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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 31D2154847 | (X3) Date Survey Completed 05/03/2023 |
| Name of Provider or Supplier Amg Hematology & Oncology | Street Address, City, State 1000 Galloping Hill Road, Union, 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 |
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| 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 all PT events in 2021. 2) The TP confirmed on 5/3/23 at 10:15 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 first event of 2022. The findings include: The finding include: 1. The laboratory received a coded result (Code 26 -Educational Challenge) for Blood Cell ID upgraded for event FH9-A 2022. 2. There was no documented evidence that coded PT results were reviewed. 3. The TP confirmed on 5/3/23 at 10:15 am that the laboratory did not review coded PT results.</p> |
| D5437 | <p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p> |

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 8/16/21 to the date of survey. The findings include: 1. A review of Cal records revealed that the laboratory last performed CAL 8/16/21. 2. The TP confirmed on 5/3/23 at 11:32 am that the laboratory failed to perform and document Cal once every six months.

D5783

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(2)

(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.

This STANDARD is not met as evidenced by:
Based on surveyor review of the Insight Quality Control Report (IQCR) and interview with Testing Personnel (TP), the laboratory failed to document corrective action for Accuracy Bias codes From 8/31/22 to 12/6/22 . The findings include: 1. The IQCR had accuracy bias codes for Red Cell Distribution Width (RDW-CV), Mean Corpuscular Volume (MCV), and Hematocrit (HCT) from 8/31/22 - 12/6/22 2. There was no documented corrective action for the above mentioned biases. 3. The TP confirmed on 5/3/23 at 11:00 am that the laboratory failed to document all corrective action.

D6021

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 quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on a lack of a Quality Assurance (QA) plan and interview with the Testing Personnel (TP), the Laboratory Director failed to establish a QA plan from 11/21/21 to the date of the survey. The TP confirmed on 5/3/23 at 11:00 am that a QA plan had not been established.