Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0677171	05/23/2018
Name of Provider or Supplier	**Street Address, City, State**	
Decatur County Hospital	1405 Nw Church Street, Leon, IA	

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
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 lack of Individualized Quality Control Plan (IQCP) records, review of the Alere Triage test system quality control (QC) records for 2018, and confirmed by laboratory supervisor identifier #3 (refer to Laboratory Personnel Report) at approximately 1:50 pm on 05/23/2018, the laboratory failed to perform two levels of QC each day of patient testing on the Alere Triage test system for D-dimers. The findings include: 1. For D-dimer testing, the laboratory performed QC with each new lot of test cartridges, each new shipment and monthly. 2. Laboratory personnel identifier #6 indicated that the laboratory intended to follow manufacturer's instructions for performing QC. 3. At the time of the survey, the laboratory did not have an IQCP for the Alere Triage test system.
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 blood bank refrigerator and freezer alarm systems procedures and records and previous survey notes from 04/21/2016 and confirmed by the laboratory supervisor, identifier #3 (refer to the Laboratory Personnel Report) at 2:15 pm on 05 /23/2018, the laboratory failed to inspect and check the blood bank refrigerator and freezer alarm systems semi-annually for four out of four time periods from 04/21 /2016 - 05/23/2018. The findings include: 1. According to the procedures, the laboratory is to perform semi-annual checks of the blood bank refrigerator and freezer alarm systems by activating the alarms and documenting the temperature at which it activates. 2. Previous survey records from 04/21/2016 documented the last alarm checks as 01/22/2016. 3. The laboratory supervisor confirmed that laboratory failed to check the blood bank refrigerator and freezer alarms during the past two years.