26, 2025 at 4:30 pm, the laboratory supervisor confirmed the laboratory's policy for competency did not detail how competency is to be evaluated for testing personnel and the frequency assessments are performed. II. Based on</p>

review of the laboratory's policies, CMS-209 form, and personnel records as well as interview with personnel, the laboratory failed to establish written policies and procedures to assess competency of the Technical Consultant. Findings: 1. Review of the laboratory's policy manual revealed the laboratory did not include procedures to assess competency for the individuals serving as Technical Consultant as well as the frequency at which the assessment is performed. 2. Review of the laboratory's CMS-209 (Laboratory Personnel Report) form revealed Personnel 6 serves as Technical Consultant. 3. Review of personnel records for Personnel 6 revealed a competency assessment was not performed for her role as Technical Consultant. 4. In interview on March 26, 2025 at 4:30 pm, the Laboratory Supervisor confirmed the laboratory did not have a policy related to competency assessment of the Technical Consultant. The Laboratory Supervisor also confirmed that a competency assessment was not performed for the Technical Consultant.

D6030

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(12)

(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 review of laboratory policy and personnel records as well as interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Findings: 1. The laboratory failed to establish complete procedures to assess competency for testing personnel. Refer to D5209 I. 2. The laboratory failed to establish written policies and procedures to assess competency of the Technical Consultant. Refer to D5209 II. 3. The Technical Consultant failed to perform a competency assessment semi-annually during the first year for one (1) of five (5) testing personnel in 2024. Refer to D6053.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

(b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's policies and personnel records as well as interview with personnel, the Technical Consultant failed to perform a competency assessment semi-annually during the first year for one (1) of five (5) testing personnel in 2024. Findings: 1. Review of the laboratory's "Laboratory Personnel" policy revealed the laboratory did not include six (6) month competency assessment frequency during the first year of employment. 2. Review of personnel records for Testing Personnel 3 revealed that an initial assessment was performed in December 2023 and a six (6) month assessment was due in June 2024; however, the assessment was not performed as required by CMS regulations. 3. In interview on March 26,

2025 at 4:30 pm, the Laboratory Supervisor confirmed the laboratory did not have documentation of a semi-annual competency assessment for Testing Personnel 3.