Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D2073760	02/04/2020
Name of Provider or Supplier	**Street Address, City, State**	
The Iowa Clinic - Indianola	1504 North 1st Street, Indianola, 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 the Medonic hematology analyzer background checks and confirmed by laboratory personnel identifer #2 (refer to the Laboratory Personnel Report) at approximately 2:00 pm on 2/4/2020, the laboratory failed to retain the hematology background check records for four out of 42 days of patient testing (9/3/2019, 9/5/2019, 9/25/2019, and 10/3/2019) in September and October 2019. The findings include: 1. The laboratory performed a background check on the Medonic hematology analyzer each day of patient testing. 2. Laboratory personnel then placed the background check in the specific folder for each month. 3. At the time of the survey, the laboratory did not have background checks for 9/3/2019, 9/5/2019, 9/25/2019, and 10/3/2019.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the

	laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the Medonic hematology analyzer background checks and confirmed by laboratory personnel identifer #2 (refer to the Laboratory Personnel Report) at approximately 2:00 pm on 2/4/2020, the laboratory failed to document corrective action when the hematology analyzer did not meet the established operating parameters for five out of 43 days of patient testing (9/6/2019, 9/11/2019, 9/12/2019, 9 /19/2019 and 10/18/2019) in September and October 2019. The findings include: 1. Each day of patient testing the laboratory performed background checks on the Medonic hematology analyzer. 2. The laboratory received the error "LP-lyse system problem-run prime cycle" on 9/6/2019, 9/11/2019, 9/12/2019, 9/19/2019 and 10/18 /2019. 3. At the time of the survey, the laboratory did not document corrective action when the background counts did not meet the established operating parameters.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on review of the Lab Temperature Log, observations made during the survey and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 2:30 pm on 2/4/2020, the laboratory failed to document corrective action when the laboratory refrigerator temperatures fell outside the established range for four out of 43 days of patient testing (9/13/2019, 9/16/2019, 9/17 /2019 and 10/23/2019) in September and October 2019. The findings include: 1. The laboratory stored the hematology quality controls in the refrigerator labeled "blood fridge". 2. The laboratory established the temperature range for the refrigerator as 2 - 8 degrees Celsius. 3. The laboratory recorded the following out of range temperatures on the "blood fridge" temperature log: *9/13/2019 = 10 degrees Celsius *9/16/2019 = 17 degrees Celsius *9/17/2019 = 9 degrees Celsius *10/19/2019 = 9 degrees Celsius 4. At the time of the survey, the laboratory did not document corrective action for the dates when the refrigerator temperatures fell outside the established ranges.