Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0385020	06/22/2022
Name of Provider or Supplier	**Street Address, City, State**	
Akron Clinic - Hrh	321 Mill Street, Akron, 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
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 procedure manual and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report), at approximately 8: 45 am on 06/22/2022, the laboratory failed to have a written procedure defining criteria for referral or review of abnormal complete blood count (CBC) differentials.
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 XP-300 operator's guide, and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 8:45 am on 06/22/2022, the laboratory failed to perform and document corrective action when hematology equipment failed to meet the laboratory's established operating parameters for one out of three patients (patient identifier A) reviewed from January 2022. The findings include: 1. Patient identifier A had a complete blood count (CBC) and differential performed on 01/12/2022. 2. The instrument flagged the platelet result for Patient A with an agglutination (AG*) flag. 3. Review of the Sysmex XP-300 operator's guide revealed that test results flagged with an agglutination flag indicates that the instrument failed to meet established operating parameters and requires additional action be taken as specified by the manufacturer. 6. At the time of the survey, laboratory personnel identifier #1 confirmed that additional action had not been taken for CBC test results flagged with an agglutination flag for patient identifier A.