Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D2298653	05/23/2024
Name of Provider or Supplier	**Street Address, City, State**	
The Iowa Clinic S Waukee	1025 Se Tallgrass Ln Ste 130, Waukee, 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
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 patient test records, the Sysmex Instrumentation procedure, and confirmed by laboratory personnel identifier #8 (refer to the Laboratory Personnel Report) at 10:25 am on 05/23/2024, the laboratory failed to perform and document corrective action when hematology equipment failed to meet the laboratory's established operating parameters for three out of three patients (patient identifiers A, B, and C) reviewed from April 2024. The findings include: 1. Patient identifier A had a complete blood count (CBC) and differential performed on 04/11/2024. 2. Patient identifier B had a CBC and differential performed on 04/15/2024. 3. Patient identifier C had a CBC and differential performed on 04/25/2024. 4. The Sysmex XN-530 hematology instrument flagged patient results with the following: *Patient A: "Blasts /Abn Lympho?" and "Atypical Lympho?" *Patient B: "Blasts/Abn Lympho?" *Patient C: "Blasts/Abn Lympho?" and "Atypical Lympho?" 5. The laboratory's Sysmex Instrumentation procedure stated, "Abnormal differential results such as atypical lymphocytes, left shifts, abnormal scattergrams, and blasts need to be sent out for a

	slide review per manufacturer guidelines." 6. At the time of the survey, laboratory personnel identifier #8 confirmed that the CBC test results for patient identifiers A, B, and C did not get sent out for slide reviews.