Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0649392	04/10/2025
Name of Provider or Supplier	**Street Address, City, State**	
Bunkie General Hospital	427 Evergreen Highway, Bunkie, 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 April 7, 2025 through April 10, 2025 at Bunkie General Hospital, LLC, CLIA ID # 19D0649392. 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: 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 policy "Employee Competency" revealed the policy did not include assessment of problem solving skills for testing personnel. 2. In interview on April 7, 2025 at 3:14 p.m., the Laboratory Manager confirmed assessment of problem solving skills was not included in the competency policy as identified above.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and proficiency testing records as well as interview with laboratory personnel, the laboratory failed to perform assessment

	activities for an unacceptable proficiency testing (PT) result for one (1) of sixty (60) events reviewed. Findings: 1. Review of the laboratory's policy "Lab Proficiency Testing" section "Unacceptable Challenge" revealed "An 'Action Needed Form' must be completed for an unacceptable challenge. All related data * must be reviewed to determine the exact cause for the failure and this data is attached to the ANF and all routed within one week for review by the Lab Director." 2. Review of the laboratory's College of American Pathologists (CAP) proficiency testing records from January 2024 through April 2025 revealed the following event had a result graded as "unacceptable," but the laboratory did not perform corrective actions: a) CM-A 2024 Clinical Microscopy sample CMP-04 3. In interview on April 7, 2025 at 2:39 p.m., the Laboratory Manager stated the unacceptable result was missed when the report was evaluated. She confirmed the laboratory did not perform corrective actions for the unacceptable result identified above.
D5305	TEST REQUEST CFR(s): 493.1241(c) (c) The laboratory must ensure the test requisition solicits the following information: (c)(1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (c)(2) The patient's name or unique patient identifier. (c)(3) The sex and age or date of birth of the patient. (c)(4) The test(s) to be performed. (c)(5) The source of the specimen, when appropriate. (c)(6) The date and, if appropriate, time of specimen collection. (c)(7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (c)(8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on review of patient test records and interview with laboratory personnel, the laboratory failed to document the specimen collection time for twelve (12) of twelve (12) patient specimens reviewed. Findings: 1. Review of a random selection of patient test records revealed the following patients did not have an accurate time of collection documented: - MRN 057261 on 04/06/2025 - Collection and received time both documented as 1910 for DDimer testing. - MRN 073115 on 04/03/2025 - Collection and received time both documented as 0420 for Protime, INR, and Partial Thromboplastin Time testing. - MRN 072336 on 10/13/2024 - Collection and received time both documented as 2244 for blood gas testing. - MRN 028642 on 10/15/2024 - Collection and received time both documented as 0028 for blood gas testing. - MRN 001614 on 10/15/2024 - Collection and received time both documented as 1804 for blood gas testing. - MRN 054356 on 11/11/2024 - Collection and received time both documented as 1351 for blood gas testing. - MRN 034728 on 01/21/2025 - Collection and received time both documented as 2240 for blood gas testing. - MRN 048530 on 01/24/2025 - Collection and received time both documented as 0212 for blood gas testing. - MRN 015783 on 01/27/2025 - Collection and received time both documented as 1940 for blood gas testing. - MRN 049767 on 01/15/2025 - Collection and received time both documented as 2210 for lactic acid testing. - MRN 024279 on 01/29/2025 - Collection and received time both documented as 0940 for lactic acid testing. - MRN 068533 on 01/29/2025 - Collection and received time both

	documented as 2133 for lactic acid testing. 2. In interview on April 9, 2025 at 11:40 a. m., the Laboratory Manager confirmed the collection time and received times were documented as the same times as identified above.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, review of emergency release transfusion records, and interview with personnel, the laboratory failed to follow their established policy for ABO/Rh typing of blood products prior to patient testing. Findings: 1. Review of the laboratory's policy "Blood Bank Compatibility Testing" revealed "The AABB Standards for Blood Banks and Transfusion Services requires that the following procedures be performed before blood components are issued for transfusion: Confirmation of the ABO group of red cell components" and "Confirmation of the Rh type of Rh-negative red cell components." 2. In interview on April 8, 2025 at 12:30 p.m., the Laboratory Manager confirmed blood bank personnel do not verify the ABO/Rh typing of units received from their contracted blood center until performing patient and unit crossmatch testing. 3. Review of a random selection of emergency release transfusion records from 2024 and 2025 revealed the laboratory issued eight (8) of eight (8) emergency release units without confirming the blood type prior to release for patient transfusion for the following patients: a) 03/22/2024 - MRN 004378 b) 04/14/2024 - MRN 025951 c) 12/25/2024 - MRN 027855 d) 04/02 /2025 - MRN 031692 4. In interview on April 8, 2025 at 12:30 p.m., the Laboratory Manager confirmed the laboratory did not confirm the ABO/Rh blood type before releasing units for emergency release blood products.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation, review of manufacturer's instructions and laboratory temperature records, as well as interview with personnel, the laboratory failed to define acceptable refrigerator temperature limits within the manufacturer's required range for supplies stored in the Blood Bank refrigerator. Findings: 1. Observation by surveyor during the laboratory tour on April 7, 2025 at 11:12 a.m. revealed the following supplies stored in the Blood Bank refrigerator: a) Ortho Reagent Red Blood

	Cells Selectogen - Manufacturer's storage requirements 2 - 8 degrees Celsius b) Ortho Reagent Red Blood Cells (Pooled Cells) 0.8% Affirmagen - Manufacturer's storage requirements 2 - 8 degrees Celsius c) Ortho Reagent Red Blood Cells (Pooled Cells) Ortho Coombs Control - Manufacturer's storage requirements 2 - 8 degrees Celsius 2. Review of the laboratory's 2025 Blood Bank refrigerator temperature records revealed the laboratory defined the acceptable temperature limits as 1 - 6 degrees Celsius which exceeded the manufacturer's lower temperature limits. 3. In interview on April 8, 2025 at 10:24 a.m., the Laboratory Manager confirmed the laboratory's acceptable refrigerator temperature exceeded the manufacturer's limits as identified above.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the laboratory's performance specification studies and interview with personnel, the laboratory failed to verify complete performance specification studies to include reference range studies for C-reactive protein (CRP) testing. Findings: 1. Review of performance specification studies for CRP testing on the Siemens Dimension EXL with LM revealed "Verification of Manufacturer Reference Range was obtained from running ten (10) normal patients; 5 males and 5 females." 2. Further review of the performance specification studies revealed the laboratory failed to provide data to support the verification of the 3. In interview on April 8, 2025 at 9:16 a.m., the Laboratory Manager confirmed the laboratory did not have the data to support the verification of the reference range for CRP as identified above.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on observation, review of the laboratory's maintenance logs, and interview with laboratory personnel, the laboratory failed to ensure weekly maintenance was performed on the Cepheid GeneXpert System as required by the manufacturer for four (4) of fifty-six (56) weeks reviewed. Findings: 1. Observation by surveyor during the laboratory tour on April 7, 2025 at 11:12 a.m. revealed the laboratory utilized the Cepheid GeneXpert System for Influenza A, Influenza B, Respiratory syncytial virus (RSV), Sars-CoV-2, Chlamydia trachomatis, Neisseria gonorrhoeae, Trichomonas vaginalis, and Group A Streptococcus testing. 2. Review of the laboratory's maintenance logs provided by the manufacturer for the Cepheid GeneXpert analyzer revealed the following required weekly maintenance tasks: a) Power down the GeneXpert instrument b) Power down the GeneXpert computer 3. Further review of

	the laboratory's Cepheid GeneXpert maintenance logs from January 2024 through January 2025 revealed the laboratory failed to perform weekly maintenance during the following weeks: a) March 31 - April 6, 2024 b) June 30 - July 6, 2024 c) September 29 - October 5, 2024 d) December 29, 2024 - January 4, 2025 4. In interview on April 8, 2025 at 4:07 p.m., the Laboratory Manager confirmed weekly maintenance was not performed as identified above.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) (b)(2)(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. (b)(2)(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, review of the laboratory's policies, and interview with laboratory personnel, the laboratory failed to establish complete function check protocols for the Clay Adams serofuge. Findings: 1. Observation by surveyor during the laboratory tour on April 7, 2025 at 11:12 a.m. revealed the laboratory utilized the Clay Adams serofuge for blood bank testing. 2. Review of the laboratory's policy "Serologic Centrifuge Calibration (Immediate Agglutination Testing)" revealed "The centrifuge should be calibrated upon receipt, after adjustments or repairs, and periodically" but did not define "periodically." 3. In interview on April 8, 2025 at 1:11 p.m., the Laboratory Manager confirmed the laboratory did not define "periodically" for the calibration of the serofuge.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on record review, and interview with personnel, the Laboratory Director failed to ensure that complete verification procedures were performed. Refer to D5421.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) (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 record review and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D5305.

D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) (e)(4)(iv) An approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure the laboratory performed corrective actions for unacceptable proficiency testing results. Refer to D5221.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) (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 observation, record review, and interview with personnel, the Laboratory Director failed to ensure that the laboratory performed required maintenance. Refer to D5429.
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 record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Refer to D5209.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. The technical consultant is not required to be onsite at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide consultation, as specified in paragraph (a) of this section. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Technical Consultant failed to provide technical and scientific oversight to the laboratory. Findings: 1. The laboratory failed to perform assessment activities for an unacceptable

	proficiency testing (PT) result for one (1) of sixty (60) events reviewed. Refer to D5221. 2. The laboratory failed to document the specimen collection time for twelve (12) of twelve (12) patient specimens reviewed. Refer to D5305. 3. The laboratory failed to ensure weekly maintenance was performed on the Cepheid GeneXpert System as required by the manufacturer for four (4) of fifty-six (56) weeks reviewed. Refer to D5429.
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) (b)(2) Verification of the test procedures performed and the establishment of the laboratorys test performance characteristics, including the precision and accuracy of each test and test system; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Consultant failed to ensure performance specification verification studies were complete. Refer to D5421.
D6052	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(vi) (b)(8)(vi) Assessment of problem-solving skills; and This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS-209 (Laboratory Personnel Report) and personnel records as well as interview with personnel, the Technical Consultant failed to ensure competency assessments for ten (10) of ten (10) testing personnel included assessment of problem solving skills for moderate complexity testing in 2024. Findings: 1. Review of the laboratory's CMS-209 form revealed the following testing personnel: Personnel 2 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 records revealed annual competency assessments were performed in 2024, but the laboratory failed to provide documentation to support the assessment of problem solving skills for the testing personnel identified above. 3. In interview on April 7, 2025 at 3:14 p.m., the Laboratory Manager confirmed the laboratory did not have documentation to support the assessment of problem solving skills.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) (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, record review, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to follow their established policy for ABO/Rh typing of blood products prior to patient testing. Refer to D5401. 2. The laboratory failed to define acceptable refrigerator temperature limits within the

	manufacturer's required range for supplies stored in the Blood Bank refrigerator. Refer to D5413.
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) (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 observation, record review, and interview with personnel, the Laboratory Director failed to ensure the establishment of maintenance procedures as required. Refer to D5435.