Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D1033284	05/31/2023
Name of Provider or Supplier	**Street Address, City, State**	
Bienville Medical Center	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 Certification survey was performed on May 31, 2023 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.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of the laboratory policy and proficiency testing records as well as interview with personnel, the laboratory failed to ensure the Laboratory Director signed the attestation forms for one (1) of three (3) proficiency testing events reviewed. Findings: 1. Review of the laboratory's policy "Proficiency Testing" revealed "The testing personnel is responsible for filling out the survvey results form, signing the testing form, and maintaining copies of all testing printouts and documentation. Both the signed results form and any instrument printouts should be given to the Laboratory Consultant. When evaluation results are returned, they should be reviewed by the Laboratory Director and Laboratory Consultant. Any unacceptable results will be investigated and a plan of action formulated in conjuction with the Laboratory Director and Laboratory Consultant". 2. Review of the laboratory's

	American Proficiency Institute (API) proficiency testing records revealed the laboratory director did not sign the following document for one (1) of three (3) proficiency testing events reviewed in 2022 and 2023: a. 2022 Microbiology 2nd event - Laboratory Director signature on attestation statement 3. In interview on May 31, 2023 at 1:27 pm, the Laboratory Director confirmed the identified attestation statement was not signed by the laboratory director.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on observation by surveyor, review of hematology quality control (QC) records and interview with personnel, the laboratory failed to maintain instrument printouts to ensure quality of testing for at least two (2) years. Findings: 1. Direct observation by surveyor during the laboratory tour on May 31, 2023 at 10:00 am revealed the laboratory utilizes the Sysmex XP-300 analyzer for Complete Blood Count (CBC) testing in the specialty of Hematology. 2. Review of the laboratory's CBC quality control records revealed the laboratory did not retain the QC instrument printouts for the Sysmex XP-300 analyzer for the following two (2) of sixteen (16) months reviewed: a) August 2022 b) September 2022 3. In interview on May 31, 2023 at 3:15 pm, the Laboratory Director confirmed the laboratory could not produce the QC records identified above.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure, proficiency testing records and interview with personnel, the laboratory failed to retain proficiency testing records for six (6) of sixteen (16) events reviewed for at least two (2) years. Findings: 1. Review of the laboratory's proficiency testing policy revealed "All proficiency testing records are to be kept for at least two years. Records include, but are not limited to: worksheets, instrument tapes, reporting forms, attestation forms, evaluation reports, participant summaries, and corrective action documentation". 2. Review of the laboratory's American Proficiency Institiute (API) proficiency testing records for 2022 and 2023 revealed the laboratory did not retain proficiency testing records for the following six (6) of sixteen (16) events reviewed: a) 2022 Chemistry Core 1st event: no performance review b) 2022 Hematology/Coagulation 2nd event: no performance review c) 2022 Immunology/Immunohematology 1st event: no attestation statement d) 2022 Microbiology 2nd event: no performance review e) 2023 Chemistry Miscellaneous 1st event: no performance review f) 2023 Immunology /Immunohematology 1st event: no performance review 3. In interview on May 31, 2023 at 1:27 pm, the Laboratory Director confirmed the laboratory did not have the proficiency records for the identified events.

D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on observation by surveyor, review of the manufacturer's package insert and laboratory records along with interview with personnel, the laboratory failed to document the visual inspection of blood culture bottles per manufacturer's requirements. Findings: 1. Observation by surveyor during the laboratory tour on May 31, 2023 at 10:20 am revealed the laboratory utilizes BacT/ALERT Adult Blood Culture Collection Kits. 2. Further observation by surveyor on May 31, 2023 at 10:20 am revealed the laboratory has a form established to visually inspect blood culture bottles upon receipt located on the wall above cabinet that blood culture bottles are stored. 3. Review of the laboratory's policies revealed the laboratory does have a policy related to visual inspection of blood culture bottles. 4. Review of the manufacturer's package insert revealed "Inspect each blood culture bottle before use to ensure integrity of bottle and sensor on bottom of bottle is intact. The sensor is normally a uniform grayish-green color and a yellow color would indicate contamination of the medium. Discard any bottle found to be damaged or with a sensor that is yellow." 5. Review of the laboratory's blood culture bottle visual inspection form revealed the laboratory did not document new shipments upon receipt for the last six (6) of twelve (12) months reviewed. 6. In interview on May 31, 2023 at 10:25 am, Technical Consultant 1 confirmed the laboratory did not document visual inspections of the blood culture bottles received.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on observation by surveyor, review of laboratory policy and periodic maintenance records and interview with personnel, the laboratory failed to ensure timer and thermometer checks were performed annually as required by laboratory policy. Findings: 1. Direct observation by surveyor during the laboratory tour on May 31, 2023 at 10:00 am revealed the laboratory utilizes handheld timers for multiple kit testing. 2. Futher observation by surveyor on May 31, 2023 at 10:00 am revealed the laboratory utilizes thermometers for refrigerator and freezer temperature checks. 3. Review of laboratory policy revealed the laboratory performs periodic maintenance checks for timers and thermometers annually. 4. Review of the periodic maintenance

	records revealed the laboratory did not document performance of the annual checks for timers and thermometers for 2022 and 2023. 5. In interview on May 31, 2023 at 1: 50 pm, the laboratory director confirmed the laboratory did not have documentation for periodic maintenance checks for the identified years.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: I. Based on observation by surveyor, review of laboratory policy and calibration records, as well as interview with personnel, the laboratory failed to perform calibration verification procedures at least every six (6) months for the Abbott i Stat analyzer. Findings: 1. Direct observation by surveyor during the laboratory tour on May 31, 2023 at 10:00 am revealed the laboratory utilizes the Abbott i STAT analyzer for Brain Natriuretic Peptide (BNP) and Prothrombin Time (PT) testing. 2. Review of the laboratory policy for calibration verification revealed that the laboratory performs calibration verification every six (6) months for BNP and PT. 3. Review of the calibration records from 2022 and 2023 revealed the laboratory did have documentation of calibration verification performed for the following dates: a) BNP: * June 7, 2022 * April 15, 2023 b) PT: * June 7, 2022 * April 15, 2023 4. Further review of the calibration records from 2022 and 2023 revealed the laboratory did not have documentation of calibration verificaton for both analytes from the following months: a) December 2021 and/or January 2022 b) December 2022 and/or January 2023 5. In interview on May 31, 2023 at 3:30 pm, the Laboratory Director confirmed the laboratory did not have documentation of calibration verification for the identified analytes. II. Based on observation by surveyor, review of laboratory policy and calibration records, as well as interview with personnel, the laboratory failed to perform calibration verification procedures at least every six (6) months for the Quidel Triage Meter Pro analyzer. Findings: 1. Direct observation by surveyor during the laboratory tour on May 31, 2023 at 10:00 am revealed the laboratory utilizes the Quidel Triage Meter Pro analyzer for Creatine Kinase MB (CKMB) and Troponin (TROP) testing. 2. Review of the laboratory policy for calibration verification

	revealed that the laboratory performs calibration verification every six (6) months for CKMB and TROP. 3. Review of the calibration records from 2022 and 2023 revealed the laboratory did have documentation of calibration verification performed for the following dates: a) CKMB: * June 22, 2021 * June 7, 2022 * January 31, 2023 * May 1, 2023 b) TROP: * June 22, 2021 * June 7, 2022 * January 31, 2023 * May 1, 2023 4. Further review of the calibration records from 2022 and 2023 revealed the laboratory did not have documentation of calibration verificaton for both analytes from the following months: a) December 2021 and/or January 2022 5. In interview on May 31, 2023 at 3:30 pm, the Laboratory Director confirmed the laboratory did not have documentation of calibration verification for the identified analytes.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) 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. This STANDARD is not met as evidenced by: Based on observation by surveyor, review of laboratory policy and records, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D5411.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records and interview with personnel, the Laboratory Director failed to ensure proficiency testing evaluations were maintained and signed by the Laboratory Director. Findings: 1. The laboratory failed to ensure the Laboratory Director signed the attestation forms for one (1) of three (3) proficiency testing events reviewed. Refer to D2015. 2. The laboratory failed to retain proficiency testing records for six (6) of sixteen (16) events reviewed for at least two (2) years. Refer to D3037.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) 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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on review of laboratory policy and records as well as interview with personnel, the Laboratory Director failed to ensure that the laboratory performed required maintenance and/or calibration. Findings: 1. The laboratory failed to ensure timer and thermometer checks were performed annually as required by laboratory policy. Refer to D5435. 2. The laboratory failed to perform calibration verification procedures at least every six (6) months for the Abbott i Stat analyzer. Refer to D5439 I. 3. The laboratory failed to perform calibration verification procedures at least every six (6) months for the Quidel Triage Meter Pro analyzer. Refer to D5439 II.