Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0649392	04/18/2019
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 Certification Survey was performed on April 15, 2019 through April 18, 2019 at Bunkie General Hospital, CLIA ID # 19D0649392. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to establish complete detailed written instructions for providers to maintain the integrity of samples and ensure accurate and reliable testing. Findings: 1. Review of a random selection of the laboratory's manual for outside facilities versus the manufacturer assay instructions revealed the laboratory did not address the following examples (not meant to be an inclusive list): a) Calcium (CA): Laboratory manual states: Must be separated within 2 hours; Specimen stability 8 hours at room temperature, 2 days refrigerated Siemens Dimension EXL: Serum must be separated from red cells and analyzed promptly; Specimen stability 8 hours at room temp, 2 days refrigerated. b) Quicklyte (NA\K\CL) Laboratory manual states: Must be separated within 2 hours; Specimen stability 1 week at room temperature and refrigerated Siemens Dimension EXL: Serum must be separated within 1 hour; Specimen stability 1 week at room temperature and refrigerated c) Free Triiodothyronine (FT3) Laboratory manual states: Must be separated within 2 hours; Specimen stability 8 hours at room temperature, 7 days refrigerated Siemens Dimension EXL: Separate serum or plasma

	from cells as soon as possible; Specimen stability 8 hours at room temperature, 7 days refrigerated 2. In interview on April 16, 2019, the General Supervisor confirmed the manual for outside facilities did not reflect the manufacturer's requirements.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(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 record review and interview with personnel, the laboratory failed to establish a complete policy and procedure manual. Findings: 1. Review of the laboratory's policies and procedures revealed it did not include the following: a) Detailed instructions for blood banking to include but not limited to: How the laboratory is to identify in a conspicuous fashion that compatibility testing was not complete at the time of issue (Emergency Release). 2. In interview on April 17, 2019 at 2:51 pm, the General Supervisor stated that Emergency Release units are not identified differently than routine transfusions upon leaving the laboratory. The General Supervisor confirmed the laboratory did not have a written policy for identification of emergency units.
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, record review and interview with personnel, the laboratory failed to ensure the donor questionnaires for Mean Prothrombin Time studies corresponds with the raw data on the instrument tapes. Findings: 1. Observation by surveyor during laboratory tour on April 15, 2019 revealed the laboratory utilizes the Sysmex CA-600 analyzer for Prothrombin Time (PT) and International Normalized Ratio (INR) testing. 2. Review of the laboratory's policy "Establishing Patient Normal Mean/Patient Correlation" revealed the laboratory did not have detailed , written instructions for the identification of the donor questionnaire and the corresponding raw data. 3. Review of the Normal Mean Prothrombin Time study (NMPT) revealed the laboratory did have twenty (20) donor questionnaires; however, the laboratory did not identify each questionnaire to correspond with the raw data provided for the NMPT study. 3. In interview on April 17, 2019 at 11:20 am, the General Supervisor stated the laboratory usually identifies the donor questionnaires with numbers one (1) through twenty (20) and uses that number to identify the raw data for that donor. The General Supervisor further stated she did not know why the questionnaire did not have identifiers to correspond to the instrument tapes. 4. In further interview on April 17, 2019, the General Supervisor confirmed the laboratory did not identify questionnaires to correspond with the raw data provided for the studies. 5. Review of

	the Task 1 and 3 forms provided to surveyors revealed the laboratory performs 918 PT /INR tests annually.
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, record review, and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed testing as required. Refer to D5411.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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; 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 an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Findings: 1. The laboratory failed to establish complete detailed written instructions for providers to maintain the integrity of samples and ensure accurate and reliable testing. Refer to D5317. 2. The laboratory failed to establish a complete policy and procedure manual. Refer to D5401.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Technical Consultants failed to provide technical and scientific oversight to the laboratory. Findings: 1. The laboratory failed to establish complete detailed written instructions for providers to maintain the integrity of samples and ensure accurate and reliable testing. Refer to D5317. 2. The laboratory failed to establish a complete policy and procedure manual. Refer to D5401. 3. The laboratory failed to ensure the donor

	questionnaires for Mean Prothrombin Time studies corresponds with the raw data on the instrument tapes. Refer to D5411.