

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0649392	(X3) Date Survey Completed 07/20/2023
Name of Provider or Supplier Bunkie General Hospital	Street Address, City, State 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 July 20, 2023 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.
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing records and the laboratory's policy and procedure manual and interview with laboratory personnel, the laboratory failed to review the proficiency testing performance evaluation for one (1) of thirty (30) events reviewed. 1. Review of the laboratory's College of American Pathologists (CAP) proficiency testing records revealed the laboratory did not review the performance evaluation for J-B 2022 Transfusion Medicine. 2. Review of the laboratory's policy "Proficiency Testing" revealed "The Lab Manager is to perform the survey result evaluation review, upon receipt of the result evaluation and return it to the Laboratory Director as soon as possible." 3. In interview on July 17, 2023 at 4:38 p.m., the Technical Consultant confirmed the laboratory did not review the performance evaluation identified above.</p>
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p>

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policy and procedure manual and proficiency testing records as well as interview with laboratory personnel, the laboratory failed to follow their quality assessment policy for proficiency testing (PT) for one (1) of thirty (30) events reviewed. Findings: 1. Review of the laboratory's "Proficiency Testing" policy 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) C-A 2022 General Chemistry/Therapeutic Drugs proficiency testing records revealed the laboratory had a grade of unacceptable for sample CHM-01 Salicylates. 3. Further review of the laboratory's proficiency testing records with raw data revealed the laboratory did not complete an "Action Needed Form" per their policy for the unacceptable sample identified above. 4. In interview on July 17, 2023 at 4:38 p.m., the Technical Consultant confirmed the laboratory did not follow their policy for proficiency testing.

D5403

PROCEDURE MANUAL

CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

I. Based on observation, review of the laboratory's policy and procedure manual, and interview with personnel, the laboratory failed to maintain complete policies and procedures for chemistry testing. Findings: 1. Observation by surveyors during the laboratory tour on July 17, 2023 at 1:30 p.m. revealed the laboratory utilized patient pooled serum prepared by the laboratory for quality control of serum acetone and human chorionic gonadotropin (HCG) testing. 2. Further observation revealed the quality control material identified above did not have expiration dates documented on the vials. 3. Review of the laboratory's policy and procedure manual revealed a reagent policy that stated "Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: 1. Identity and when significant, titer, strength or concentration. 2.

Storage requirements. 3. Preparation and expiration date." 4. In interview on July 17, 2023 at 1:30 p.m., the Technical consultant stated the laboratory did not define the stability requirements for the laboratory prepared pooled patient serum quality control identified above. II. Based on review of the laboratory's policy and procedure manual and quality control records as well as interview with laboratory personnel, the laboratory failed to follow their policy for quality control (QC) of blood bank testing. Findings: 1. Review of the laboratory's policy and procedure manual revealed a policy "Blood Bank Quality Controls" which stated the following: - The Ortho Confidence System should be performed with each day (24 hours) of blood bank testing. - If unexpected results occur, the procedure should be repeated carefully following the instructions given. Fresh bottle of reagents or blood bank saline can be opened also. - All lots and expiration dates must be reviewed and documented in the blood bank log in the area provided. 2. Review of quality control records for blood bank revealed the laboratory did not follow their policy for quality control documentation on the following dates: - January 2, 2023 - QC Cell I - Rh result interpretation not documented - January 7, 2023 - saline lot number and expiration date not documented - January 30, 2023 - saline open expiration date not documented (Lot 511544, manufacturer's expiration date February 29, 2024) - February 1, 2023 - saline open expiration date not documented (Lot 511544, manufacturer's expiration date February 29, 2024) - February 23, 2023 - saline open expiration date not documented (Lot 511544, manufacturer's expiration date February 29, 2024) - April 6, 2023 - time quality control performed not documented - May 12, 2023 - time quality control performed not documented - June 19, 2023 - time quality control performed not documented 3. In interview on July 19, 2023 at 12:50 p.m., the Technical Consultant confirmed the laboratory did not follow their blood bank quality control policy for the dates identified above.

D5415

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(c)**

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:
Based on observation, review of manufacturer's requirements, and interview with personnel, the laboratory failed to document the open expiration date for laboratory quality control and reagents as required. Findings: 1. Observation by surveyors during the laboratory tour on July 17, 2023 at 1:30 p.m. revealed the laboratory had the following open items but did not document the open expiration date: a) e-Check Hematology control: Lots 31490805, 31490804, 31490806, manufacturer's original expiration date August 20, 2023, documented open date July 10, 2023 b) Nerl reagent grade water: Lot 572502, expiration date Jan 2024; date documented on the reagent box by the laboratory was June 30, 2023, but did not document the meaning of the date 2. Review of manufacturer's requirements revealed the following: a) e-Check Hematology controls - "Opened and recapped vials and vials whose caps have been pierced will retain stability for 14 days if stored at 2-8 degrees Celsius." b) Nerl reagent grade water - open stability stated on the box by the manufacturer was thirty

(30) days 3. In interview on July 17, 2023 at 2:06 p.m., the Technical Consultant confirmed the laboratory did not document the open expiration date on the items identified above.

D5555

IMMUNOHEMATOLOGY

CFR(s): 493.1271(c)(f)

(c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policy and procedure manual and alarm verification records, as well as interview with laboratory personnel, the laboratory failed to ensure the quarterly blood bank alarm verification was performed for two (2) of six (6) quarters reviewed. Findings: 1. Review of the laboratory's policy "Blood Bank Audible Alarm Check" revealed the blood bank alarm system "...will be tested (low and high alarm activation) and documented on the circle chart every three months preferably within 1 week of each other on the same blood bank circle chart." 2. Review of the blood bank's "Thermo Scientific TSX Blood Bank Fridge Maintenance Log" revealed the laboratory's quarterly maintenance due dates were defined on the log as "01/22, 04/22, 08/22, 12/22" and were not every three months for the third and fourth quarter of 2022. 3. Further review of blood bank refrigerator maintenance records revealed the laboratory did not perform alarm checks every three months in the third quarter of 2022 (due July 2022) and fourth quarter of 2022 (due October 2022). 4. In interview on July 19, 2023 at 10:18 a.m., the Technical Consultant confirmed the laboratory did not perform the blood bank alarm checks every three months for third and fourth quarters in 2022.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on observation, record review, and interview with personnel, the laboratory failed to have Quality Assurance monitors in place to identify and correct quality issues in Analytic Systems. Findings: 1. Review of the laboratory's policy and procedure manual revealed a quality assurance policy, but it did not identify the following issues: a) The laboratory failed to maintain complete policies and procedures for chemistry testing. Refer to D5403 I. b) The laboratory failed to follow their policy for quality control (QC) of blood bank testing. Refer to D5403 II. c) The laboratory failed to document the open expiration date for laboratory quality control

	<p>and reagents as required. Refer to D5415. d) The laboratory failed to ensure the quarterly blood bank alarm verification was performed for two (2) of six (6) quarters reviewed. Refer to D5555.</p>
D6014	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii)</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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel were performing test methods as required for accurate and reliable results. Refer to D5415.</p>
D6031	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13)</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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D5403 I.</p>
D6036	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413</p> <p>The technical consultant is responsible for the technical and scientific oversight of the laboratory.</p> <p>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 maintain complete policies and procedures for chemistry testing. Refer to D5403 I. 2. The laboratory failed to document the open expiration date for laboratory quality control and reagents as required. Refer to D5415.</p>
D6087	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii)</p>

The laboratory director must ensure that 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. Findings: 1. The laboratory failed to follow their policy for quality control (QC) of blood bank testing. Refer to D5403 II. 2. The laboratory failed to ensure the quarterly blood bank alarm verification was performed for two (2) of six (6) quarters reviewed. Refer to D5555.

D6091

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(4)(iii)

The laboratory director must ensure 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 record review and interview with personnel, the Laboratory Director failed to ensure 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. Refer to D5211.

D6094

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on observation, record review and interview with laboratory personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided. Findings: 1. The laboratory failed to follow their quality assessment policy for proficiency testing (PT) for one (1) of thirty (30) events reviewed. Refer to D5291. 2. The laboratory failed to have Quality Assurance monitors in place to identify and correct quality issues in Analytic Systems. Refer to D5791.

D6144

GENERAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1463

The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results.

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the General Supervisor failed to

provide day-to-day supervision to testing personnel to ensure accurate and reliable test performance of laboratory testing. Findings: 1. The laboratory failed to ensure the quarterly blood bank alarm verification was performed for two (2) of six (6) quarters reviewed. Refer to D5555. 2. The laboratory failed to follow their policy for quality control (QC) of blood bank testing. Refer to D5403 II.