Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0303966	06/01/2023
Name of Provider or Supplier	**Street Address, City, State**	
Bullock County Hospital	102 Conecuh Avenue, Union Springs, AL	

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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) proficiency testing (PT) records and an interview with Testing Personnel #1 and #3, the surveyor determined the Laboratory Director (or Designee) failed to sign the attestation statements for fifteen out of sixteen 2021-2023 survey events, and the personnel performing moderate-complexity testing failed to sign the attestation statements for two of sixteen survey events. The findings include: 1. A review of the 2021-2023 API records revealed the Laboratory Director failed to sign the attestation statements for 15 out of 16 survey events; only the 2022 Event-1 Immunohematology/Immunology statement was signed by the Director. The surveyor also noted Testing Personnel #5 had signed one attestation as the Director, however there was no record documenting this individual was the Laboratory Director's Designee. 2. A further review of the 2021-2023 API records revealed the attestation statements for Chemistry /Endocrinology surveys, Events 2021 Event-3 and 2022 Event-1 were not signed by the moderate-complexity testing personnel. Only Testing Personnel #1 had signed as a waived testing personnel (for Urine Drug Screening) on the latter event. 3. A review of the API Attestation Statement page revealed the following instructions: "SIGNATURES REQUIRED-Testing personnel and the laboratory director must physically sign an attestation statement for all PT results. ...". The surveyor noted the words "physically sign" were underlined. 4. During an interview on 5/31/2023 at 2:15 PM, Testing Personnel #1 and #3 confirmed the above findings. .
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT

	CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on a review of the API (American Proficiency Institute) proficiency testing (PT) records, and an interview with Testing Personnel #1 and #3, the surveyor determined the laboratory failed to perform effective Quality Assurance (QA) reviews of the PT records to ensure: (I) All attestation statements were signed by the Laboratory Director (or designee) and the testing personnel; (II) Corrective Actions were documented for all unsuccessful PT performance (any scores less that 100 percent); and (III) All surveys were reviewed for clerical errors before submission to API. The surveyor noted insufficient QA review for all surveys reviewed from August 2021 through January 2023. The findings include: 1. A review of API PT records revealed the following: A) Attestation statements: the Laboratory Director (or Designee) failed to sign the attestation statements for fifteen out of sixteen 2021-2023 survey events, and the personnel performing moderate-complexity testing failed to sign the attestation statements for two of sixteen surveys. [Refer to D2009.] B) The surveyor noted no documented corrective actions for analytes with scores less that 100%, as follows: i) 2021 Chemistry-Event #3: Acetaminophen with a score of 80% ii) 2021 Hematology-Event #3: MCHC (Mean Corpuscular Hemoglobin Concentration) with a score of 80% C) Clerical Errors, as follows: i) 2021 Immunohematology-Event #2: Crossmatching ii) 2022 Chemistry/Endocrinology-Event #1: TSH (Thyroid Stimulating Hormone), Free T4 (Free Thyroxine) and LDL (Low Density Lipoprotein) iv) 2023 Chemistry/Endocrinology-Event #1: Folate 2. During an interview on 5/31/2023 at 2:15 PM, these concerns were reviewed and confirmed with Testing Personnel #1 and #3. .
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on reviews of Seimens Dimension EXL-200 Chemistry / Immunoassay analyzer records, Sysmex CA-600 Coagulation analyzer records, and ABL 80 Arterial Blood Gas (ABG) analyzer records, and interviews with Testing Personnel #1, #5 and the current Laboratory Manager, the laboratory failed to ensure the quality of the analytic systems, as follows: A) Failure to ensure the validation for the Innovin Reagent, lot number 549786 was performed and documented before use for patient testing on 9/5/2022. The laboratory further failed to perform and document the manual INR (International Normalized Ratio) checks on the new lot # of Innovin. (Refer to D5411.) B) Failure to ensure calibration verification was performed and

	documented semi-annually on the Seimens Dimension EXL-200 Chemistry / Immunoassay analyzer and the ABL 80 ABG analyzer. (Refer to D5439.) C) Failure to implement a mechanism to allow review of the Dimension EXL-200 Chemistry analyzer QC and the Sysmex CA-600 Coagulation analyzer QC for shifts and trends. (Refer to D5441.) .
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 a lack of validation documentation for the current lot number (#) of Innovin (Prothrombin Time) reagent, a review of the manufacturer's and laboratory's procedures, and interviews with Testing Personnel #5 and the new Laboratory Manager (also the General Supervisor), the laboratory failed to perform and document the validation for the Innovin Reagent, lot number 549786 before patient testing began on 9/5/2022. The laboratory further failed to perform and document the manual INR (International Normalized Ratio) checks on the new lot # of Innovin. The laboratory utilized the new lot # of Innovin for nearly nine months without performing and documenting the "Lot Rollover" studies, as required by the manufacturer. The findings include: 1. During the entrance tour on 5/31/2023 at approximately 9:45 AM, the surveyor reveiwed the laboratory test menu, which included coagulation testing (PT [Prothrombin Time] and PTT [Partial Thromboplastin Time]) on the Sysmex CA-600. The surveyor requested a printout of the current lot # of PT reagent and the ISI (International Sensitivity Index) from instrument. The printout documented the following: Lot # 549786, Expiry Date 9/24/2023, and the ISI was 1.05. This information matched the manufacturer's assay from the Innovin in the refrigerator. The printout also documented the Geometric Mean Normal was 10.6 seconds. 2. On 6 /1/2023 at 9:30 AM, the surveyor requested the validation records for Innovin lot # 549786, however Testing Personnel #5 stated they were having trouble finding the records, and were not sure a validation was performed. 3. On 6/1/2023 at 10:05 AM the new Laboratory Manager explained they believe Testing Personnel #2 had run the PT on 20 normal patients. They had found the instrument printouts tucked into a binder. During a phone conversation with the Manager, Testing Personnel #2 confirmed she had run the PT testing on the normal patient samples, however she had thought Testing Personnel #1 would calculate the Geometric Mean Normal PT, and perform any tasks required for the validation. 4. As the interview continued, the Manager stated they had calculated the Geometric Mean Normal PT using the data Testing Personnel #2 had left in the binder, and determined the actual value was 10.4, not 10.6 seconds (the value in the Sysmex CA-600). The Laboratory Manager was unable to give a definitive answer on who had entered the information for Innovin lot # 549786 into the the Sysmex, or why they entered 10.6 seconds as the Geometric Mean Normal PT. The surveyor then asked for the laboratory procedures for running PT's, and the manufacturer's information on the Innovin reagent. 5. A review of the laboratory procedure titled, "Dade Innovin Prothrombin Time" revealed information on the specimen, reagent, quality control (QC) and test performance, however there were no instructions on validation requirements for new lot numbers of Innovin reagent. 6. A review of the "Seimens Healthineers Sysmex CA-600 Series Customer

	Bulletin" titled, "Sysmex CA-600 Series Lot Rollover Information" on page 2 revealed, "...Before using the new reagent lot ... it is common practice to perform the following procedures: Establish or verify reference intervals (reference ranges) Establish geometric mean normal PT (MNPT) value for new PT reagent Establish QC ranges ... Perform a lot-to-lot method correlation with patient samples on both your current lot and new reagent lots..." In addition, page 11-12 of the bulletin provides instructions on entering the new information correctly into the Sysmex CA-600 analyzer. 7. The surveyor's review of the "New Lot of PT Reagent Worksheet" revealed the laboratory also failed to perform the Manual INR (International Normalized Ratio) Check (for three patients with normal and abnormal PT's) to ensure the instrument accurately calculated the patient's INR whenever a new lot # of Innovin was implemented. 8. During the exit summation on 6/1/2023 at 3:30 PM these concerns were reviewed and confirmed with the Laboratory Manager, Testing Personnel #1 and #5, and Hospital Administrators. .
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: Based on a review of calibration verification (C-V) records and an interview with Testing Personnel #1, the laboratory failed to ensure C-V was performed and documented on the Seimens Dimension EXL-200 Chemistry / Immunoassay analyzer the second half of 2021 and the second half of 2022 (two of four C-V's missed). The laboratory further failed to provide any C-V records for the ABL-80 Arterial Blood Gas (ABG) analyzer for 2021-2023 during the survey process. The findings include: 1. A review of the records for the Seimens Dimension EXL-200 Chemistry / Immunoassay analyzer revealed the electrolytes (Sodium, Potassium, and Chloride) were calibrated with two on-board calibrators. Analytes calibrated with less than three calibrators must have a semi-annual C-V, as per CLIA regulatory requirements. 2. A review of the Dimension EXL-200 records revealed documentation of C-V performed on 4/26/2022 and 5/4/2023 only. 3. During a review of the records and an interview on 5/31/2023 at 4:55 PM, Testing Personnel #1 stated in 2021 a previous Laboratory

	Manager was in charge, and she did not know if any C-V's were performed in 2021. Testing Personnel #1 further stated she did not think the lab had performed a C-V the second half of 2022. 4. On 6/1/2023 at approximately 3:00 PM, the surveyor requested the ABL-80 ABG analyzer records. Calibrations are performed with two on-board calibrators, thus semi-annual C-V was required. No C-V records were provided with the quality control records during the survey. On 6/5/2023 the surveyor asked if the laboratory would like to forward the ABL-80 ABG C-V records to the CLIA office for review, however no records were received. .
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of Quality Control (QC) records for the Seimens Dimension EXL 200 Chemistry analyzer and the Sysmex CA-600 Coagulation analyzer, and interviews with Testing Personnel #1 and #5, the surveyor determined the laboratory failed to implement mechanisms to track for shifts and trends over time since the previous survey on 9/8/2021. The findings include: 1. A review of Chemistry records for the Seimens Dimension EXL 200 Chemistry /Immunoassay analyzer revealed only the individual daily QC printouts. The laboratory had no mechanism to track for shifts and trends over time in the QC. 2. During an interview on 6/1/2023 at 9:40 AM, Testing Personnel #1 and #5 confirmed the laboratory did not print Levey Jennings charts for the Chemistry QC, and did not submit their QC data to an Interlaboratory Quality Assurance Program (IQAP) as an alternate means of tracking for shifts and trends. Later (during the exit summation), as an example, the surveyor discussed the Level-2 Calcium QC trending in the lower ranges of acceptability on the printouts from 5/19--5/20/2022 (when proficiency testing [PT] was performed), and for most of the month of June 2022. (The PT evaluation also showed a negative bias in laboratory's Calcium results.) However, the laboratory failed to note the problem and perform corrective actions since there was no method to track for shifts and trends. 3. A review of the Coagulation QC performed on the Sysmex CA-600 Coagulation analyzer revealed the laboratory recorded results on a "Daily QC Log". The laboratory had no mechanism to track for shifts and trends over time in the QC. 4. During an interview on 6/1/2023 at 2:05 PM, Testing Personnel #1 confirmed the laboratory did not print Levey Jennings charts for the Coagulation QC, and did not submit their QC data to the Seimens IQAP for evaluation, as an alternate means of tracking for shifts and trends. .
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 a lack of Quality Assurance (QA) records and an interview with Testing Personnel #1, the laboratory failed to implement and document QA reviews to ensure the quality of the analytical systems. Failures were noted to occur from the date of the previous survey on 9/8/2021 until the current survey. The findings include: 1. A review of laboratory records revealed a lack of QA reviews to ensure the quality of the analytical systems, as follows: A) Failure to ensure the validation for the Innovin Reagent, lot number 549786 was performed and documented before use for patient testing on 9/5/2022. The laboratory further failed to perform and document the manual INR (International Normalized Ratio) checks on the new lot # of Innovin. (Refer to D5411.) B) Failure to ensure calibration verification was performed and documented semi-annually on the Seimens Dimension EXL-200 Chemistry / Immunoassay analyzer and the ABL-80 Arterial Blood Gas (ABG) analyzer. (Refer to D5439.) C) Failure to implement a mechanism to allow review of the Dimension EXL-200 Chemistry analyzer QC and the Sysmex CA-600 Coagulation analyzer QC for shifts and trends. (Refer to D5441.) 2. During an interview on 6/1/2023 at approximately 3:28 PM, Testing Personnel #1 confirmed the laboratory had no QA records for review. In addition, at approximately 3:40 PM during the exit summation, these concerns were reviewed with Testing Personnel #1 and #5, and Hospital Administration. .
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on reviews of Proficiency Testing (PT), Seimens Dimension EXL-200 Chemistry / Immunoassay analyzer records, Sysmex CA-600 Coagulation analyzer records, and ABL-80 Arterial Blood Gas (ABG) analyzer records, and interviews with Testing Personnel #1, #5 and the current Laboratory Manager, the surveyor determined the Laboratory Director failed to provide technical and scientific oversight, or appoint a qualified individual to perform these duties from the date of the previous survey on 9/8/2021 to the current survey. The findings include: 1. Refer to D6036. .
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409

	The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on reviews of Proficiency Testing (PT), Seimens Dimension EXL-200 Chemistry / Immunoassay analyzer records, Sysmex CA-600 Coagulation analyzer records, and ABL-80 Arterial Blood Gas (ABG) analyzer records, and interviews with Testing Personnel #1, #5 and the current Laboratory Manager, the surveyor determined the Technical Consultant (also the Laboratory Director) failed to provide technical and scientific oversight and direction from the date of the previous survey on 9/8/2021 to the current survey. The findings include: 1. Refer to D6036.
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 reviews of Proficiency Testing (PT), Seimens Dimension EXL-200 Chemistry / Immunoassay analyzer records, Sysmex CA-600 Coagulation analyzer records, and ABL Arterial Blood Gas (ABG) analyzer records, and interviews with Testing Personnel #1, #5 and the current Laboratory Manager, the surveyor determined the Technical Consultant (also the Laboratory Director) failed to provide technical and scientific oversight and direction from the date of the previous survey on 9/8/2021 to the current survey. The findings include: 1. A review of laboratory records revealed a lack of technical and scientific oversight and direction contributed to the following deficiencies: A) Failure to ensure PT attestation statements were signed; corrective actions were documented for all unsuccessful PT performance; and all PT surveys were reviewed for clerical errors before submission. (Refer to D2009 and D5291.) B) Failure to ensure the validation for the Innovin Reagent, lot number 549786 was performed and documented before use for patient testing on 9/5/2022. The laboratory further failed to perform and document the manual INR (International Normalized Ratio) checks on the new lot # of Innovin. (Refer to D5411.) C) Failure to ensure calibration verification was performed and documented semi-annually on the Seimens Dimension EXL-200 Chemistry / Immunoassay analyzer and the ABL Arterial Blood Gas (ABG) analyzer. (Refer to D5439.) D) Failure to implement a mechanism to allow review of the Dimension EXL-200 Chemistry analyzer QC and the Sysmex CA-600 Coagulation analyzer QC for shifts and trends. (Refer to D5441.) 2. During the exit summation on 6/1/2023 at 3:30 PM, the lack of technical and scientific oversight and direction was discussed and confirmed with Testing Personnel #1, #5, the current Laboratory Manager, and Hospital Administration. SURVEYOR IS #32558 Licensure and Certification Surveyor