

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  16D0382881	<b>(X3) Date Survey Completed</b>  05/11/2022
<b>Name of Provider or Supplier</b>  Infinity Health	<b>Street Address, City, State</b>  802 East Ackerly Street, Lamoni, IA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5783</b>	<p><b>CORRECTIVE ACTIONS</b> CFR(s): 493.1282(b)(2)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.</p> <p>This STANDARD is not met as evidenced by: Based on review of the hematology quality control (QC) results, patient test logs and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 10:30 am on 5/11/2022, the laboratory failed to take and document correct action when the hematology QC failed to meet the laboratory's established criteria for one out of 23 days from 12/1/2022 - 12/31/2022. The findings include: 1. The laboratory established the acceptable range of 3.92 - 4.42 for the normal control (N1291) red blood cell count. 2. On 12/2/2021, the laboratory received an out of range result of 4.46 for the normal control (N1291) red blood cell count. 3. The laboratory established the following acceptable ranges for the high control (H1291): 15.5 - 20.5 white blood cell count 11.5 - 18.5 absolute granulocyte count 4.90 - 5.50 red blood cell count 15.1 - 17.1 hemoglobin 44.3 - 51.2 hematocrit 4. On 12/2/2021 the laboratory received the following out of range QC results for the high control (H1291): 22.5 - white blood cell count 18.8 - absolute granulocyte count 6.59 - red blood cell count 19.8 - hemoglobin 61.9 - hematocrit 5. On 12/2/2021 the laboratory performed complete blood cell counts (including white blood cell count, red blood cell count, hemoglobin, hematocrit and absolute granulocyte counts) on nine patients. 6. At the time of the survey, no correct action could be found for the out of range QC. This is a repeat deficiency from the survey performed on 9/30/2020.</p>