Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0385057	10/14/2020
Name of Provider or Supplier	**Street Address, City, State**	
Hawarden Regional Healthcare	1111 11th Street, Hawarden, 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
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 10: 30 am on 10/14/2020, the laboratory failed to perform a self evaluation of ungraded PT scores for one out of five testing events (2019 event 2) in 2019 and 2020. The findings include: 1. For 2019 testing event 2, the laboratory received ungraded PT test scores for the following: *2019 Hematology/Coagulation survey- Lymphocyte percentage, specimen ABT-08 2. At the time of the survey, the laboratory did not have additional documentation or corrective action for the ungraded PT test scores.
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 review of the Laboratory Test List & Annual Volume form, proficiency testing (PT) records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 10:30 am on 10/14/2020, the

	laboratory failed to verify the accuracy of the analytes, urine microalbumin and urine creatinine, at least twice annually for three out of three time periods from May 2019-October 2020. The findings include: 1. The laboratory began performing urine microalbumin and urine creatinine testing in May 2019. 2. Personnel identifier #1 confirmed that the laboratory did not enroll in PT for the analytes, urine microalbumin and urine creatinine, in 2019 or 2020. 3. At the time of the survey, personnel identifier #1 confirmed that the laboratory did not have additional records indicating the verification of accuracy for the analytes, urine microalbumin and urine creatinine, in 2019 or 2020.
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 Sysmex CA-660 calibration records, lack of calibration verification records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 1:30 pm on 10/14/2020, the laboratory failed to perform and document calibration verification every six months on the Sysmex CA-660 test system for the analyte, D-dimer, for two out of four time periods from 09/18/2018- 09/18/2020. The findings include: 1. The laboratory performed calibrations on new lots of Innovance D-dimer reagent using six levels of calibrator on 09/18/2018 and 12/14/2019. 2. At the time of the survey, the laboratory did not have additional calibration or calibration verification records for the time periods between 03/18/2019 and 09/18/2019 or 03/18/2020 and 09/18/2020. THIS IS A REPEAT DEFICIENCY, CITED ON 07/26/2018.
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 review of quality control (QC) records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 11: 30 am on 10/14/2020, the laboratory failed to perform a negative and positive control at least each day of patient testing for infectious mononucleosis antibody testing for one out of one day of patient testing (04/10/2020) in April 2020. The findings include: 1. According the the laboratory's "Diagnostic Immunology (Serology) Quality Control Practices" policy, a known positive and negative control must be run each day of testing for any diagnostic immunology procedure performed in the laboratory. 2. An infectious mononucleosis antibody test was performed 04/10/2020 on patient identifier A. 2. At the time of the survey, personnel identifier #1 confirmed that the laboratory did not have infectious mononucleosis antibody testing QC records for testing performed on 04/10/2020.
D6055	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the Laboratory Test List & Annual Volume form, testing personnel records, performance specification records, and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 11: 30 am on 10/14/2020, the technical consultant failed to document training for the Siemens DCA Vantage and Quidel QuickVue serum human chorionic gonadotropin (HCG) test systems prior to reporting patient test results for three out of three testing personnel (laboratory personnel identifiers #1, #2, and #4). The findings include: 1. The Laboratory Test List & Annual Volume form indicated that the laboratory began using the DCA Vantage (urine microalbumin and urine creatinine) and Quidel QuickVue serum HCG test systems since the last survey on 07/26/2018. 2. At the time of the survey, personnel identifier #1 confirmed that the laboratory did not have training records for testing personnel identifiers #1, #2, or #4 for either the DCA Vantage or Quidel QuickVue Serum HCG test systems.
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 review of personnel records and confirmed by laboratory personnel

	identifier #1 (refer to the Laboratory Personnel Report) at approximately 11:00 am on 10/14/2020, the technical supervisor failed to assess the competency of individuals performing high complexity testing at least semiannually during the first year the individual tests patient specimens for one out of three testing personnel (personnel identifier #2). The findings include: 1. The laboratory hired personnel identifier #2 in March 2018. 2. The laboratory's policy "Laboratory Employee Orientation and Competency" stated that the competency of testing personnel is assessed and documented within the first six months of employment and on an annual basis thereafter. 2. At the time of the survey, the laboratory did not have competency assessment documented within the first six months of employment for personnel identifier #2.