| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 07D0994636 | 09/10/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Oncology Hematology Care Of Connecticut | 849 Boston Post Road, Suite 100, Milford, CT | |

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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| **D5209** | PERSONNEL COMPETENCY ASSESSMENT POLICIES<br>CFR(s): 493.1235<br><br>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and staff interview, the laboratory failed to have a policy in place to assess the competency of all laboratory personnel. Findings include: 1. Review of the laboratory personnel competency records on 9/10/19 revealed the following: a. The laboratory did not have policy in place to assess the competency of the technical consultant (TC) and clinical consultant. b. Competency documentation for the above laboratory personnel was not available. 2. Staff interview with the TC on 9/10/19 at 10:10 AM confirmed the laboratory did not have a policy in place to assess the competency of the above laboratory personnel and they were not assessed. |
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.<br><br>This STANDARD is not met as evidenced by: |

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| | Based on observation, record review and staff interview, the laboratory failed to ensure proper storage of reagents, patient samples and quality control (QC) materials in the specialty of hematology. Findings include: 1. Record review on 9/10/19 of the laboratory's temperature log for the specimen refrigerator and freezer revealed: a. Refrigerator temperature was documented as 6 degree Celsius (C)in 2018 and through out 2019 to-date. b. Freezer temperature was documented as -15 degree C in 2018 and through out 2019 to-date. 2. Surveyor observation on 9/10/19 at 11:45 AM revealed: a. A thermometer (Cooper SN#54546-4) kept in the refrigerator was due for calibration on 12/23/16. It was observed that the temperature was showing as 13C for the above thermometer. b. A second thermometer intended to measure refrigerator temperature was kept in the freezer. c. Another thermometer (Cooper MSN#54546-1) kept in the freezer was due for calibration on 12/23/16. d. The laboratory is storing reagents, patient samples and QC materials in the refrigerator. 3. Current calibration documentation for the above Cooper thermometers were functioning properly was not available. 4. Record review of the QC package insert on 9/10/19 revealed it needs to be to stored at 2-8 degrees C. 5. Staff interview with the technical consultant on 9/10 /19 at 12:30 PM confirmed the above findings. 6. The laboratory performs 2,000 complete blood count tests annually. |
| **D5431** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(a)(2)<br><br>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor observation and staff interview, the laboratory failed to document centrifuge function checks every 6 months to ensure platelet poor plasma (PPP) is obtained. Findings include: 1. Record review on 9/10/19 of the laboratory's procedure manual titled 'Platelet poor plasma check' revealed "PPP procedure must be performed semi-annually and recorded in the QC report for review by the director". 2. Record review on 9/10/19 of the centrifuge maintenance records reveled: a. The above procedure is not followed and documentation for semi-annual PPP is not available. b. The laboratory failed to provide documentation of yearly centrifuge taching for 2017 and 2018. 3. Staff interview with the technical consultant (TC) on 9/10/19 at 11:20 AM, confirmed the above findings. The TC further stated coagulation specimens are sent to an outside reference laboratory. 4. This is a repeat deficiency. |
| **D5439** | CALIBRATION AND CALIBRATION VERIFICATION<br>CFR(s): 493.1255(b)<br><br>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following |

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| | occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and staff interview, the laboratory failed to perform calibration of the hematology analyzer in the required frequency. Findings include: 1. Calibration record review on 9/10/19 revealed the following: a. Medonic M hematology analyzer: SN# 20806 was calibrated on 10/4/18. b. Records of semi-annual calibration was not available since 10/4/18. 2. Record review on 9/10/19 of the procedure manual titled "Medonic M Calibration" revealed 'In order to verify the accuracy of CBC results produced by the hematology instrument, a calibration must be performed semi-annually'. 3. Staff interview with the technical consultant (TC) on 9/10/19 at 11:30 AM confirmed the six month calibrations were not performed in a timely manner as stated in the procedure. TC further stated he/she was under the impression semiannual calibration was performed along with preventive maintenance. 4. This is a repeat deficiency and the laboratory performs 2,000 CBC tests annually. |
| **D5481** | CONTROL PROCEDURES<br>CFR(s): 493.1256(f)(g)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and staff interview, the laboratory failed to follow the laboratory policy for acceptable quality control (QC) prior to reporting patient test results in the specialty of hematology. Findings include: 1. Record review on 9/10/19 of the laboratory procedure titled 'Daily Quality Control and Action Limits, Hematology' revealed "three levels of assayed whole blood controls are run on each day of operation, on the analyzer (Medonic M). Should the result of any parameter of any control exceed the acceptable limits, that parameter is considered out of control and the control(s) need to be repeated and within acceptable limits before patient results may be released". 2. Record review of the March 25, 2019 'daily QC log' on 9/10/19 revealed the laboratory director reviewed and signed off the background counts and the low, normal and high controls. 3. Record review of the Medonic March 2019 'Quality Control Summary Report' on 9/10/19 revealed asterisks next to low and high QC results on March 25, 2019. 4. Record review of the March 25, 2019 Medonic instrument quality control (QC) printouts on 9/10/19 revealed the following: a. Low QC: Lot # 2181121 run indicates an error code 'EC'. b. High QC: Lot # 2181123 run indicates an error code 'EC'. 5. Record review of the Medonic operators manual on 9/10/19 revealed the error code 'EC' means expired controls. Documentation for corrective action was not available. 6. Staff interview with technical consultant (TC) |

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| | on 9/10/19 at 10:45 AM revealed the TC was unaware the meaning of the asterisks on the QC Summary Report and TC had seen them but did not investigate. 7. Staff interview with testing personnel #1 (TP1) on 9/10/19 at 10:50 AM confirmed: a. Low and High QC was expired on 3/22/19. b. Investigation or corrective action was not documented. c. The laboratory ran 40 patient samples on 3/25/19. 8. The laboratory performs 2,000 complete blood count tests annually. |
| **D6051** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(8)(v)<br><br>The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and staff interview, the laboratory failed to ensure all testing personnel (TP) have tested unknown samples to demonstrate competency in performing laboratory tests in the specialty of hematology. Findings Include: 1. Record review on 9/10/19 of the College of American Pathologists complete blood count (CBC) proficiency testing attestation sheets revealed 2 of 3 TP did not examine proficiency testing material to accurately assess their skills in 2018. 2. Record review of employee competency records on 9/10/19 revealed 2 of 3 TP did not examine previously analyzed specimens, internal blind testing samples or external proficiency testing samples to accurately assess their skills in 2018. 3. Staff interview with the technical consultant on 9/10/19 at 10:15 AM confirmed the above TP had not examined unknown samples including proficiency testing material to accurately assess their skills in the specialty of hematology in 2018. 4. The laboratory performs 2,000 CBC tests annually. 5. This is a repeat deficiency. |