Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0956276	04/28/2022
Name of Provider or Supplier	**Street Address, City, State**	
Story Medical Clinic- Maxwell	403 First Street, Maxwell, 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 XP-300 operator's guide, and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 11:00 am on 04/28/2022, the laboratory failed to perform and document corrective action when hematology equipment failed to meet the laboratory's established operating parameters for two out of four patients (patient identifiers A and B) reviewed from December 2021. The findings include: 1. Patient identifiers A and B had a complete blood count (CBC) and differential performed on 12/07/2022. 2. The instrument flagged the platelet results for both Patient A and B 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 identifiers A and B.