Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0385057	07/26/2018
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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of hematology quality control (QC) records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 11:00 am on 7/26/2018, the laboratory failed to retain the daily quality control records for 28 out of 28 days in February 2018 for the analytes: percent and absolute neutrophil count, percent and absolute lymphocyte count, percent and absolute monocyte count, percent and absolute eosinophil count, percent and absolute basophil count, mean corpuscular hemoglobin (MCH), mean corpuscular hemoglobin concentration (MCHC), platelet count, and mean platelet volume (MPV). The findings include: 1. The laboratory performed two levels of QC (rotating between low, normal, and high) each day of patient testing. 2. At the end of each lot number of QC the laboratory printed a levy-jennings chart documenting the QC results. 3. The levy-jennings chart for lot numbers L7359 (low), N7359 (normal), and H7359 (high) of QC from February 2018 did not contain QC results for the analytes: percent and absolute neutrophil count, percent and absolute lymphocyte count, percent and absolute monocyte count, percent and absolute eosinophil count, percent and absolute basophil count, mean corpuscular hemoglobin (MCH), mean corpuscular hemoglobin concentration (MCHC), platelet count, and mean platelet volume (MPV). 4. The laboratory could not retrieve additional QC records for the listed analytes, as the hematology analyzer did not retain more than four months worth of QC records. 5. At the time of the survey, the laboratory did not have any additional QC records for the listed analytes.

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 calibration verification records and confirmed by laboratory personnel identifier #1 (refer to Laboratory Personnel Report) at approximately 9:15 am on 07/26/2018, the laboratory failed to perform calibration verification using a low, mid-point and high value every six months for two out of two time periods from June 2017 - June 2018 for the analytes: sodium, potassium, chloride, and vitamin D. The findings include: 1. On 10/11/2017 the laboratory performed calibration verification for the analytes: sodium, potassium and chloride using a low and high value. The calibration verification did not include a mid-point value. 2. On 10/11 /2017 the laboratory performed calibration verification for the analyte, vitamin D, using a mid-point and high value. The calibration verification did not include a low value. 3. On 3/14/2018 the laboratory performed calibration verification for the analytes: sodium, potassium and chloride using a mid-point value. The calibration verification did not include a low or high value. 4. On 4/18/2018 the laboratory performed calibration verification for the analyte, vitamin D, using a mid-point value. The calibration verification did not include a low or high value. 5. At the time of the survey, the laboratory did not have any additional calibration verification records.