| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 25D1006836 | 09/05/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Delta Oncology | 333 Hwy 82 W, Greenwood, MS | |

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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| **D5437** | CALIBRATION AND CALIBRATION VERIFICATION<br>CFR(s): 493.1255(a)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the Vitros 350 chemistry calibration records from 10/25/17 through 9/5/19 and interview with lab manager/testing personnel #1 at 3:00 pm on the day of survey, 9/5/19, the laboratory failed to perform calibration on chemistry analytes every 6 months or with each lot number change, which ever comes first, as required in the manufacturer's instructions. Findings include: 1. Review of the Vitros 350 Operator's manual indicated that the manufacturer's requirements for calibration are with each lot number change and every 6 months. 2. Interview with lab manager /testing personnel #1 confirmed calibrations were performed with each change of lot number throughout the year. 3. Review of the Vitros 350 calibration records revealed that at least one calibration interval for each of the following analytes exceeded the every 6 month requirement: Alkaline Phosphatase- calibrated on 12/14/17, 3/11/19 ALT - calibrated on 11/21/17, 3/11/19 AST - calibrated on 10/9/17, 11/21/18, 6/25/19 Bu (Unconjugated Bilirubin)- calibrated on 8/17/17, 1/30/19 Bc (Conjugated Bilirubin) - calibrated on 8/17/17, 1/30/19 BUN- calibrated on 12/27/17, 2/13/19 Calcium - calibrated on 11/22/17, 12/4/18, 6/6/18, 7/1/19 Chloride - calibrated on 10 |

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| | /11/17, 8/30/18, 7/1/19 Creatinine - calibrated on 11/22/17, 2/28/19 Carbon Dioxide - calibrated on 11/29/17, 3/4/19, Glucose - calibrated on 12/6/17, 3/18/19 Magnesium - calibrated on 11/14/17, 7/17/19 Sodium - calibrated on 11/8/17, 7/2/18, 11/21/18, 7/1 /19 Total Bilirubin - calibrated on 11/1/17, 6/21/18 Total Protein - calibrated on 11/16 /17, 11/13/18 Urine Protein - calibrated on 10/4/17, 8/30/18, 9/16/19 |
| **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 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 review of chemistry calibration records from the last survey on 10/25/17 through 9/5/19, the day of the current survey, and confirmation with laboratory manager/testing personnel #1 at 2:30 pm on 9/5/19, the laboratory failed to perform calibration verifications on the Ortho Vitros 350 chemistry analyzer every 6 months for Sodium (Na), Potassium (K) and Chloride (Cl). Findings include: 1. Review of the Vitros 350 Calibrator materials revealed that the calibrators for Na, K, and Cl only have 2 levels. 2. Calibration Verification is required every 6 months for assays calibrated with less than 3 calibrators--the three calibrators must extend throughout the reportable range of the assay. 3. Review of Vitros 350 chemistry calibration records revealed that a calibration verification was not performed on Na, K, and Cl every 6 months. A calibration verification had not been performed since the last survey on 10/25/17. 4. Interview with laboratory manager/testing personnel #1 at 2:30 pm on 9/5/19 confirmed that Na, K, and Cl calibration verifications had not been performed on the Vitros 350 chemistry analyzer since 10/25/17. |