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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br>33D0132628 | <b>(X3) Date Survey Completed</b><br>01/22/2019 |
| <b>Name of Provider or Supplier</b><br>Joseph D Ament Md   | <b>Street Address, City, State</b><br>920 Park Avenue, New York, NY    |   |
| 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>   |
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| <b>D5211</b>              | <p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br/>CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on a review of the proficiency test (PT) reports from the American Society of Internal Medicine (ML), the laboratory failed to review and evaluate the PT scores that are less than 100%. Findings Include: On December 13, 2018, at approximately 12:30 pm, it was confirmed by the testing person that the laboratory failed to review and evaluate the following: 2018 first event RBC = 80% HGB= 80% WBC = 80% 2018 third event Platelets = 80%</p>   |
| <b>D5401</b>              | <p>PROCEDURE MANUAL<br/>CFR(s): 493.1251(a)</p> <p>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:<br/>Based on a lack of hematology procedures and an interview with the laboratory testing person, the laboratory failed to have a procedure manual in place for hematology testing. Findings: On January 22, 2019, at approximately 10:15 am the testing person confirmed that the laboratory failed to have a written procedure manual for hematology testing. The procedure manual must include: 1) Patient preparation; specimen collection, labeling, storage, preservation, and processing; 2) The criteria for</p> |

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|                     | <p>specimen acceptability and rejection; 3) Control procedures (number/level of controls tested, acceptability, number of times control are tested before acceptance); 4) Lot to lot verification of new controls; 5) Calibration and calibration verification procedures; 6) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. 7) The laboratory's system for entering test results in the patient record.</p>   |
| <p><b>D5481</b></p> | <p><b>CONTROL PROCEDURES</b><br/>CFR(s): 493.1256(f)(g)</p> <p>(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on a review of hematology quality control (QC) records from June 2018 through the date of this survey, the laboratory failed to meet the established criteria for acceptability and to have all three levels of QC material come within an acceptable range prior to patient testing. Findings Include: It was confirmed by the laboratory testing person on January 22, 2019, at approximately 11:00 am, that following parameters were out of acceptable range in August, October and November 2018 and remediation was not performed. Platelet: August 7, 8, and September 4, 2018 - normal control August 14, 2018 - low control Hemoglobin: October 23, 24, 2018 - Low, normal and high October 26, 2018 - low and high November 2, 9, and 14, 2018 - low and normal October 30, and November 16, 2018 - normal and high October 31, November 6, 20, 2018 - normal November 9, 2018 - low and normal November 7 and 13, 2018 - low control Approximately 200 patient specimens were tested and test results released for hematology testing.</p> |
| <p><b>D5783</b></p> | <p><b>CORRECTIVE ACTIONS</b><br/>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:<br/>Based on a review of the hematology QC records and confirmed in an interview with the laboratory testing person, the laboratory failed to perform and document corrective action when QC results were out of acceptable range and failed to evaluate all patient test results obtained for each unacceptable test run through the last acceptable test run to determine if patient test results were adversely affected. Approximately 200 patient specimens were tested and results reported in August, October and November 2018. Refer to: D5481</p>   |
| <p><b>D5787</b></p> | <p><b>TEST RECORDS</b><br/>CFR(s): 493.1283(a)</p>  |

The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:

Based on a review of patient test records, and an interview with the laboratory testing person, five of five electronic laboratory test reports reviewed for hematology patient testing failed to have the identity of the person who performed the test noted in the electronic test records.

**D5793**

**ANALYTIC SYSTEMS QUALITY ASSESSMENT**

CFR(s): 493.1289(b)(c)

(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's quality assessment (QA) policy, QC records and an interview with the laboratory testing person, the laboratory failed to follow the QA procedure. Findings Include: On January 22, 2018, at approximately 12:30 PM, and confirmed with the laboratory testing person, the laboratory failed to follow their QA procedure to identify, take corrective action and revise policies necessary to prevent the recurrence of hematology QC problems. Refer to: D5481 & D5783

**D6000**

**MODERATE COMPLEXITY LABORATORY DIRECTOR**

CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

Based on surveyor findings and interview with the laboratory testing person, the director failed to provide overall management and direction for the laboratory. Findings Include: The director failed to ensure that: 1. The QC program for hematology was maintained. Refer to D6020 2. The QA program for hematology was maintained. Refer to D6021

**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 a review of QC records, and an interview with the laboratory testing person, the laboratory director failed to ensure that the QC program for hematology was maintained to assure the quality of laboratory services. Refer to: Refer to D5481 and D5783

**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 the a review of the laboratory's policy/procedure manual and an interview with the laboratory testing person, the laboratory director failed to ensure that the laboratory's quality assessment (QA) policy/procedure was followed. Refer to D5211, D5401, D5787 and D5793