Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0303966	09/08/2021
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
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on a review of American Proficiency Institute (API) Proficiency Testing records and an interview with the General Supervisor, the Laboratory failed to verify the accuracy of Antibody Screen, Urine Sediment, and Blood Cell Identification that were not evaluated by American Proficiency Institute (API). This was noted on eight out of thirteen 2019 - 2021 Immunology/Immunohematology and Hematology /Coagulation proficiency testing events. The findings include: 1. A review of Proficiency Testing records revealed the following: a.) 2019 2nd Hematology /Coagulation Event - Blood Cell Identification (all samples) was not graded due to educational samples b.) 2019 3rd Hematology/Coagulation Event - Blood Cell Identification (all samples) was not graded due to educational samples c.) 2020 1st Hematology/Coagulation Event - Blood Cell Identification (all samples) was not graded due to educational samples d.) 2020 2nd Hematology/Coagulation Event - Blood Cell Identification (all samples) was not graded due to educational samples e.) 2020 3rd Hematology/Coagulation Event - Blood Cell Identification (all samples) was not graded due to educational samples and Urine Sediment (US-06) was not graded due to no consensus f.) 2020 3rd Immunology/Immunohematology Event - Antibody Screen (SER-11) was not graded due to no consensus g.) 2021 1st Hematology /Coagulation Event - Blood Cell Identification (all samples) was not graded due to educational samples h.) 2021 2nd Hematology/Coagulation Event - Blood Cell Identification (all samples) was not graded due to educational samples 2. During an interview on 09/07/2021 at 4:45 PM, the General Supervisor confirmed the above events were not graded by API and the results were not internally evaluated.

D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on a review of American Proficiency Institute (API) proficiency testing records and an interview with the General Supervisor, the laboratory failed to verify the accuracy of Microalbumin (a moderate complexity Chemistry test performed on the Siemens Dimension EXL200) at least twice annually. This was noted from 2019 to 2021. The findings include: 1. A review of the proficiency testing records revealed a lack of accuracy verification being performed at least twice annually for Microalbumin. 2. During an interview on 09/07/2021 at 5:00 PM, the General Supervisor confirmed proficiency testing or accuracy verifications were not being performed for Microalbumin at least twice annually.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (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 a review of the temperature records, a review of the Quidel Triage Total 5 Control Product Insert, and an interview with the General Supervisor, the laboratory failed to ensure the criteria (acceptable ranges) for freezer temperatures were consistent with the manufacturer's instructions. The laboratory further failed to ensure Triage Total 5 Controls were stored as per manufacturer's instructions from January 2020 to August 2021. The findings include: 1. A review of temperature records revealed the acceptable range for the freezer (where Quidel Triage Total 5 Controls were stored) was -15 to -25 degrees Celsius. The temperature records also revealed the temperatures recorded were between -15 to -20 degrees Celsius from January 2020 to August 2021. 2. A review of the Quidel Triage Total 5 Control Product Insert revealed "...Store frozen at -20 degrees Celsius or colder in a non-defrosting freezer..." 3. During interview on 09/08/2021 at 4:45 PM, the General Supervisor confirmed the above findings.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number

	and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of the IQCP (Individualized Quality Control Plan), the Quality Control (QC) records, the patient logs for the Quidel Triage Meter (D-Dimer), and an interview with the General Supervisor, the laboratory failed to ensure two levels of quality control (QC) were performed and documented every 30 days of patient testing as per the IQCP. This was noted one time from July 2019 to August 2021. The findings include: 1. A review of the IQCP for the Triage Meter (D-Dimer) revealed a QC Plan which specified two levels of QC should be performed and documented every 30 days of patient testing, or with each new lot number. 2. A review of the July 2019 to August 2021 Triage Meter QC data log revealed QC was performed on 07/27 /2020, next QC run was 09/22/2020. So, QC being performed every 30 days lapsed from 08/27/2020 to 09/21/2020, 25 patients were performed during this time period. 3. During an interview on 08/08/2021 at 2:33 PM, the General Supervisor confirmed the laboratory failed to follow their IQCP and performed QC at least every 30 days.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of the personnel records and an interview with the General Supervisor, the Technical Supervisor failed to evaluate and document the performance of individuals at least semiannually during the first year of patient testing. This was noted on one of two new testing personnel records reviewed by the surveyor. The finding include: 1. A review of the personnel records revealed Testing Personnel #7's semiannual evaluation was not performed. Testing Personnel #7's initial training was documented on 08/18/2019, and annual evaluation in August 2020 (this evaluation was redone on 05/16/2021 due to missing elements). 2. During an interview on 09/07 /2021 at 2:00 PM, the General Supervisor confirmed the semiannual evaluation was not performed for Testing Personnel #7.