Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0641802	01/18/2019
Name of Provider or Supplier	**Street Address, City, State**	
Lake Martin Community Hospital	201 Mariarden Road, Dadeville, 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
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 review of quality assurance (QA) and control records (QC) for Coagulation testing [Prothrombin (PT) / International Normalized Ratio (INR)], a review of the laboratory's policies and procedures, and an interview with the laboratory manager, the surveyor determined the laboratory failed to follow its policies to manually verify the accuracy of the INR calculation, and failed to validate the platelet poor plasma, at least every six months. The findings include: 1. A review of the policies and procedures revealed the laboratory should verify the platelet poor plasma and accuracy of the INR calculation every six months. 2. A review of the QA and QC records for Coagulation revealed: a) The laboratory validated the platelet poor plasma on 11/07/16, and not again until 11/01/17, a one year time lapse. b) The laboratory performed the PT/INR manual verifications on 11/07/16 and not again until 11/01/17, a one year time lapse. 3. The above noted findings were discussed with the laboratory manager on 1/18/19 at 11:30 AM. The laboratory manager confirmed the policy and procedure to perform these verification every six months; and confirmed the verifications were not performed between November 2016 and November 2017.
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 laboratory's test menu and installation records with the laboratory manager, a review of policies and procedures, a review of quality control (QC) records and patient test logs, and an interview with the laboratory manager, the surveyor determined the laboratory failed to ensure an IQCP (Individualized Quality Control Plan) for CDiff (Clostridium Difficile) was completed, prior to reducing the frequency of testing quality control to every thirty days. In the absence of an acceptable and complete IQCP, the laboratory failed to perform quality control testing each day of patient testing. The findings include: 1. On January 17, a review of the installation records revealed the laboratory installed CDiff testing (via an Alere non-waived test kit) on October 24, 2017. At 2:00 PM, the laboratory manager, along with the surveyor, reviewed the records and confirmed the installation and patient testing. 2. At 2:00 PM, the laboratory manager stated the laboratory had established an IQCP for the CDiff testing. 3. The surveyor's review of the IQCP, with the laboratory manager, revealed the plan did not include risk assessments of potential risks, associated with the five elements; Specimen, Test System, Reagent, Environment, and Testing Personnel. At this time, the surveyor confirmed with the laboratory manager, potential risks associated with the above mentioned elements had not been considered; and the IQCP only included a Quality Assurance Plan and a Quality Control Plan (to test two levels of quality control at least every thirty days). 4. Further review of the manufacturer's package insert included the following: External positive and negative controls - the reactivity of CDiff kit should be verified upon receipt... Additional tests can be performed with the controls to meet the requirements of local, state and/or federal regulations. 5. A review of the QC records for 2018 and 2017 (October) for CDiff revealed the laboratory performed two levels of quality control testing at least once per month, with the controls being testing twice in April and June of 2018. 6. At 2:40 PM, A review of the patient logs and QC records revealed the laboratory performed patient testing on days when at least two levels of quality control were not tested.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of the laboratory's test menu and installation records with the laboratory manager, a review of policies and procedures, a review of quality control (QC) records and patient test logs, and an interview with the laboratory manager, the surveyor determined the laboratory failed to test at least two levels of QC for CDiff

	(Clostridium Difficile) each day of patient testing, in the absence of a completed (acceptable) IQCP (Individualized Quality Control Plan). The findings include: 1. On January 17, a review of the installation records revealed the laboratory installed CDiff testing (via an Alere non-waived test kit) on October 24, 2017. At 2:00 PM, the laboratory manager, along with the surveyor, reviewed the records and confirmed the installation and patient testing. 2. At 2:00 PM, the laboratory manager stated the laboratory had established an IQCP for the CDiff testing. 3. The surveyor's review of the IQCP, with the laboratory manager, revealed the plan did not include risk assessments of potential risks, associated with the five elements; Specimen, Test System, Reagent, Environment, and Testing Personnel. At this time, the surveyor confirmed with the laboratory manager, potential risks associated with the above mentioned elements had not been considered; and the IQCP only included a Quality Assurance Plan and a Quality Control Plan (to test two levels of quality control at least every thirty days). 4. Further review of the manufacturer's package insert included the following: External positive and negative controls - the reactivity of CDiff kit should be verified upon receipt... Additional tests can be performed with the controls to meet the requirements of local, state and/or federal regulations. 5. A review of the QC records for 2018 and 2017 (October) for CDiff revealed the laboratory performed two levels of quality control testing at least once per month, with the controls being testing twice in April and June of 2018. 6. At 2:40 PM, A review of the patient logs and QC records revealed the laboratory performed patient testing on days when at least two levels of quality control were not tested.