Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0677171	05/10/2022
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
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 review of proficiency testing (PT) records and confirmed by laboratory personnel identifier #1, at approximately 10:50 am on 5/10/2022; the testing personnel and laboratory director failed to attest to the routine integration of PT samples into the patient workload for six out of six proficiency testing events in 2020 and 2021. The findings include: 1. For 2020 - event 1, the laboratory director or designee did not sign the PT attestation statements for chemistry core, hematology/coagulation, immunology /immunohematology and chemistry miscellaneous. 2. For 2020 -event 2, the laboratory director or designee did not sign the PT attestation statements for chemistry core, hematology/coagulation, immunology/immunohematology and chemistry miscellaneous. Additionally, the testing personnel did not sign the PT attestation statement for chemistry miscellaneous. 3. For 2020 - event 3, the laboratory director or designee did not sign the PT attestation statements for chemistry core, hematology /coagulation, and immunology/immunohematology. 4. For 2021 - event 1, the laboratory director or designee did not sign the PT attestation statements for chemistry core, hematology/coagulation, immunology/immunohematology and chemistry miscellaneous. Additionally, the testing personnel did not sign the PT attestation statements for hematology/coagulation and chemistry miscellaneous. 5. For 2021 - event 2, the laboratory director or designee did not sign the PT attestation statements for chemistry core, hematology/coagulation, immunology/immunohematology and chemistry miscellaneous. Additionally, the testing personnel did not sign the PT attestation statements for immunology/immunohematology and chemistry miscellaneous. 6. For 2021 - event 3, the laboratory director or designee did not sign

	the PT attestation statements for chemistry core, hematology/coagulation, and immunology/immunohematology.
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 review of the CA-660 coagulation records and confirmed by laboratory personnel identifier #1 (refer to Laboratory Personnel Report) at approximately 12:15 pm on 05/10/2022, the laboratory failed to perform calibration verification every six months for two out of three time periods for the analyte, D-Dimer from 1/1/2021 - 5 /10/22. The findings include: 1. The laboratory calibrated the analyte, D-Dimer on 9/7 /2021. 2. The D-Dimer calibration used at least 3 calibrators, and therefore met the calibration verification requirement. 3. At the time of the survey, the laboratory did not have calibration and/or calibration verification records for the time period between 1/1/2021 - 9/7/2021 and the time period between 9/7/2021 - 5/10/2022 for the analyte, D-Dimer.