

<p>Statement of Deficiencies</p>	<p>(X1) Provider/Supplier/CLIA Identification Number</p> <p>31D2170513</p>	<p>(X3) Date Survey Completed</p> <p>08/27/2025</p>
<p>Name of Provider or Supplier</p> <p>Amg Ada Advanced Care Oncology And</p>	<p>Street Address, City, State</p> <p>657 Willow Grove Street Suite 305, Hackettstown, NJ</p>	
<p>For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.</p>		

<p>(X4) ID Prefix Tag</p>	<p>Summary Statement of Deficiencies</p>
<p>D5781</p>	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Sysmex Insight XN L Check (SIX) Reports and interview with the Testing Personnel (TP), the laboratory failed to take Corrective Action (CA) when the SIX report displayed an accuracy bias code for Platelets (PLT) testing performed on the Sysmex XN550 from 3/12/25 through 4/12/25. The findings include: 1. The SIX report generated 4/24/25 had an Accuracy bias code "W" for PLT for the date range 3/12/25 through 4/12/25. 2. The CA Standard Operating Procedure (SOP) for Accuracy bias code "W" was as follows "Your mean on the level is approaching a statistical bias in accuracy. Please follow your SOP for troubleshooting" 3. There was no documented evidence that CA was performed for the Accuracy bias code as mentioned above. 4. The TP #2 listed on CMS-209 form confirmed on 8/27/25 at 11:00 am corrective action was not taken.</p>