| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 10D2085798 | 02/06/2018 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Bethel Blood And Cancer Center Pa | 11660 Sw 97th Terr Unit 201, Ocala, FL | |

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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| **D2122** | HEMATOLOGY<br>CFR(s): 493.851(b)<br><br>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and staff interview, the facility failed to have a passing proficiency test score for the second testing event of 2016 for the speciality of Hematology. The findings include: The 2/6/18 record review of the American Proficiency Institute testing results for the second event of 2016 showed a score of 0% for Mean Corpuscular Volume (MCV) and 60% for Platelets. The 2/6/18 interview with the laboratory manager at 2:30pm confirmed the laboratory had failed proficiency testing and determined it was due to contaminated cleaner. |
| **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 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 |

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| | 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 facility failed to perform and/or document the calibration verification at least once every 6 months for the Cell Dyn Emerald hematology analyzer. The findings include: The record review on 2/6/18 of the calibration documentation for the Cell Dyn Emerald hematology analyzer showed calibration was performed in June 2016 and August 2017. The interview with the laboratory manager on 2/6/18 at 2:00pm confirmed calibration had not been performed every 6 months as manufacturer instructions require. |
| **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 interview with laboratory staff, the laboratory failed to have quality controls (QC) in acceptable range prior to reporting patient results for 1 of 31 days in July 2016. The findings include: Record review of the laboratory's QC records for July 2016 showed on 7/7/2016, the normal level control for the hematology test of Mean Corpuscular Hemoglobin (MCH) was out of range at 32.0 (acceptable range was 25.9-30.9), the low level control for the hematology test of MCH was 28.1 (acceptable range was 23.0-2.0), and the high level control for MCH was 34.6 (acceptable range was 27.2-34.2). The laboratory failed to document corrective action and performed/reported testing on approximately 45 patients. During interview on 2/6/18, the laboratory manager confirmed the QC was out of range for all three control levels on 7/7/2016 and verified that patient testing should not have been performed. |