Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0385424	04/10/2019
Name of Provider or Supplier	**Street Address, City, State**	
Hegg Health Center	1202 21st Avenue, Rock Valley, 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 #2 (refer to the Laboratory Personnel Report) at approximately 11:00 am on 04/10/2019, the laboratory failed to retain hematology complete blood count (CBC) QC records for one out of three lot numbers of QC (lot 370718, expiration 09/05/2018) and 41 out of 62 days from 07/01/2018-08/31/2018. The findings include: 1. The laboratory performed two levels of CBC QC for each 24-hour period of patient testing, rotating between low, normal, and high. The laboratory documented which two levels were performed on the AcTDiff Maintenance Log. 2. At the end of use for each lot number, the laboratory printed the QC files stored on the hematology instrument and kept them as documentation of QC results. 3. The QC records from 07/01/2018- 08/31/2018 contained data for lot numbers 360718, expiration 09/05/2018 (low) and 380718, expiration 09/05/2018 (high), but not 370718 (normal). 4. Review of the July and August 2018 AcTDiff Maintenance Logs indicated the laboratory performed QC with lot number 370718 on the following dates: 07/01, 07/03, 07/04, 07/06, 07/07, 07/09, 07/10, 07/12, 07/13, 07/15, 07/16, 07 /18, 07/19, 07/21, 07/22, 07/24, 07/25, 07/27, 07/28, 07/30, 07/31, 08/02, 08/03, 08 /05, 08/06, 08/08, 08/09, 08/11, 08/12, 08/14, 08/15, 08/17, 08/18, 08/20, 08/21, 08 /23, 08/24, 08/26, 08/27, 08/29, and 08/30. 5. Laboratory personnel identifier #2 stated that the QC file for lot number 370718 had been deleted before it could be printed. 6. At the time of the survey, the laboratory did not have additional QC records for the previously listed dates.

D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report), at approximately 1: 30 pm on 04/10/2019, the laboratory failed to have the following written procedures: defined critical or panic values and the laboratory's system for reporting critical or panic values.
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 the laboratory's blood bank policies and procedures, blood bank records, and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 9:45 am on 04/10/2019, the laboratory failed to establish the frequency with which it performs blood bank refrigerator alarm checks and failed to perform and document blood bank refrigerator alarm checks from April 2018 to the date of the survey. The findings include: 1. The laboratory's "Testing Refrigerator Alarms" policy stated the following: "Blood bank refrigerator alarms are checked periodically to ensure proper functioning. High and low temperatures of activations should be checked periodically either by lab personnel or the McKennan technical consultant." 2. Personnel identifier #2 stated that the laboratory installed a new ThermoScientific TSX Series blood bank refrigerator in April 2018 and began using an electronic temperature monitoring and alarm system. 3. At the time of the

	survey, personnel identifier #2 confirmed that the laboratory had not performed or documented alarms checks from April 2018 to the date of the survey.
D6053	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 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 #2 (refer to the Laboratory Personnel Report) at approximately 8:30 am on 04/10/2019, the technical consultant failed to assess the competency of individuals performing moderate complexity testing at least semiannually during the first year the individual tests patient specimens for two out of two new testing personnel (laboratory personnel identifiers #3 and #7) hired in December 2017. The findings include: 1. The Laboratory Personnel Report indicated that the highest level of testing for which personnel identifier #3 is qualified to perform is high complexity testing. 2. The annual competency assessment performed in December 2018 indicated that personnel identifier #3 performs both moderate and high complexity testing. 3. The Laboratory Personnel Report indicated that the highest level of testing for which personnel identifier #7 is qualified to perform is moderate complexity testing. 4. The annual competency assessment performed in December 2018 indicated that personnel identifier #7 performs only moderate complexity testing. At the time of the survey, the laboratory did not have semiannual moderate complexity testing competency assessments for personnel identifiers #3 and #7.
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 #2 (refer to the Laboratory Personnel Report) at approximately 8:30 am on 04/10/2019, 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 one new testing personnel (laboratory personnel identifier #3) hired in December 2017. At the time of the survey, the laboratory did not have semiannual competency assessments for personnel identifier #3.