

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  04D2280364	<b>(X3) Date Survey Completed</b>  03/06/2024
<b>Name of Provider or Supplier</b>  Highlands Oncology Group	<b>Street Address, City, State</b>  639 Hospital Dr, Mountain Home, AR	
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:                      . Through a review of Laboratory quality control (QC) policy, Chemistry quality control records , lack of documentation and interviews with staff, it was determined the laboratory failed to note control data that met the laboratory 's criteria for a warning flag. As evidenced by: A. A review of the Quality Control Program policy revealed the rules for warnings which states: "QC rules for warning. Warning may or may not have to be troubleshoot, but special attention should be given. i.-10s/10x-ten consecutive results on one side of the mean..." B. A review of Quality Control data for January of 2024 revealed the Uric acid-vitros (1832) multiquial level 2, Uric acid-vitros (1832) multiquial level 3, and the Total Protein-vitros (1827) multiquial level 1 controls were all above the mean for 21 of 21 days of testing. A review of Quality Control data for January of 2024 revealed the LDL-vitros (1830) multiquial level 3 and the IGA-vitros (1817) multiquial level 1 controls were all below the mean for 21 of 21 days of testing. No flags or notes were present indicating the above controls were being shown special attention. C. In an interview on 3/6/24, 1:43pm, lab personell #1 (as listed on entrance/exit conference form) confirmed the lack of documented special attention paid to the above analytes in January 2024.</p>