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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 16D0386363 | (X3) Date Survey Completed 01/26/2023 |
| Name of Provider or Supplier Veterans Memorial Hospital | Street Address, City, State 40 First Street Se, Waukon, IA | |
| 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 | <p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of Vitros verification of performance specification and calibration records, lack of calibration verification records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 2:30 pm on 1/26/2023, the laboratory failed to perform calibration verification procedures every six months for the analytes, procalcitonin and beta-hydroxybutyrate for two out of three time periods from 6/1/2021 - 1/26/2023. The findings include: 1. The laboratory</p> |

verified the reportable range for the analytes, procalcitonin and beta-hydroxybutyrate using a minimum value, mid-point value and maximum value when they implemented the new Vitros chemistry analyzer in June 2021. 2. The calibrations performed for the analytes, procalcitonin and beta-hydroxybutyrate each used 2 calibrators. 3. At the time of the survey, the laboratory did not have documents indicating calibration verification procedures had been performed on the analytes, procalcitonin and beta-hydroxybutyrate since their implementation in June 2021.