

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0106272	(X3) Date Survey Completed 04/19/2023
Name of Provider or Supplier Amg Hematology & Oncology	Street Address, City, State 99 Beauvoir Avenue, Overlook Med Ctr, Summit, 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
D3037	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to retain graded results for Hematology auto differentials performed with the College of American Pathologists (CAP). The findings include: 1) There were no Graded results for Event FH-9C 2022, FH-9 A 2022, FH-9 B 2021. 2) The TP confirmed on 4/18/22 at 10:45 am that all PT graded results were not retained.</p>
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP) the laboratory failed to review coded results for Hematology Testing performed with the College of American Pathologists (CAP) in the Calendar year 2022 and the first event of 2023. The findings include: The finding include: 1. The laboratory received a coded result (Code 26 -Educational Challenge) for Blood Cell ID Upgraded for all three PT events in 2022 and the first event of 2023. 2. There was no documented evidence that coded PT results were reviewed. 3. The TP confirmed on 4/19/23 at 10:15 pm that the laboratory did not review coded PT results. Note: This was previously cited.</p>

D5437

CALIBRATION AND CALIBRATION VERIFICATION

CFR(s): 493.1255(a)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:

Based on surveyor review of Calibration (CAL) records, Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory failed to perform and document Calibration procedures at least once every six months for Hematology Tests performed on the Sysmex XN-L 430 analyzer from 3/4/20 to the date of survey. The findings include: 1. A review of Cal records revealed that the laboratory last performed CAL 3/4/20. 2. The TP confirmed on 4/19/23 at 11:32 am that the laboratory failed to perform and document Cal once every six months.

D6020

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Quality Control (QC) records, Procedure Manual (PM) and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to ensure that the QC program was maintained for laboratory services provided from 8/31/22 to 12/6/22 to the date of the survey. The findings include: 1. The QC peer group review stated the laboratory had an "accuracy Bias code for Red Cell Distribution Width (RDW-CV)" 2. There was no documented corrective action for the aforementioned Bias. 3 The TP confirmed on 4/19/23 at 11:30 am the LD did not ensure the QC plan was maintained. .