| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 01D2116823 | 08/24/2023 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Madison Core Laboratories | 2705 Artie St Sw Bldg 400 Suite 25, Huntsville, AL | |

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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| **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 a review of the Cobas Chemistry analyzer calibration verification (C-V) records and an interview with the Laboratory Manager, the laboratory failed to ensure C-V was performed and documented on the Cobas 501C and 601E Chemistry analyzers the first half of 2023. The surveyor noted one of two C-V's was later than the semiannual frequency required by CLIA. The findings include: 1. A review of the Cobas 501C and 601E Chemistry analyzer C-V records revealed 49 of 56 assays were |

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| | calibrated with either one or two calibrators. Analytes calibrated with less than three calibrators must have a C-V every six months, as per CLIA regulatory requirements. 2. A review of the Cobas 501C and 601E records revealed documentation of C-V performed on 10/13/2022, however the next C-V was not performed until 7/31/2023, approximately nine and a half months later. 3. During an interview on August 24,2023, at 12:10 PM, the Laboratory Manager confirmed the C-V due the first half of 2023 was late because of a scheduling error. SURVEYOR ID#'s: 32558 and 46291 Licensure and Certification Surveyors |