

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2172458	(X3) Date Survey Completed 03/31/2026
Name of Provider or Supplier Amg Ada Advanced Care Oncology &	Street Address, City, State 333 Mount Hope Ave, Rockaway, NJ	
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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), and interview with the Office Manager (OM), the laboratory failed to have a procedure for Continuous Calibration Verification Certificate and Insight reports run for the Sysmenx XN analyzer from 2/28/24 to 3/10/26. The finding includes: 1. The laboratory did not have procedure on how to create Continuous Calibration Verification Certificate and Insight reports . 2. The laboratory did not have procedure on the frequency in which to run Continuous Calibration Verification Certificate and Insight reports . 3. The OM confirmed on 3/31/26 at 12:00 pm that the aforementioned procedures were missing.</p>
D5469	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g)</p> <p>(d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters.</p>

This STANDARD is not met as evidenced by:

Based on surveyor review of the Quality Control (QC) records and interview with the Office Manager (OM), the laboratory failed to verify commercially assayed QC material with each new lot and/or shipment of XN-L Check QC material used on the Sysmex XN analyzer from 10/10/22 to 3/31/26. The findings includes: 1. There was no documented evidence that the laboratory verified the values of incoming commercially assayed QC material. 2. There was no documented evidence that the laboratory verified new QC lots while the old lot was still in use. 3. The OM confirmed on 3/31/26 at 11:10 am, there was no documented evidence the above mentioned procedures where documented.